No. 24-

In the United States Court of Appeals for the Federal Circuit

IN RE TRANSGENDER AMERICAN VETERANS ASSOCIATION, Petitioner.

PETITION FOR WRIT OF MANDAMUS TO THE DEPARTMENT OF VETERANS AFFAIRS

Michael J. Wishnie

Counsel of Record

VETERANS LEGAL SERVICES

CLINIC

JEROME N. FRANK LEGAL

SERVICES ORGANIZATION

YALE LAW SCHOOL

P.O. BOX 209090

NEW HAVEN, CT 06520-9090

(203) 436-4780

michael.wishnie@ylsclinics.org

 $Counsel\ for\ Petitioner$

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INTRODUCTION

Transgender and gender non-conforming veterans (collectively, "transgender veterans") serve this country at nearly twice the rate of their cisgender counterparts. Yet for nearly eight years, the U.S. Department of Veterans Affairs ("VA") has ignored their request for essential health care commensurate with that it provides to other veterans. Specifically, VA categorically excludes gender-confirmation surgery from its medical benefits package, even though this treatment is often lifesaving care and VA provides the same procedures when not used to treat gender dysphoria.

On May 9, 2016, the Transgender American Veterans Association ("TAVA"), along with two veterans that were denied gender-confirmation surgery by VA—against the recommendations of VA's own doctors—submitted a formal petition for rulemaking on gender-confirmation surgery under the Administrative Procedure Act. App'x 1-38. The petition requested that VA amend its regulations, including 38 C.F.R. § 17.38(c)(4) and implementing directives, that exclude medically necessary gender-confirmation surgery for transgender veterans from the medical benefits package. TAVA's proposed rule would ensure that transgender veterans receive the medically necessary care they earned through their service. It would also mean that those veterans do not have to seek this care through private doctors, which is often prohibitively expensive. And since these veterans often rely on VA doctors for their other health care, including and especially their other transition-related care, VA

provision of gender-confirmation surgery would allow continuity of care with the doctors who know their medical history best.

VA has publicly stated that it intends to provide gender-confirmation surgery to its veteran patients, prepared multiple proposed rules for cost-benefit analysis, and received public comment on the rulemaking petition. Yet it has taken no formal action granting or denying TAVA's petition in nearly eight years since it was filed. Nor, despite its vague public statements, has VA made this essential care available. Such informal statements do not satisfy VA's obligation to respond to TAVA's rulemaking petition. Transgender veterans deserve the gender-confirmation surgery that VA has promised. At the very least, VA has a legal duty to TAVA and its members to grant or deny their rulemaking petition. Transgender veterans should not have to wait any longer.

Left with no other options, TAVA now seeks a writ of mandamus under the All Writs Act, 28 U.S.C. § 1651(a). TAVA asks this Court to compel a formal response from VA to its May 2016 rulemaking petition, which has been unreasonably delayed, *see* 5 U.S.C. § 706(1), and to require VA to conclude this matter within a "reasonable time." *See id.* § 555(b).

FACTS & PROCEEDINGS

A. Factual Background

Transgender people are a disproportionally high percentage of the veteran community. Over 20% of transgender people in the United States have served in the military, or approximately more than 134,000 veterans. *See* App'x 93-94. Like other veterans, transgender veterans frequently rely on VA health care, including for treatment of gender dysphoria, the medical diagnosis for the distress caused by incongruence between gender identity and sex assigned at birth. Transgender veterans are more likely than cisgender veterans to rely on VA health care, because they are more likely to be uninsured and to face cost barriers to care. *See id.* 96-98. At least 10,000 transgender veterans currently receive transition-related care through VA. *See id.* 107.

However, VA does not meet the medical needs of transgender veterans in the same way it does for other veterans. VA categorically excludes gender-confirmation surgery from its medical benefits package, 38 C.F.R. § 17.38(c)(4), App'x at 39-77, even though this surgery is essential care for many people who have gender dysphoria. As a result, transgender veterans for whom gender-confirmation surgery is medically necessary cannot receive it from VA, even while they receive other care—including transition-related care—from VA doctors at VA facilities.

VA's failure to provide gender-confirmation surgery puts transgender veterans at increased risk of physical harm, psychological distress, and suicide. Major medical associations have long recognized that gender-confirmation surgery is effective, and often critical, treatment for gender dysphoria. *See id.* 11-13; *see also id.* 436-439 (Resolution 122 of the American Medical Association), 440-474 (Report of the APA Task Force), 475-509 (guidelines from the Endocrine Society). Gender-confirmation surgery is associated with significantly lowered psychological distress and suicidal ideation. *See id.* 13, 108-115 (2021 study finding lower risk of suicidal ideation and attempt after transgender patients receive gender-confirmation surgery), 402-403 (declaration of Dr. Marci Bowers), 416-421 (declaration of Dr. Randi Ettner), 515 (APA guidelines).

For instance, the American Medical Association has concluded that "[a]n established body of medical research demonstrates the effectiveness and medical necessity of . . . sex reassignment surgery" for people with gender dysphoria. *Id.* 436. The American Psychiatric Association has concurred that "medical research demonstrates the effectiveness and necessity of mental health care, hormone therapy and sex reassignment surgery for many individuals diagnosed with" gender dysphoria. *Id.* 448. Additionally, the Endocrine Society has explained that "[f]or many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender

role" and that "[t]he mental health of the individual seems to be improved by participating in a treatment program that defines a pathway of gender-affirming treatment that includes . . . surgery." *Id.* 499.

Access to this care can represent the difference between life and death. Veterans experience suicide at a rate 57.3% higher than civilians, *see id.* 122, and higher rates of depression as well. *See id.* 159-160. Suicide-related events are over 20 times more common for veterans with gender dysphoria who rely on VA care than for veterans who rely on VA care generally. *Id.* 170.

VA's categorical exclusion forces transgender veterans to forego the necessary care, increasing these mental health risks. To obtain care, they must pay out-of-pocket at a non-VA facility. Forcing them to seek gender-affirming care at multiple facilities and from different providers disrupts continuity of care for transgender veterans, to the detriment of their health and well-being. *See, e.g., id.* 176-177; *id.* 584-585 ¶ 6 (describing how VA denied TAVA President Eshler a referral letter to receive gender-confirmation surgery elsewhere). Maintaining continuity of care would also decrease costs for VA, in part because it mitigates the risk of more serious—and more expensive—medical interventions. *Id.* 553-563.

VA's refusal to provide gender-confirmation surgery is particularly arbitrary given that it recognizes that gender dysphoria requires medical attention. In fact, VA covers "all medically necessary gender-affirming care to transgender Veterans with

the exception of gender-affirming surgical interventions." App'x 181 (emphasis added). VA even provides gender-confirmation surgery to treat conditions other than gender dysphoria. See id. 15-17; see also, e.g., 38 C.F.R. § 17.38(a)(1)(x) (providing plastic surgery to veterans "required as a result of disease or trauma"); App'x 40 (clarifying that VA provides to "intersex Veterans... surgery to correct inborn conditions related to reproductive or sexual autonomy"). VA's refusal to cover this medical care for transgender veterans is discordant with its stated "commit[ment] to health addressing disparities, including disparities among our transgender... veterans." Id. 55. In fact, VA's categorical exclusion of genderconfirmation surgery has caused transgender veterans to lose access to the VA care to which they are presently entitled. See, e.g., id. 581-582 ¶¶ 13-14 (describing how VA denied post-operative care to a TAVA member, Ray Gibson, who received this surgery elsewhere).

Without access to medically necessary care, some transgender veterans lose their lives. Natalie Kastner, a TAVA member diagnosed with gender dysphoria and denied gender-confirmation surgery at the VA, was nearly one of those veterans. *Id.* 576-577 ¶ 6. Desperate and unable to access gender-confirmation surgery via the VA or alternative means, she removed her right testicle at home on March 5, 2022, without anesthesia or formal medical training. *Id.* In doing so, she accidentally severed an artery. *Id.* Ms. Kastner managed to drive herself to the local emergency

room, where she received life-saving care. *Id.* 577 ¶ 7. Though Ms. Kastner survived this harrowing incident, she continues to struggle with gender dysphoria daily while anxiously awaiting the VA's response to TAVA's petition. *Id.* 578-579 ¶¶ 14-15, 17-18.

Some transgender veterans are racing against time to access gender-confirmation surgery. Another TAVA member, Ray Gibson, is a Black transgender male veteran of the U.S. Air Force. *Id.* 580 ¶¶ 2-3. At 66 years old, Mr. Gibson fears that he is nearly too old to safely access phalloplasty. *Id.* ¶ 4; *id.* 583 ¶ 19. As he has aged, recovery from surgeries has become harder. VA is his only health care provider, and he lives on a fixed income. *Id.* 581 ¶¶ 13, 10. He is unable to pay out-of-pocket for gender-confirmation surgery. *Id.* ¶ 11; *id.* 582 ¶ 17. If VA continues to delay its decision, he may be unable to avoid suffering gender dysphoria for the rest of his life. *Id.* ¶ 18; *id.* 583 ¶ 19.

B. Procedural History

Given the importance of this issue to its members, on May 9, 2016, TAVA and two individual veterans filed the rulemaking petition that is the subject of this action. *Id.* 1-38. VA promptly acknowledged receipt. *Id.* 249. In the media and in response to inquiries from Members of Congress, the agency stated that it would explore a regulatory change to allow VA to provide gender-confirmation surgery in its medical benefits package. *Id.* 249-250. In 2016, VA drafted a proposed rule, entitled

"Removing Exclusion of Gender Alterations from the Medical Benefits Package," performed an impact analysis for the draft proposed rule, and issued a memorandum from the Veterans Health Administration's Chief Financial Officer regarding the impact analysis. *See id.* 254. But on November 10, 2016, then-Under Secretary David J. Shulkin of VA wrote 47 Members of Congress that VA would not include a Notice of Proposed Rulemaking ("NPRM") in the Fall 2016 Unified Agenda. *See id.* 228-234 ("Shulkin Letter").

VA changed direction under the next Administration. In 2017, it re-issued VHA directive 2013-003, declaring that "[s]ex reassignment surgery cannot be performed or funded by VA." *Id.* 78-90. That remains VA's position. *Id.* 52-77.

In response, TAVA and two individual veterans filed suit requesting that this Court set aside VA's constructive denial of the rulemaking petition as stated in the Shulkin Letter or, in the alternative, compel VA to act on the grounds of unreasonable delay. *See Fulcher v. Sec'y of Veterans Affs.*, No. 2017-1460 (Fed. Cir. filed June 21, 2017); App'x 184-236, 237-308. VA argued that it had neither denied the rulemaking petition nor engaged in unreasonable delay. *Id.* 320-330, 343-349. This Court held oral argument in May 2018. *Id.* 363. In July, VA sought comment on the rulemaking petition in the Federal Register, although without publishing an NPRM or proposed rule, *id.* 364-365, and TAVA and the other plaintiffs voluntarily dismissed the case before this Court issued a decision. *Id.* 371-372.

Since the start of the Biden Administration, VA has returned to its 2016 posture, making repeated public promises that it will provide gender-confirmation surgery. Secretary McDonough first made public assurances that VA will provide gender-confirmation surgery in 2021, soon after he was confirmed by the Senate. *See id.* 373-376, 377-378. More recently, in June 2023, VA Press Secretary Terrence Hayes said that VA is "moving ahead methodically" to provide gender-confirmation surgery "because we want this important change in policy to be implemented in a manner that has been thoroughly considered" and "meets VA's rigorous standards for quality health care." *Id.* 379-383. But Hayes declined to say which steps VA has taken thus far and which steps are left. *See id.* Secretary McDonough made a similar statement—again without details—at a VA town hall in November 2023. *See id.* 388.

VA has also submitted five proposed rules for gender-confirmation surgery to the Office of Information & Regulatory Affairs ("OIRA"), including as recently as fall 2023, each of which has specified an intended publication date for an NPRM. One of those rules went through full OIRA review. *See id.* 397; *id.* 393 (indicating intended NPRM date of July 2022); *id.* 394 (same); *id.* 395 (indicating intended NPRM date of December 2022); *id.* 396 (indicating intended NPRM date of October 2023); *id.* 398 (indicating intended NPRM date of November 2023). Yet VA has not adhered to *any* of these intended publication dates, even though it has a proposed rule drafted for OIRA review. Each of these submissions also contains the following

language, confirming that VA understands that it has both the legal authority under 38 U.S.C. § 1710 and the obligation to provide gender-confirmation surgery:

The Department of Veterans Affairs (VA) is proposing to revise its medical regulations by removing the exclusion on gender alterations from the medical benefits package. VA is proposing these changes so that transgender and gender diverse veterans may receive medically necessary health care, including surgical interventions for gender transition. This proposed change would be consistent with medical industry standards and would ensure that VA provides a full continuum of care to transgender and gender diverse veterans.

Id. 393-398. Despite these public comments and representations in the Unified Agenda, VA has neither published an NPRM nor a proposed rule in the Federal Register.

Seven and one-half years since submitting its rulemaking petition, and after more than two and one-half years of public promises by current VA leadership unmatched by any concrete agency action, TAVA sent a demand letter to VA's Acting General Counsel on November 20, 2023, International Transgender Day of Remembrance. TAVA stated that if VA failed to grant its 2016 rulemaking petition and initiate the rulemaking process within 30 days, the organization would file suit. *See id.* 543-547. VA replied by letter on December 22, 2023, repeating the same noncommittal representations it has made for years—even recycling the exact language it has previously used in its public statements. *Compare id.* 548 *with id.* 373-376, 379-383. VA's reply did not, however, grant or deny TAVA's petition, let

alone identify any concrete steps it had taken or specify any timeline by which it would act. *See id.* 548.

It has been over two years since Secretary McDonough publicly committed to initiating the rulemaking process on this matter and *nearly eight years* since TAVA filed its rulemaking petition. Having tried and failed to secure this relief short of litigation, TAVA now has no choice but to seek this Court's intervention.

JURISDICTION

The United States Court of Appeals for the Federal Circuit has exclusive jurisdiction to review VA rules and regulations, including the VA Secretary's responses to petitions for rulemaking. 38 U.S.C. § 502.

STANDING

TAVA submitted a petition for rulemaking on May 9, 2016, which VA has neither granted nor denied. TAVA has associational standing on behalf of its members, including its members denied medically necessary gender-confirmation surgery by VA, because TAVA has members who have standing to sue in their own right, the interests TAVA seeks to protect are germane to its purpose, and neither the claim asserted nor relief requested requires participation of individual TAVA members in this suit. *See Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977); *Inst. Nat'l Des Appellations D'Origine v. Vintners Int'l Co., Inc.*, 958 F.2d 1574, 1579 (Fed. Cir. 1992); *E. Paralyzed Veterans Ass'n, Inc. v. Sec'y of*

Veterans Affs., 257 F.3d 1352, 1356 (Fed. Cir. 2001) (holding veterans group has associational standing under *Hunt* standard to challenge VA regulation). Indeed, in every year since the rulemaking petition was filed, continuing through 2023, VA has denied gender-confirmation surgery to multiple TAVA members. App'x 587 ¶ 15.

TAVA also has organizational standing because the petition is germane to TAVA's purpose, which is to ensure that all transgender veterans receive full services and dignified treatment from VA. VA's delay in deciding TAVA's rulemaking petition has forced TAVA to divert scarce resources to address the VA's failure to act. *Id.* 586 ¶ 11. This diversion of resources is an injury-in-fact. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378-79 (1982); *see also Warth v. Seldin*, 422 U.S. 490, 511 (1975).

ARGUMENT

This Court should issue a writ of mandamus ordering VA to respond to TAVA's 2016 rulemaking petition on the grounds of unreasonable delay. Forty years ago, the D.C. Circuit established a multifactor test for agency delay. *Telecomms. Rsch. & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) ("*TRAC*"). This and other courts of appeals have adopted the standard in the years since then. As applied here, the six *TRAC* factors confirm that VA's delay in responding to TAVA's rulemaking petition has been unreasonable and warrants mandamus.

On the first and arguably most important factor (and, by extension, the second factor), no "rule of reason" governs VA's nearly eight-year delay, especially given that VA has already prepared multiple NPRMs. The third and fifth *TRAC* factors further confirm that mandamus is warranted, as VA's failure to respond to TAVA's rulemaking petition has directly impacted "human health and welfare" and prejudiced the interests of transgender veterans who rely on VA to provide medically necessary care. Gender-confirmation surgery is essential care, and its provision is especially urgent given the increased risks of suicide and self-harm faced by transgender and veteran populations.

VA cannot argue that responding to the rulemaking petition will delay actions of a higher or competing priority, given both the negligible cost of publishing an already-drafted proposed rule and VA's own recognition in its submissions to OIRA that any costs imposed by the rule TAVA requests are not economically significant. This analysis should also inform the Court's analysis of the traditional mandamus requirements, *see Cheney v. U.S. Dist. Ct. for D.C.*, 542 U.S. 367, 380-81 (2004), as VA's failure to respond leaves TAVA with no other means to attain adequate relief, TAVA's right to a response from VA is clear and indisputable, and a writ of mandamus is appropriate in these high-stakes circumstances.

This Court should grant this petition for writ of mandamus and compel VA to grant or deny TAVA's rulemaking petition from nearly eight years ago.

I. The TRAC factors are the appropriate standard for this Court to evaluate mandamus petitions based on unreasonable delay.

This Court should use the *TRAC* factors to evaluate whether VA has engaged in unreasonable delay in failing to respond to TAVA's 2016 rulemaking petition. As the D.C. Circuit laid out, these factors establish a framework for evaluating claims of unreasonable agency delay under the All Writs Act:

- (1) the time agencies take to make decisions must be governed by a "rule of reason";
- (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;
- (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;
- (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;
- (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and
- (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

TRAC, 750 F.2d at 80 (cleaned up).

The *TRAC* factors are the appropriate standard in this matter. Every circuit to have considered the question employs the *TRAC* factors for mandamus claims based on unreasonable delay. The D.C. Circuit has repeatedly explained that it "analyzes unreasonable delay claims under the now-familiar criteria set forth in *TRAC*[,]" *In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000), including when it "exercise[es] our equitable powers under the All Writs Act . . . for assessing claims of agency delay[.]" *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 549

(D.C. Cir. 1999); see also, e.g., In re Core Commc'ns, Inc., 531 F.3d 849, 855 (D.C. Cir. 2008) (analyzing All Writs Act mandamus claim based on unreasonable delay under *TRAC* factors); In re Ctr. for Biological Diversity, 53 F.4th 665, 670 (D.C. Cir. 2022) (same).

The First and the Ninth Circuits have followed suit. See Towns of Wellesley, Concord & Norwood, Mass. v. FERC, 829 F.2d 275, 277 (1st Cir. 1987) (applying TRAC factors to analyze mandamus claim based on unreasonable delay); In re A Cmty. Voice, 878 F.3d 779, 783-84 (9th Cir. 2017) (explaining that the Ninth Circuit "applies the six factor balancing test set out by the D.C. Circuit in TRAC" in "deciding whether to grant a mandamus petition on the grounds of unreasonable delay" (citing Indep. Mining Co. v. Babbitt, 105 F.3d 502, 507 (9th Cir. 1997))); In re Nat. Res. Def. Council, Inc., 956 F.3d 1134, 1138 (9th Cir. 2020) (same) ("NRDC").

In particular, the *TRAC* factors are the proper standard for evaluating whether an agency has engaged in unreasonable delay in responding to a rulemaking petition. *See NRDC*, 956 F.3d at 1138; *A Cmty. Voice*, 878 F.3d at 786 (finding agency's eight-year delay—only a few months more than that in this case—in responding to rulemaking petition to be unreasonable, and granting writ of mandamus).

This Court has indicated that the *TRAC* factors are the proper standard to review mandamus claims based on unreasonable delay and claims under 5 U.S.C.

§ 706(1). In 2018, this Court held that the *TRAC* factors govern evaluation of unreasonable delay claims in the context of individual veterans' benefits decisions. *Martin v. O'Rourke*, 891 F.3d 1338, 1348 (Fed. Cir. 2018). There, the Court relied on several of the above-listed decisions, *see*, *e.g.*, *id.* at 1345 (citing *Towns*, 829 F.2d at 277), including those pertaining to agency failures to respond to a rulemaking petition. *See*, *e.g.*, *id.* (citing *A Cmty. Voice*, 878 F.3d at 783-84). And in 2010, this Court relied on *TRAC* to confirm that it has the authority under the All Writs Act to review mandamus claims based on agency action unlawfully withheld under 5 U.S.C. § 706(1)—which also prohibits unreasonable agency delay. *In re Paralyzed Veterans of Am.*, 392 F. App'x 858, 859-60 (Fed. Cir. 2010).

This Court should follow other circuit courts and its own reasoning by adopting the *TRAC* factors as the standard for evaluating mandamus claims based on unreasonable delay under 5 U.S.C. § 706(1) and 5 U.S.C. § 555(b).

II. VA's delay has been unreasonable under the TRAC factors.

VA has failed to act on TAVA's rulemaking petition for nearly eight years. VA is obligated by law "to conclude a matter presented to it" within "a reasonable time " 5 U.S.C. § 555(b); see also id. § 706(1) (authorizing courts to "compel

¹ The Court also clarified that the "three traditional requirements" for mandamus still "must be demonstrated for mandamus to issue." *Id.* at 1343 n.5 (citing *Cheney*, 542 U.S. at 391). The *TRAC* factors are relevant to each of these requirements, as described *infra*.

agency action . . . unreasonably delayed"). Although "[t]here is no *per se* rule as to how long is too long to wait for agency action," *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004), the well-established *TRAC* factors provide guidance to courts to determine how long an agency can reasonably wait to act. *In re Barr Labs.*, *Inc.*, 930 F.2d 72, 74-75 (D.C. Cir. 1991). Considering these factors, VA has unjustifiably failed to either grant or deny the petitioners' rulemaking request. All of the *TRAC* factors strongly support issuance of mandamus.

A. No "rule of reason" justifies VA's failure to respond.

The first *TRAC* factor weighs heavily in favor of mandamus because the length of VA's delay is beyond a rule of reason. Under the first factor, "the time agencies take to make decisions must be governed by a rule of reason." *TRAC*, 750 F.2d at 80 (cleaned up). The length of agency delay is "the most important factor" in multiple circuits. *Martin*, 891 F.3d at 1345 (citing *A Cmty. Voice*, 878 F.3d at 786); see also Core Commc'ns, 531 F.3d at 855 (time is "[t]he first and most important factor" (quoting *TRAC*, 750 F.2d at 80)); *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1102 (D.C. Cir. 2003) (first factor is the "ultimate issue."); *NRDC*, 956 F.3d at 1139 ("The most important *TRAC* factor is the first factor, the rule of reason") (cleaned up).

Even though there is no "hard and fast rule with respect to the point in time at which a delay becomes unreasonable," *Martin*, 891 F.3d at 1346, courts agree that

"a reasonable time for agency action is typically counted in weeks or months, not years." *Am. Rivers*, 372 F.3d at 419 (citing *Midwest Gas Users Ass'n v. FERC*, 833 F.2d 341, 359 (D.C. Cir. 1987)). Here, VA received and prepared all the necessary materials to respond to the rulemaking petition years ago. Yet VA has still not decided the petition, nor has it published an NPRM or a proposed rule in the Federal Register.

The D.C. Circuit, as well as courts across the country, have found similar delays to be unreasonable. See, e.g., Am. Rivers, 372 F.3d at 419 (finding "six-yearplus delay nothing less than egregious"); Core Commc'ns, 531 F.3d at 857 (same for seven-year delay); NRDC, 956 F.3d at 1139 (same for ten- and twelve-year delays). These decisions include agency failures to respond to rulemaking petitions. See In re Int'l Chem. Workers Union, 958 F.2d 1144, 1150 (D.C. Cir. 1992) (finding sixyear delay in responding to rulemaking petition unreasonable because "[t]here is a point when the court must let the agency know, in no uncertain terms, that enough is enough, and we believe that point has been reached") (cleaned up). Courts have even found shorter delays in responding to such petitions to be unreasonable. See Air Line Pilots Ass'n, Int'l v. Civil Aeronautics Bd., 750 F.2d 81, 86 (D.C. Cir. 1984) (fiveyear delay unreasonable); MCI Telecomms. Corp. v. FCC, 627 F.2d 322, 324-25 (D.C. Cir. 1980) (three-year delay unreasonable); Pub. Citizen Health Rsch. Grp. v. Auchter, 702 F.2d 1150, 1157-59 (D.C. Cir. 1983) (per curiam) (same); Fams. for

Freedom v. Napolitano, 628 F. Supp. 2d 535, 536 (S.D.N.Y. 2009) (holding nearly two-and-one-half years-delay in responding to rulemaking petition unreasonable and ordering response).

VA's repeated public promises that it is taking steps to change the rule, *see supra* Facts & Proceedings, are no justification for the delay. Courts considering comparable delays have found inaction egregious even when an agency "publicly and privately . . . appears to have done some work." *A Cmty. Voice*, 878 F.3d at 783. The Secretary has failed to offer a meaningful reason for why a decision cannot be made on the existing administrative record.

On a similar note, the second *TRAC* factor does not cut against mandamus. Under the second factor, courts consider whether Congress has indicated a time frame for when an agency is expected to act. *See Martin*, 891 F.3d at 1345 ("[A] timetable or other indication of the speed with which [Congress] expects the agency to proceed' may 'supply content' for the rule of reason." (quoting *TRAC*, 750 F.2d 70 at 80)). When there is no specific statutory timetable for agency action, courts will apply the APA's "reasonable time" standard and grant mandamus when the agency's delay is unreasonable. *See NRDC*, 956 F.3d at 1140 (citing 5 U.S.C. § 555(b)). Accordingly, the lack of a rule of reason for VA's delay here also counsels in favor of mandamus under this factor.

B. The third and fifth TRAC factors strongly support issuance of mandamus given the health and welfare interests at stake.

As other circuits have noted, the same analysis often applies to both the third and fifth *TRAC* factors. *See, e.g.*, *Barr Labs.*, 930 F.2d at 75 (noting the third factor "overlaps with the fifth"); *Martin*, 891 F.3d at 1346 (same); *A Cmty. Voice*, 878 F.3d at 787 (referring to analysis under third factor when concluding that "the fifth factor thus favors issuance of the writ").

Application of the third TRAC factor strongly favors mandamus, as VA's unreasonable delay impacts "human health and welfare" for tens of thousands of veterans. Cf. Martin, 891 F.3d at 1346 ("Veterans' disability claims always involve human health and welfare." (citing TRAC, 750 F.2d at 80)). The Veterans Health Care Eligibility Reform Act of 1996, Pub. L. 104-262, which established the current framework for veteran eligibility for medical benefits under VA's health care system, was passed to ensure the medical needs of all American veterans would be met through the provision of quality health care. Medical necessity is the standard for whether veterans are eligible for care, and all veterans who enroll in VA health care are eligible to receive the care their VA doctor determines they need. See 38 C.F.R. § 17.36(b); 38 U.S.C. § 1710. As of May 2014, there were an estimated 129,700 transgender veterans of the U.S. Military, as well as 4,600 retired transgender members of the U.S. Reserves and National Guard. See App'x 94 fig.4.

VA's approach to gender dysphoria is inconsistent with the way it identifies medically necessary treatment for other conditions for which veterans seek VA treatment. As it stands, VA prohibits coverage for "gender alterations" and does not allow for medically necessary sex reassignment surgery to treat gender dysphoria. But the *Diagnostic and Statistical Manual of Mental Disorders*—on which VA ratings for disability relating to mental disorder rely, *see* 38 C.F.R. § 4.130—dedicates an entire chapter to the diagnosis of gender dysphoria. *See* App'x 564-575.

As TAVA made clear in its original petition, gender-confirmation surgery is critical and often lifesaving care for those who live with gender dysphoria. *See* App'x 25, 403 (Bowers declaration), 416-421 (Ettner declaration); *see also supra* Facts & Proceedings. Additional evidence and guidance from major medical organizations since TAVA submitted its petition further confirms the importance of gender-confirmation surgery as effective treatment of gender dysphoria. *See supra* Facts & Proceedings; App'x 108-115. Thorough treatment of gender dysphoria is particularly essential because veterans are already at a unique risk of suicide compared to their civilian counterparts. *See supra* Facts & Proceedings. As the original petition shows, gender-confirmation surgery is therefore a critical bulwark against exacerbation of that risk. *See* App'x 23 & n.30, 402-403 (Bowers declaration), 414-415 (Ettner declaration); *see also supra* Facts & Proceedings.

Application of the fifth *TRAC* factor, which examines the nature of the interests prejudiced by delay, aligns with much of the analysis under the third *TRAC* factor, since they "are often considered together and require the Court to consider Plaintiff's interests, health, and welfare." *Rezaei v. Garland*, No. CV 23-1645 (CKK), 2023 WL 5275121, at *3 (D.D.C. Aug. 16, 2023). This delay prejudices the interests of transgender veterans who served this country by denying them the medically necessary health care that they have earned and that VA has a statutory obligation to provide. Further delay exacerbates these significant harms.

C. Responding to the rulemaking petition will not interfere with agency activities of a higher or competing priority.

Under the fourth *TRAC* factor, courts consider the effect of expediting delayed action on agency activities of a higher or competing priority. *TRAC*, 750 F.2d at 80. Here, VA has no colorable argument that responding to the rulemaking petition will unduly burden or divert its resources, whether financial or administrative.

An agency's concerns about cost, complexity, or limited resources do not excuse unreasonable delay. *See Cobell v. Norton*, 240 F.3d 1081, 1097 (D.C. Cir. 2001) ("[N]either a lack of sufficient funds nor administrative complexity, in and of themselves, justify extensive delay, nor can the government claim that it has become subject to unreasonable expectations."); *Sierra Club v. Gorsuch*, 715 F.2d 653, 659 (D.C. Cir. 1983) ("Judicial review of decisions not to regulate must not be frustrated by blind acceptance of an agency's claim that a decision is still under study."); *In re*

Pub. Emps. for Env't Resp., 957 F.3d 267, 275 (D.C. Cir. 2020) (recognizing "that agencies have legitimate resource-based concerns," but finding "agencies' competing obligations cannot justify their nineteen-year holdup").

Resource-based arguments are particularly unpersuasive here. The record shows that responding to the rulemaking petition would impose negligible financial and administrative costs on VA. Petitioners ask only that VA formally respond to the rulemaking petition. VA has already drafted multiple proposed rules, *see* App'x 393-398; conducted a thorough financial impact analysis, *see id.* 553-563, 326; gone through OIRA cost-benefit analysis, *see id.* 399, 401; and published and received comment on the rulemaking petition. *See id.* 364-365. All that remains to be done is formal resolution of the petition.

Moreover, VA provision of gender-confirmation surgery is not financially burdensome. In its submissions to OIRA, VA has repeatedly classified its proposed rule as "non-major" under 5 U.S.C. § 801, see App'x 393-394, 396, 398, as it is "[un]likely to result in an annual effect on the economy of \$100 million or more" See id. 551. VA has also repeatedly characterized the proposed rule's priority status as "other significant," see id. 394-396, 398, which means a "rulemaking that is not 'economically significant' but is considered significant by the agency." See id. 551; cf. id. 397 (clarifying that the rule which went through full OIRA review is not economically significant under definitions provided). It is thus

undisputed that TAVA's proposed rulemaking will not unduly burden or divert VA's financial resources.

In fact, according to VA's own economic impact analysis, the projected cost of providing gender-confirmation surgery at VA hospitals is minimal—and VA might even realize cost savings. *Id.* 553-563. Already, VA "must pay for post-operative care and complications from transition surgeries provided outside" VA. *Id.* 560. "By ensuring that the entire transition process is handled within the VHA system, [VA] ha[s] better continuity of care and better control of pricing." *Id.* Furthermore, "transition-related surgery has been proven effective at mitigating serious health conditions including suicidality, substance abuse and dysphoria that, left untreated, impose treatment costs on the VHA." *Id.*

By VA's own admissions, responding to the rulemaking petition and promulgating the rule requested therein will have little to no financial impact, nor will it impact agency activities of a higher or competing priority. Under the fourth *TRAC* factor, Petitioner unequivocally prevails.²

² Under the sixth factor, a "court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed." *TRAC*, 750 F.2d at 80 (cleaned up). VA's repeated assurances that it plans to act are thus immaterial to the reasonableness of its nearly eight-year delay.

III. TAVA satisfies the *Cheney* conditions for mandamus to issue.

The TRAC analysis overlaps with each of the traditional requirements for mandamus: namely, that (1) "the party seeking issuance of the writ must have no other adequate means to attain the relief he desires," (2) the party "must satisfy the burden of showing that his right to issuance of the writ is clear and indisputable," and (3) "the issuing court, in the exercise of its discretion, must be satisfied that the writ is appropriate under the circumstances." *Cheney*, 542 U.S. at 391 (cleaned up). This Court has never had occasion to clarify the relationship between the TRAC and Cheney standards for issuance of a writ of mandamus to redress unreasonable agency delay. Cf. Martin, 891 F.3d at 1343 n.5 (remanding to court of original jurisdiction over writ of mandamus "to consider the traditional mandamus requirements as informed by the TRAC analysis"). Nor is undersigned counsel aware of any other court of appeals that has done so. But it is plain that TAVA satisfies both the TRAC and Cheney standards. Mandamus should issue.

A. TAVA has no other means to attain adequate relief.

This request for mandamus is Petitioner's only means to obtain relief. TAVA has repeatedly tried to prompt VA to act, including through previous litigation, *see* App'x 184-372, and attempts at pre-suit resolution. *See id.* 543-548. In response to TAVA's recent demand letter, VA recited the same language it has used previously to describe its vague plans to act on the petition and declined to adjudicate TAVA's

rulemaking petition. See supra Facts & Proceedings. This most recent VA statement is not final agency action, such that it would be subject to judicial review. See, e.g., Her Majesty the Queen in Right of Ontario v. EPA, 912 F.2d 1525, 1534 (D.C. Cir. 1990) (holding letter stating that agency is "actively working to develop the kind of information that would enable it to" grant rulemaking petition "do[es] not represent final agency action . . . on petitioners' request for rulemaking"). "An agency cannot avoid its obligation to 'fully and promptly consider' a petition for rulemaking—and shield itself from future judicial review—merely by issuing a noncommittal response." Whale & Dolphin Conservation v. Nat'l Marine Fisheries Serv., 573 F. Supp. 3d 175, 180 (D.D.C. 2021) (finding unreasonable delay lawsuit not mooted by agency letter that fails to provide definitive answer as to whether agency was granting or denying rulemaking petition).

TAVA has no choice but to seek a writ of mandamus from this Court in order to receive the response it is due. There is no other avenue for judicial review. Veterans who have served this country and suffer from gender dysphoria rely on VA health care and need a resolution on the question of whether and when VA will act.

The *TRAC* factors are relevant to this prong of the *Cheney* test, since TAVA cannot directly challenge an agency's decision if none exists. This Court has recognized this logic before, noting that "[a] veteran who is claiming the VA has failed to render a timely decision [on his benefits] cannot seek relief through direct

appeal" and "must [instead] petition for a writ of mandamus before the Veterans Court to obtain that relief." *Proceviat v. McDonough*, No. 2021-1810, 2021 WL 4227718, at *3 (Fed. Cir. Sept. 16, 2021) (cleaned up). There, this Court applied the *TRAC* factors and issued mandamus. *Id.*; *cf. Am. Rivers*, 372 F.3d at 419 ("[T]he primary purpose of the writ in circumstances like these is to ensure that an agency does not thwart our jurisdiction by withholding a reviewable decision." (citing *TRAC*, 750 F.2d at 76)).

Here, if VA denied the rulemaking petition, TAVA could challenge the decision under 5 U.S.C. § 706(2); if VA promulgated a rule with which TAVA disagreed, it could challenge it under the same provision. But in the absence of any action that TAVA can challenge by other means, mandamus is the only solution. Accordingly, the analysis of the *TRAC* factors above demonstrating unreasonable delay also proves that TAVA has no other means to attain adequate relief.

B. TAVA's right to issuance of the writ is clear and indisputable.

Under the APA, "each agency shall proceed to conclude a matter presented" to it "within a reasonable time." 5 U.S.C. § 555(b); see also id. § 706(1) (empowering courts to "compel agency action unlawfully withheld or unreasonably delayed"). "This has been interpreted to mean that an agency has a duty to fully respond to matters that are presented to it under its internal processes." A Cmty. Voice, 878 F.3d at 784 (citing 5 U.S.C. § 555(b)); see also Am. Rivers, 372 F.3d at

418-19 (holding that, under 5 U.S.C. § 706(1), federal agency must respond to rulemaking petition); KRISTIN E. HICKMAN & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 4.10 (7th ed. 2024) ("At a minimum, the right to petition for rulemaking entitles a petitioning party to a response to the merits of the petition."); Nat'l Parks Conservation Ass'n v. U.S. Dep't of Interior, 794 F. Supp. 2d 39, 44 (D.D.C. 2011) ("[A]n agency 'is required to at least definitively respond to . . . [a] petition—that is, to either deny or grant the petition." (quoting Fams. for Freedom, 628 F. Supp. 2d. at 540, and citing 5 U.S.C. §§ 555(b), 706(1))); Env't Integrity Proj. v. EPA, 160 F. Supp. 3d 50, 54 (D.D.C. 2015) ("[T]he APA is the source of an agency's duty to respond to a petition for rulemaking . . . within a reasonable time"). VA has a duty to respond to the rulemaking petition TAVA submitted.

The *TRAC* factor analysis is also relevant to this prong of the *Cheney* test. *Cf. Oil, Chem. & Atomic Workers Union v. Occupational Safety & Health Admin.*, 145 F.3d 120, 124 (3d Cir. 1998) (applying several *TRAC* factors to determine whether "[t]he legal duty [was] 'clear and indisputable"). TAVA has a clear and indisputable right to a formal response to its rulemaking petition absent a reasonable explanation from VA for its delay.

Other circuits' application of *TRAC* factors to the "clear duty" requirement for mandamus is instructive. There, as here, the critical question is whether petitioners

have a right to the relief requested. The D.C. Circuit has repeatedly applied the TRAC factors in assessing whether the agency's duty to petitioners was violated through unreasonable delay. For instance, in Am. Hosp. Ass 'n v. Burwell, the court explained that, "where plaintiffs allege that agency delay is unreasonable despite the absence of a specific statutory deadline, the entire TRAC factor analysis may go to the threshold jurisdictional question: does the agency's delay violate a clear duty?" 812 F.3d 183, 189-90 (D.C. Cir. 2016); see also, e.g., Bluewater Network, 234 F.3d at 1315 (explaining that "[i]n the case of agency inaction, we not only must satisfy ourselves that there indeed exists such a duty [to act], but that the agency has 'unreasonably delayed' the contemplated action" and "[t]his court analyzes unreasonable delay claims under the now-familiar criteria set forth in TRAC"); In re People's Mojahedin Org. of Iran, 680 F.3d 832, 836 (D.C. Cir. 2012) (same); Am. Rivers, 372 F.3d at 418 (same). These principles extend to claims under the All Writs Act. See Core Commc'ns, 531 F.3d at 855 (citing Bluewater Network, 234 F.3d at 1315, to explain that TRAC factors govern unreasonable delay analysis after agency's duty to act has been established). The Fourth and Ninth Circuits have taken similar approaches, see e.g., In re City of Virginia Beach, 42 F.3d 881, 884-86 (4th Cir. 1994), including on agency failure to respond to rulemaking petitions. See, e.g., A Cmty. Voice, 878 F.3d at 784-85.

This Court should look to the above analysis of the *TRAC* factors in determining whether TAVA's right to a formal response from VA to its May 2016 rulemaking petition is clear and indisputable. Just as the *TRAC* factors establish when an agency violated its clear duty for purposes of the Mandamus Act, so too do they establish whether a petitioner has a clear and indisputable right to a writ of mandamus under *Cheney*. Application of these factors demonstrates that Petitioner has such a clear and indisputable right.

C. Issuance of the writ is appropriate under the circumstances.

Over the course of nearly eight years, thousands of transgender veterans have been left in limbo, unable to access vital medical care, and confused by the contradictions between the Secretary's public statements and VA's lack of official action. This delay is egregious, and this confusion requires correction in the form of mandamus.

Every day that the VA further delays its response to TAVA's petition, TAVA members' mental and physical health suffers. For example, without access to an orchiectomy at the VA, Ms. Kastner is left with no choice but to take a testosterone blocker that manages her gender dysphoria—yet simultaneously risks exacerbating her Type 2 diabetes. App'x 578 ¶ 16. Other TAVA members are approaching an age at which they fear gender-confirmation surgery may no longer be a safe medical

procedure. See, e.g., id. 583 ¶ 19. For such veterans, the VA's response may come too late.

The *TRAC* factors analysis once more confirms that this Court should exercise its equitable power to issue mandamus, given the unreasonable and egregious nature of this nearly eight-year delay. As the D.C. Circuit has explained, "[o]n the equities, the central question is whether the agency's delay is so egregious as to warrant mandamus" under the All Writs Act, and "[t]he hexagonal *TRAC* factors guide this inquiry" *Ctr. for Biological Diversity*, 53 F.4th at 670 (cleaned up); *see also id.* at 671 (granting writ of mandamus); *United Mine Workers*, 190 F.3d at 549 (noting the *TRAC* factors apply in the "exercis[e of] our equitable powers under the All Writs Act"). The *TRAC* assessment of reasonableness bears directly on this Court's determination of the appropriate remedy.

CONCLUSION

Transgender veterans have kept their promise to serve the United States. In return, the Government must honor its commitment to them by providing services and care necessary for their health and survival. VA has failed to meet its obligation under the Administrative Procedure Act to respond to TAVA's rulemaking petition within a reasonable time. The health and welfare of TAVA's members are at stake, and VA has already completed the necessary steps to respond to the petition. TAVA has no other adequate means to obtain relief. Petitioner respectfully requests that the

Court issue a writ of mandamus and compel VA to respond to the petition for rulemaking within thirty days.

January 25, 2024

Respectfully submitted,

(203) 432-4800

michael.wishnie@ylsclinics.org

/s/ Michael J. Wishnie
John Baisley, Law Student Intern*
Alexandra Johnson, Law Student Intern*
K.N. McCleary, Law Student Intern*
Sonora Taffa, Law Student Intern*
Michael J. Wishnie, Supervising Attorney
Veterans Legal Services Clinic
Jerome N. Frank Legal Services Organization
Yale Law School**
P.O. Box 209090
New Haven, CT 06520-9090

^{*} Motion for law student appearance forthcoming.

^{**} This brief does not purport to state the views of Yale Law School, if any.

FORM 19. Certificate of Compliance with Type-Volume Limitations

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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No. 24-____

In the United States Court of Appeals for the Federal Circuit

IN RE TRANSGENDER AMERICAN VETERANS ASSOCIATION, Petitioner.

APPENDIX VOLUME I (1-398)

Michael J. Wishnie

Counsel of Record

VETERANS LEGAL SERVICES

CLINIC

JEROME N. FRANK LEGAL

SERVICES ORGANIZATION

YALE LAW SCHOOL

P.O. Box 209090

New Haven, CT 06520-9090

(203) 436-4780

michael.wishnie@ylsclinics.org

Counsel for Petitioner

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¹ Some items in the appendix are taken from the appendices in *Fulcher v. Sec'y of Veterans Affs.* (No. 2017-1460) (Fed. Cir.). The Bates numbers on these items have been struck through in red.

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- 543-547: Letter from Michael Wishnie, Counsel for TAVA, to U.S. Dep't of Veterans Affs. Acting General Counsel Richard J. Hipolit (November 20, 2023).
- **548**: Letter from U.S. Dep't of Veterans Affs. Acting General Counsel Richard J. Hipolit to Ilona Turner & Sasha Buchert, Former Counsel for TAVA (December 22, 2023).
- **549-552**: Frequently Asked Questions, REGULATIONS.GOV, https://www.regulations.gov/faq.
- **553-563**: Off. of the Sec'y, *Economic Impact Analysis for RIN 2900-AP69*, *Removing Gender Alterations Restriction from the Medical Benefits Package*, U.S. DEP'T VETERANS AFFS. (July 29, 2016).
- **564-575**: Am. Psychiatric Ass'n, *Gender Dysphoria*, *in* Diagnostic and Statistical Manual of Mental Disorders, Text Revisions 164.0 (5th ed. 2022).
- 576-579: Declaration of Natalie Rose Katner.

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580-583: Declaration of Ray Gibson.584-588: Declaration of Rebekka Eshler.

PETITION FOR RULEMAKING TO PROMULGATE REGULATIONS GOVERNING PROVISION OF SEX REASSIGNMENT SURGERY TO TRANSGENDER VETERANS

SUBMITTED TO

THE UNITED STATES DEPARTMENT OF VETERANS AFFAIRS MAY 9, 2016

Dee Fulcher, Giuliano Silva, and Transgender American Veterans Association

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Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association ("TAVA") (together, "Petitioners") hereby petition the Secretary of Veterans Affairs (the "Secretary") to amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4) and any implementing directives, that exclude medically necessary sex reassignment surgery for transgender veterans from the medical benefits package provided to veterans under the health care system of the Department of Veterans Affairs ("Department" or "VA"), and to promulgate regulations expressly including medically necessary sex reassignment surgery for transgender veterans in that medical benefits package.

I. INTRODUCTION

When Congress enacted the Veterans Health Care Eligibility Reform Act of 1996 (Pub. L. 104-262), establishing the current framework for veteran eligibility for medical benefits under the VA health care system, the United States sought to ensure that the medical needs of all American veterans would be met through the provision of quality health care. To implement that directive, the Department has promulgated a series of regulations establishing robust coverage for the panoply of medical needs that veterans of our armed services might confront. But in contravention of that directive, the Department also has promulgated a discriminatory regulation that singles out transgender veterans and bars the provision of medically necessary sex reassignment surgery to treat gender dysphoria. *See* 38 C.F.R. § 17.38(c)(4) (prohibiting coverage for "gender alterations") (the "Regulation").

That bar has remained in place notwithstanding the existence of a broad medical consensus about the need for sex reassignment surgery for many transgender people, and notwithstanding the United States' own evolving policies on the ability of transgender people to serve openly in the military. The Department's exclusion for sex reassignment surgery was not supported by medical evidence when it was implemented in 1999, and it is even more

indefensible today. The Department should eliminate the categorical exclusion of sex reassignment surgery as a treatment for gender dysphoria, and expressly include sex reassignment surgery in the medical benefits package available to veterans, either as an exercise of the Secretary's discretion or in recognition of the fact that the exclusion is both arbitrary and capricious and unconstitutional.

Providing sex reassignment surgery to transgender veterans for whom it is medically indicated is required by the Department's stated policy of providing medically necessary care to all veterans. That sex reassignment surgery is a medically necessary treatment for gender dysphoria is not in dispute within the medical community; all major medical associations recognize this treatment as such. Providing sex reassignment surgery to transgender veterans is essential to relieving the serious distress caused by gender dysphoria. Our Nation owes transgender veterans this treatment in the same way it owes all other veterans medically necessary care for their serious medical conditions. Finally, although the Department has never justified the exclusion for sex reassignment surgery on cost grounds, it bears emphasis here that any marginal increase in the Department's total expenditures on medical care—which should be negligible—should be offset in whole or in part by the reduced costs of long-term health care that would otherwise be necessary for some transgender veterans denied surgical treatment.

Including sex reassignment surgery in the medical benefits package is legally required, and the refusal to do so would constitute arbitrary and capricious agency action, subject to reversal by the federal courts. The established medical consensus plainly requires the inclusion of sex reassignment surgery in the medical benefits package, on equal footing with medical treatments that address other similarly serious and treatable medical conditions. Indeed, the Department recognizes the seriousness of gender dysphoria as a medical condition: It offers

other treatments that may be necessary (but not sufficient) to ameliorate that condition, such as hormone therapy, and it offers ancillary treatments supporting sex reassignment surgery, such as pre- and post-surgical care, for the few who can pay for the surgery on their own. Nor does the Department appear to have any rational objection to the forms of surgery involved in sex reassignment surgery: The Department's regulations and directives offer surgeries identical or substantially similar to those constituting sex reassignment surgery to veterans with other medical conditions. And, finally, the VA excluded sex reassignment surgery without examining any relevant data and without giving any public explanation for the exclusion. All of this lays bare the arbitrariness of the exclusion at issue here.

The Fifth Amendment to the Constitution likewise bars the exclusion. To offer certain medically necessary surgeries to veterans for some conditions, yet to deny the same or substantially similar surgeries to transgender veterans to treat gender dysphoria, constitutes unconstitutional discrimination on the basis of sex and transgender status, and the regulations implementing this discrimination fail to survive any level of scrutiny that may be applied. These regulations—lacking any connection to medical consensus or any other rational justification—are also unconstitutional under a long line of Supreme Court cases forbidding discriminatory treatment that appears to be based on "a bare ... desire to harm a politically unpopular group'[.]" *United States v. Windsor*, 133 S. Ct. 2675, 2693 (2013) (quoting *Department of Agriculture v. Moreno*, 413 U.S. 528, 534-35 (1973)).

The amendments this petition seeks are not only good policy and legally required—they also are urgent. The suicide rate for individuals with untreated gender dysphoria is significantly higher than that of the general population, as is the prevalence of depression, self-harm, and drug and alcohol addiction. Appropriate treatment is necessary to prevent such suffering and long-

term harm. Petitioners respectfully request that the Secretary attend to the urgency of the need of some transgender veterans for sex reassignment surgery in his consideration of this petition.

II. LEGAL AUTHORITY

Congress granted the Secretary of Veterans Affairs the "authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department," which include laws governing veterans' benefits. 38 U.S.C. § 501(a). The Secretary thus has the authority to amend or repeal the rules and regulations that are the focus of this petition, including 38 C.F.R. § 17.38(c)(4), and to issue appropriate rules and regulations in their place.

III. PETITIONERS

Petitioners each have the statutory right to petition the Department for rulemaking pursuant to 5 U.S.C. § 553(e), which requires "[e]ach agency [to] give an interested person the right to petition for the issuance, amendment, or repeal of a rule." Petitioners also satisfy the standing requirements of Article III of the United States Constitution.

TAVA is a 501(c)(3) organization dedicated to ensuring that transgender veterans receive appropriate and necessary medical care. TAVA was founded in 2003 to advocate on behalf of transgender veterans within the VA health care system. Its mission is to work with the VA, Congress, veterans, active-duty military personnel, and LGBT groups to influence the VA and military policy, regulations, and procedures regarding the provision of medical and psychological care to veterans with gender dysphoria. While TAVA primarily focuses on ensuring the fair and equal treatment of transgender individuals, it is committed to improving the health care of all American veterans.

TAVA is a membership organization, and many of its members are transgender veterans currently enrolled in the VA health care system. Affidavit of Evan Young ("Young Aff.") ¶ 11.

Some of those individuals have been diagnosed with gender dysphoria by the VA and have been provided some medical care related to their diagnosis. *Id.* However, members who have sought sex reassignment surgery through the VA, or coverage of such surgery by the VA, have been denied such surgery or coverage because of the existing regulatory exclusion of "gender alterations" from covered benefits. *Id.* Many of those veterans rely on the VA for provision of their mental and physical health care, and they satisfy all the medical prerequisites for sex reassignment surgery: They have been diagnosed with gender dysphoria (often by VA clinicians), they have spent multiple years living in a gender role consistent with their gender identity and are currently undergoing hormone therapy to assist in their transition, and they have been prescribed sex reassignment surgery by qualified mental health providers as medically necessary treatment for their condition. Id. Nevertheless, these veterans have been unable to obtain medically necessary sex reassignment surgery due to the VA's categorical bar on "gender alterations." Id. These veterans are currently, concretely, and directly harmed by the VA's bar on sex reassignment surgery; granting the petition and repealing or amending the Regulation as requested herein would provide them with redress.

TAVA's purpose in submitting this petition is to advocate on behalf of its members who have been denied medically necessary treatment as a result of the VA's regulations. Young Aff. ¶ 12. This petition directly advances one of TAVA's central organizational goals—to achieve reform of the VA's policies regarding coverage of sex reassignment surgery and other medical procedures related to gender dysphoria. *Id.* If the VA were to amend its regulations to include coverage of sex reassignment surgery, such an amendment would significantly improve the physical and mental health of TAVA members and of other transgender veterans with gender dysphoria. *Id.*

Although the relief requested by TAVA in this petition does not require the participation of TAVA's individual members, *see, e.g., Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362, 1369 (Fed. Cir. 2007), TAVA is joined in this petition by Dee Fulcher and Giuliano Silva, individual transgender veterans whose interests are directly affected by the VA's exclusion of sex reassignment surgery.

Dee Fulcher is a veteran of the U.S. Marine Corps and a member of TAVA. Affidavit of Dee Fulcher ("Fulcher Aff.") ¶ 2. Dee is a transgender woman. *Id.* She was first diagnosed with gender dysphoria by a physician outside of the VA health care system. *Id.* ¶ 6.

Ms. Fulcher's diagnosis of gender dysphoria has been confirmed by a clinical mental health social worker and a board certified physician in internal medicine, both at the Southeast Louisiana Veterans Healthcare System (part of the VA health care network). *Id.* ¶¶ 6-7. Ms. Fulcher's VA clinicians have both recommended that she receive sex reassignment surgery as the next step in her treatment for gender dysphoria. *Id.* If that were covered by the VA, Ms. Fulcher would pursue such surgery, including penectomy, vaginoplasty, facial feminization, breast augmentation, and electrolysis. *Id.* ¶ 8. Yet due to the VA's exclusion of sex reassignment surgery, Ms. Fulcher cannot receive this medically necessary treatment that her physician and mental health provider have prescribed for her.

Giuliano Silva is a veteran of the U.S. Army and a member of TAVA. Affidavit of Giuliano Silva ("Silva Aff.") ¶ 2. Mr. Silva is a transgender man and has been diagnosed with gender dysphoria by medical providers at the Miami VA Healthcare System. *Id.* ¶ 10. While Mr. Silva would seek sex reassignment surgery (in particular, a mastectomy) if that surgery were covered, Mr. Silva also has suffered, and continues to suffer, from additional effects of the VA's exclusion of sex reassignment surgery on the medical practices of VA healthcare providers.

Id. ¶ 15. The VA's exclusion of sex reassignment surgery has had the effect of preventing Mr. Silva from receiving a mastectomy, which a VA physician has recommended to Mr. Silva to treat his severe back pain and related problems. Id. ¶ 11. The surgeon to whom this physician referred Mr. Silva appears to have determined that Mr. Silva is seeking the mastectomy primarily as transition-related surgery, rather than as a surgery to address his severe back problems, and has consequently determined that the surgery is not covered. Id. In Mr. Silva's experience, the VA's exclusion of sex reassignment surgery has left VA doctors skeptical of the medical needs of transgender veterans and outwardly hostile to treating them. Id. ¶ 12.

IV. BACKGROUND: THE CURRENT REGULATORY FRAMEWORK, GENDER DYSPHORIA, AND SEX REASSIGNMENT SURGERY

A. The VA's Provision of Medical Care

Under 38 U.S.C. § 1710, the Secretary "shall furnish" "medical services" that the Secretary determines to be "needed" by several classes of veterans, including those with a service-connected disability, former prisoners of war, veterans of World War I, and all veterans who are unable "to defray the expenses of necessary care," which include all veterans who qualify for Medicaid, receive a qualifying pension, or meet specified income thresholds.

38 U.S.C. §§ 1710(a)(1)-(2), 1722 (a)(1)-(3). In addition, under § 1710, the Secretary is authorized to provide "needed" "medical services" to all veterans "to the extent resources and facilities are available." 38 U.S.C. § 1710(a)(3). Thus, all veterans are eligible to receive medically necessary health care, as determined by the Secretary, as long as the VA has the resources to provide or pay for such care. As President Clinton explained in signing the current enabling statute into law, it "authorizes the Department of Veterans Affairs to furnish comprehensive medical services to all veterans." Presidential Statement on Signing Veterans Legislation, 32 Weekly Comp. Pres. Doc. 2018 (Oct. 9, 1996).

Veterans who enroll in the VA health care system (as well as certain other veterans meeting other criteria¹) are entitled to a "medical benefits package" as defined by regulation (the "Medical Benefits Package"). 38 C.F.R. § 17.36. The regulation sets forth a broad and overarching directive for the provision of veterans' health care: Veterans are meant to receive a given medical treatment "if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice." 38 C.F.R. § 17.38(b). Care is deemed "to promote health" if "the care will enhance the quality of life or daily functional level of the veteran." *Id.* at 17.38(b)(1). To that end, the regulation broadly covers inpatient and outpatient medical, surgical, and mental health care. *See* 38 C.F.R. § 17.38(a).

B. Gender Dysphoria and Sex Reassignment Surgery

At issue in this petition is the VA's coverage of medically necessary health care for veterans with gender dysphoria. By way of background, "gender identity" is an established medical concept, referring to one's intrinsic understanding of oneself as being a particular gender. Declaration of Dr. Randi C. Ettner ("Ettner Decl.") ¶ 11. Gender identity is an innate aspect of personality that is firmly established, generally by the age of four, although individuals vary in the age at which they come to understand and express that identity. *Id.* Typically, people who are designated female at birth based on the appearance of their genitalia identify as girls or women, and people who are designated male at birth identify as boys or men. *Id.* ¶ 12. For transgender individuals, however, the person's gender identity differs from the sex assigned to

Under 38 C.F.R. § 17.37, even veterans who are not enrolled in the VA health care system may receive the care in the Medical Benefits Package, or some subset thereof, if they fall within one of certain specified classes. For example, veterans with service-connected disabilities that meet specified severity criteria are entitled to all the care in the Medical Benefits Package (§ 17.37(a)), and a veteran with a compelling medical need to complete a course of VA treatment started when the veteran was enrolled in the VA health care system may continue to receive that treatment regardless of the veteran's continuing enrollment status (§ 17.37(d)).

that person at birth.² The medical diagnosis for that feeling of incongruence is gender dysphoria, which can cause severe distress if untreated. Id. ¶ 13.

The major medical associations and diagnostic manuals uniformly recognize gender dysphoria as a serious medical condition. For example, the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition—on which the VA regulations governing ratings for disability relating to mental disorder rely, *see* 38 C.F.R. § 4.130—dedicates an entire chapter to the diagnosis of gender dysphoria.³ Other manuals too, such as the *International Classification of Diseases*, provide for a diagnosis of gender dysphoria (albeit using different terminology).⁴ Major medical organizations—including the American Psychiatric Association, the American Medical Association, the Endocrine Society, and the American Psychological Association—likewise recognize gender dysphoria, and provide for its diagnosis and full treatment, including through sex reassignment surgery where necessary. Declaration of Dr. Marci L. Bowers ("Bowers Decl.") ¶ 36; Ettner Decl. ¶¶ 11, 13-14, 18, 24, 35.

In May 2012, the American Psychiatric Association ("APA") issued an official Position

Statement on Access to Care for Transgender and Gender Variant Individuals, which:

(1) recognizes that appropriately evaluated transgender and gender variant individuals can benefit greatly from medical and surgical gender transition treatments; (2) advocates for removal

A transgender man is a person who was assigned the sex of female at birth but whose gender identity is male. A transgender woman is a person who was assigned the sex of male at birth but whose gender identity is female.

The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition ("DSM" or "DSM-5"), is used throughout the world as the authoritative guide to the diagnosis of mental disorders and includes gender dysphoria. The DSM "provides a common language for clinicians to communicate about their patients and establishes consistent and reliable diagnoses that can be used in the research of mental disorders." American Psychiatric Association, DSM Development, *available at* http://www.dsm5.org/about/Pages/faq.aspx.

World Health Organization, "Gender Identity Disorders," International Statistical Classification of Diseases and Related Health Problems, 10th Revision (2016), at F64, *available at* http://apps.who.int/classifications/icd10/browse/2016/en#/F64.0.

of barriers to care and supports both public and private health insurance coverage for gender transition treatment; and (3) opposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician.⁵

The protocol for diagnosing and treating gender dysphoria is well established and generally accepted by the medical community. The Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People promulgated by the World Professional Association for Transgender Health ("WPATH Standards" or "Standards of Care") set forth the accepted protocol for the diagnosis and treatment of gender dysphoria, and are recognized as authoritative standards of care by the American Psychiatric Association, the Endocrine Society, and the American Psychological Association. Ettner Decl. ¶ 18.

The Standards of Care identify the following treatment protocols for treating individuals with gender dysphoria:

- Changes in gender expression and role (which may involve living part-time or full-time in another gender role, consistent with one's gender identity);
- Psychotherapy (individual, couple, family, or group) for purposes such as
 exploring gender identity, role, and expression; addressing the negative
 impact of gender dysphoria and stigma on mental health; alleviating
 internalized transphobia; enhancing social and peer support; improving body
 image; or promoting resilience;
- Hormone therapy to feminize or masculinize the body; and

American Psychiatric Association, Position Statement on Access to Care for Transgender and Gender Variant Individuals (2012), *available at* http://www.psychiatry.org/File%20Library/Learn/Archives/Position-2012-Transgender-Gender-Variant-Access-Care.pdf.

 Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring).

Sex reassignment surgery is a well-established, effective, and often critical treatment for gender dysphoria. Bowers Decl. ¶¶ 31-38; Ettner Decl. ¶¶ 15, 19-34. While not all individuals with gender dysphoria require sex reassignment surgery, the WPATH Standards recognize that hormone therapy and psychotherapy may be inadequate to treat severe cases of gender dysphoria, and in those cases, failure fully to treat gender dysphoria through sex reassignment surgery may cause serious mental and physical health issues for the patient. Bowers Decl. ¶¶ 34, 37; Ettner Decl. ¶ 19-20. Without treatment, individuals with severe gender dysphoria experience anxiety, depression, suicidality, and other attendant mental health issues. Bowers Decl. ¶ 37; Ettner Decl. ¶ 15. Many such individuals carry a burden of shame and low selfesteem, attributable to a feeling of being inherently "defective," and as a result become socially isolated. Ettner Decl. ¶ 15. This isolation in turn leads to the stigmatization of such individuals, which over time proves ravaging to healthy personality development and interpersonal relationships. Id. As a result, without treatment, many such individuals are unable to function effectively in occupational, social, or other important areas of daily living. *Id.* A recent survey shows a 41% rate of suicide attempts among transgender people, far above the baseline rates for North America. *Id.* As with the diagnosis of gender dysphoria, there is a consensus within the medical community that sex reassignment surgery may be the only adequate treatment for some cases of gender dysphoria. *Id.* ¶¶ 21, 23; Bowers Decl. ¶ 34.

Courts too have recognized that gender dysphoria is a serious medical condition and that sex reassignment surgery may be medically necessary to treat certain individuals with gender

dysphoria. In *Soneeya v. Spencer*, for example, the court held that a prisoner's gender dysphoria constituted a "serious medical need" that the Massachusetts Department of Correction ("MDOC") was required under the Eighth Amendment to address adequately. Moreover, although the MDOC had provided the prisoner with psychotherapy and hormone treatment, offering such treatment alone was inadequate, as the MDOC also was required to "consider whether sex reassignment surgery ... [was] medically indicated." Likewise, in *Fields v. Smith*, the court found that gender dysphoria was a "serious medical need" within the meaning of the Eighth Amendment, and held that a statutory prohibition on hormone therapy and sex reassignment surgery for inmates was unconstitutional on its face because it deprived inmates of access to "medically necessary" treatment.

In a recent Tax Court case, *O'Donnabhain v. Commissioner*, the court conducted a trial and an in-depth review of the medical evidence regarding treatment of gender dysphoria. ⁹ The court noted the broad acceptance of the WPATH Standards throughout the psychiatric profession, as evidenced by multiple psychiatric and medical reference texts and court opinions, all concluding that sex reassignment surgery is medically necessary to ensure the health of some patients suffering from gender dysphoria. ¹⁰ Other courts to consider the necessity of surgery to treat gender dysphoria have reached similar conclusions. ¹¹

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⁸⁵¹ F. Supp. 2d 228, 231-232, 252 (D. Mass. 2012).

⁷ *Id.* at 252.

⁸ 712 F. Supp. 2d 830, 844 (E.D. Wis. 2010).

⁹ See O'Donnabhain v. Commissioner, 134 T.C. 34, 65-70 (2010).

¹⁰ *Id*.

See, e.g., De'lonta v. Johnson, 708 F.3d 520, 526 (4th Cir. 2013) (noting that sex reassignment surgery is an "accepted, effective, medically indicated treatment for GID").

Sex reassignment surgery often may be the only adequate treatment for gender dysphoria. In certain cases, sex reassignment surgery—which can include, depending upon the circumstances, removal or construction of the breasts, penectomy, vaginoplasty, phalloplasty, and penile and testicular implants—is medically necessary to treat the symptoms of gender dysphoria, and indeed may be the only medically adequate treatment.¹²

The VA's categorical ban on sex reassignment surgery in all instances, no matter how necessary it may be for an individual, flies in the face of the medical consensus on this subject. This categorical exclusion is all the more irrational because the VA recognizes that gender dysphoria is a serious medical condition that requires treatment. For example, the VA will provide, where medically necessary, hormone treatment to address gender dysphoria. The VA also will provide pre- and post-operative care for veterans who have undergone sex reassignment surgery outside the VA system. Thus, the VA appears to have no *medical* objection to sex reassignment surgery. Yet the VA irrationally continues to exclude coverage for sex reassignment surgery—no matter how medically necessary.

C. The VA's Current Provision of Surgeries Constituting Sex Reassignment Surgery To Treat Other Conditions

The VA already provides each of the surgeries that constitute sex reassignment surgery. The VA provides these surgeries for a variety of reasons, including to address certain intersex conditions, to repair traumatic injuries, and to treat cancer, but the VA denies those same procedures to transgender veterans for the treatment of gender dysphoria. For example, VA policy covers surgery for intersex veterans "in need of surgery to correct inborn conditions related to reproductive or sexual anatomy." VHA Directive 2013-003 (Feb. 8, 2013) ("VHA

See id. (noting, in the Eighth Amendment context, that providing some treatment consistent with the WPATH Standards does not mean that constitutionally adequate treatment has been provided); see also Norsworthy v. Beard, 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015) (granting preliminary injunction where plaintiff was likely to succeed in establishing that surgery was "the only way to treat her persistent symptoms of gender dysphoria").

Directive 2013-003" or "Directive 2013-003"), at 2. Under 38 C.F.R. § 17.38(a)(1)(x), the VA offers veterans "[r]econstructive (plastic) surgery required as a result of disease or trauma," which under VHA Directive 1091 (Feb. 21, 2014) ("Directive 1091") includes "those surgical procedures performed for the revision of external bodily structures which deviate from normal either from congenital or acquired causes."

Under 38 C.F.R. § 17.38(a)(1)(x) and Directive 1091, the VA offers breast reconstruction to cisgender males whose penises or testes have been damaged. Hysterectomy and mastectomy are offered to cisgender females for, among other reasons, reduction of cancer risk. The VA also offers cisgender males orchiectomies, scrotectomies, and penectomies for various medical reasons. Moreover, under the clear language of Directive 2013-003, the VA offers various procedures, including vaginoplasty and phalloplasty, for certain intersex individuals born with ambiguous genitalia.

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[&]quot;Cisgender" is a term used to describe a person whose self-identity conforms to the sex he or she was assigned at birth—*i.e.*, someone who is not transgender. *See Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1120 n.9 (N.D. Cal. 2015).

See Leong et al., Effective Breast Reconstruction in Female Veterans, 198(5) Am. J. Surg. 658-63 (Nov. 2009) (addressing outcomes of breast reconstruction performed at VA hospitals); Shimansky v. West, 17 Vet. App. 90, 90 (1999) (patient received a penile prosthesis at the Wilmington, Delaware VA Medical Center); Brewer v. Nicholson, 21 Vet. App. 420, 420 (2006) (patient received a penile prosthesis at the Jackson, Mississippi VA Medical Center); Board of Veteran's Appeals, Docket No. 96-07-121 (Sept. 26, 1997) (stating patient received a "testicular prosthetic implantation" at a VA hospital).

See Gardella et al., Prevalence of Hysterectomy and Associated Factors in Women Veterans Affairs Patients, 50(3) J. Reprod. Med. 166, 166-72 (Mar. 2005) (estimating the prevalence of hysterectomies provided by the VA Puget Sound Health Care System); Hynes et al., Breast Cancer Surgery Trends and Outcomes: Results from a National Department of Veterans Affairs Study, 198(5) J. of the Am. College of Surgeons 707-16 (Mar. 2004) (examining trends in breast cancer surgery performed at VA hospitals).

See Norvell v. Peake, 22 Vet. App. 194, 195 (2008) (noting that the patient underwent a bilateral orchiectomy at Lexington, Kentucky, VA Medical Center), aff'd sub nom. Norvell v. Shinseki, 333 F. App'x 571 (Fed. Cir. 2009); Corman et al., Fournier's Gangrene in a Modern Surgical Setting: Improved Survival with Aggressive Management, BJU International, 84: 85-88 (July 1999) (noting that all patients covered in the survey had received scrotectomies for Fournier's Gangrene and that some of the patients had been treated at West Los Angeles Veterans Administration Hospital); Board of Veterans Appeals, Docket No. 05-31 519 (Oct. 25, 2007) (noting that the patient had undergone a total penectomy at a VA hospital due to cancer).

These procedures are excluded from coverage, however, if they are necessary to treat a transgender veteran's gender dysphoria. The regulation at issue here, *i.e.*, 38 C.F.R. § 17.38(c)(4), expressly excludes "[g]ender alterations" from the Medical Benefits Package. VHA Directive 2013-003 clarifies that this exclusion constitutes an absolute bar to coverage for "sex reassignment surgery," which the Directive defines to include "any of a variety of surgical procedures (including vaginoplasty and breast augmentation in MtF transsexuals and mastectomy and phalloplasty in FtM transsexuals) done simultaneously or sequentially with the explicit goal of transitioning from one sex to another." VHA Directive 2013-003 at 2. Heedless of the current medical consensus regarding the medical necessity of sex reassignment surgery for some individuals suffering from gender dysphoria, the Directive puts such surgery on equal footing with "plastic reconstructive surgery for strictly cosmetic purposes." It does this even though, as noted above, substantively identical procedures are available to intersex veterans under the clear language of the Directive, and to other veterans for various reasons, including to repair traumatic injuries and to treat cancer.

The illogic of the exclusion on sex reassignment surgery is underscored not only by the fact that the VA provides its constituent procedures to other veterans to treat other conditions, but also by the fact that the VA covers *other* aspects of transgender health, including hormone therapy and post-sex-reassignment-surgery health care. Specifically, the VA provides mental health care, hormone therapy, and preoperative evaluation for transgender veterans, as well as continuing hormone replacement therapy and post-operative care to veterans who have received sex reassignment surgery outside the VA health care system. VHA Directive 2013-003 at 2. The VA clearly views those treatments as medically necessary, but irrationally excludes only surgical treatments needed to treat gender dysphoria.

D. The Critical Need for Sex Reassignment Surgery in the Transgender Veteran Population

Recent empirical studies show that the estimated prevalence of transgender individuals in the Nation's military is five times greater than the estimated prevalence in the civilian population. As of May 2014, there are an estimated 129,700 transgender veterans of the U.S. Military, as well as 4,600 retired transgender members of the U.S. Reserves and National Guard. Approximately 15,500 transgender individuals currently serve as members of the U.S. Armed Forces, Reserves, and Guard. The population of transgender veterans is so significant that since 2015, clinics have opened in Cleveland, Ohio and Tucson, Arizona to specialize in providing medical care to these veterans. Similarly, the VA Boston Healthcare System has formed the Interdisciplinary Transgender Treatment Team, which provides medical care tailored to the needs of transgender veterans.

Moreover, recent progress in policies affecting transgender military personnel suggests that the population of transgender active-duty military and veterans is likely only to increase. In July 2015, United States Secretary of Defense Ashton B. Carter issued a directive to devise new rules to allow transgender individuals to serve openly in the military.²¹ These rules are expected to reverse the military's longstanding policy of preventing transgender individuals from serving

Blosnich et al., Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care, 103(10) Am. J. of Public Health e27 (2001).

Gates & Herman, *Transgender Military Service*, Williams Institute (May 2014).

Albrecht, VA's First Transgender Clinic Opens in Cleveland, Cleveland.com (Nov. 2015); Jenkins, New VA Clinic Opens for Transgender Vets, National Public Radio (Dec. 29, 2015).

Dep't of Veterans Affairs, VA Boston Healthcare Sys. (Mar. 3, 2016).

Somashekhar & Whitlock, *Military To Allow Transgender Members To Serve Openly*, Wash. Post, July 13, 2015.

and reflect a growing recognition on the part of the federal government as a whole that transgender individuals deserve fair and equal treatment under the law.²²

While the percentage of veterans who are transgender is very significant compared to the percentage of transgender individuals in the general population, the transgender veteran population nevertheless constitutes only a small percentage of the total veteran population.

Based on the best available data, only 0.6% of the national population of veterans and retirees of the U.S. Armed Forces, Army Reserves, and National Guard is transgender.²³

E. Developments in Health Care Coverage for Transgender Individuals

The VA's categorical exclusion of sex reassignment surgery from the package of medical benefits available to transgender veterans has become increasingly divorced from the practices of other federal agencies and States, which have recognized that sex reassignment surgery may be a medical necessity to treat gender dysphoria. Several federal agencies and state governments have adopted laws and policies to prohibit discrimination against transgender individuals in access to health care. In particular, these agencies and governments have prohibited categorical bars on sex reassignment surgery in coverage determinations made by insurers and health care programs receiving federal and state financial assistance.

At the federal level, the Department of Health and Human Services ("HHS") recently issued a proposed rule under Section 1557 of the Affordable Care Act ("ACA") that would prohibit sex discrimination (including on the basis of gender identity) in any health program or activity receiving federal financial assistance. 42 U.S.C. § 18116; *see* Nondiscrimination in

On January 14, 2016, Matthew Allen, a Pentagon spokesperson, stated that he anticipates that the Secretary's final approval of the rules will be issued in spring 2016. Johnson, *Pentagon Expects Decision on Trans Military Ban in Spring*, Wash. Blade, January 14, 2016, *available at* http://www.washingtonblade.com/2016/01/14/pentagon-expects-determination-on-trans-military-ban-in-spring.

Gates & Herman, *supra* note 18 at 4.

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Health Programs and Activities, 80 Fed. Reg. 54,172 (Sept. 8, 2015). That prohibition applies to all covered entities under the ACA that provide or administer health-related insurance or other health-related coverage. Although the prohibition does not apply to the VA, it is nonetheless instructive for the VA as it formulates its own nondiscriminatory practices. The proposed rule clarifies that the statutory bar on sex discrimination includes discrimination on the basis of gender identity, and voids any explicit categorical exclusion for coverage of health services related to gender transition, such as the one at issue here. The rule also would prohibit denial of any specific health services related to gender transition "where such a denial or limitation results in discrimination against a transgender individual." 80 Fed. Reg. at 54,190. For example, a health care plan may be discriminatory if it generally provides coverage of hysterectomies but denies coverage of a hysterectomy needed to treat gender dysphoria. See id.

Additionally, the HHS Departmental Appeals Board recently overturned a thirty-year-old National Coverage Determination ("NCD") denying Medicare coverage of all sex reassignment surgery as a treatment for gender dysphoria.²⁴ An NCD is "a determination by the Secretary [of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under [title XVIII (Medicare)]." Social Security Act §§ 1862(1)(6)(A), 1869(f)(1)(B); see also 42 C.F.R. § 400.202 (NCD "means a decision that [the Centers for Medicare & Medicaid Services] makes regarding whether to cover a particular service nationally under title XVIII of the Social Security Act."). NCDs "describe the clinical circumstances and settings under which particular [Medicare items and] services are reasonable and necessary (or are not reasonable and necessary)." 67 Fed. Reg. 54,534, 54,535 (Aug. 22, 2002). The Appeals Board found that the exclusion of coverage of sex reassignment surgery was unreasonable in

See Decision No. 2576, Department of Health and Human Services, Departmental Appeals Board (May 30, 2014), available at http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.

light of significant and unchallenged empirical evidence supporting the safety, effectiveness, and necessity of that treatment for certain individuals with severe gender dysphoria.²⁵

Other federal agencies and multiple States have acknowledged the need to establish clear policies that recognize the medical consensus that sex reassignment surgery may be medically necessary for a number of transgender individuals. For example, the Office of Personnel Management ("OPM") recently issued a letter to health insurance carriers participating in the Federal Employees Health Benefits Program stating that no carrier "may have a general exclusion of services, drugs or supplies related to gender transition or 'sex transformations.'"²⁶ The guidance from OPM recognizes "the evolving professional consensus that treatment may be medically necessary to address a diagnosis of gender dysphoria."²⁷ And an increasing number of States, including California, Colorado, Connecticut, Illinois, Maryland, Massachusetts, Minnesota, Nevada, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington, as well as the District of Columbia, have adopted laws and policies that recognize the discriminatory nature of health care programs that deny necessary coverage for the treatment of gender dysphoria.²⁸ These recent policy revisions and clarifications focus on the inappropriateness of blanket exclusions of sex reassignment surgery and other treatments for

²⁵ *Id*.

U.S. Office of Personnel Management, FEHB Program Carrier Letter, Letter No. 2015-12 (June 23, 2015), available at https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-12.pdf.

²⁷ *Id*.

See Pennsylvania Ins. Dep't, Notice Regarding Nondiscrimination, Pa.B. Doc. No. 16-762, 46 Pa.B. 2251 (Apr. 30, 2016), available at http://www.pabulletin.com/secure/data/vol46/46-18/762.html; 80 Fed. Reg. at 54,189; Rhode Island Office of the Health Ins. Comm'r, Bulletin No. 2015-3 (Nov. 23, 2015), available at http://www.ohic.ri.gov/documents/Bulletin-2015-3-Guidance-Regarding-Prohibited-Discrimination.pdf; Minnesota Dep't of Commerce, Administrative Bulletin 2015-5 (Nov. 24, 2015), available at http://mn.gov/commerce-stat/pdfs/bulletin-insurance-2015-5.pdf; Maryland Ins. Admin., Bulletin 14-02 (Jan. 27, 2014), available at http://insurance.maryland.gov/Insurer/Documents/bulletins/bulletin-1402-transgender.pdf.

gender dysphoria while still preserving providers' ability to make medical necessity determinations on an individual basis.

The VA is quickly becoming an outlier among health care providers in its failure to provide full coverage of the treatment necessary for patients with gender dysphoria.

V. THE VA SHOULD AMEND THE REGULATION TO COVER SEX REASSIGNMENT SURGERY

The VA should offer sex reassignment surgery to transgender veterans, first and foremost, because doing so is good policy. The VA may adopt a new policy if it "is permissible under the statute, [] there are good reasons for it, and [] the agency *believes* it to be better, which the conscious change adequately indicates." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Offering sex reassignment surgery is clearly permissible under 38 U.S.C. § 1710, which broadly authorizes the Secretary to provide "needed" medical care to veterans, and there are good reasons for this policy change: providing this surgery is consistent with, and mandated by, the VA's mission, would impose at most only a relatively minor burden on the VA health care system, and would provide medically necessary care to alleviate the physical suffering, depression, and suicidal ideation of transgender veterans who, in the absence of such care, are likely to be gravely afflicted with such conditions.

Providing sex reassignment surgery is required by the VA's mission to promote the health of veterans through coverage of medically accepted treatments that enhance the quality of life or daily functional level of veterans. The Secretary is charged with providing hospital care and medical services to veterans. *See* 38 U.S.C. § 1710. The VA has determined that this mandate includes care that is "needed to promote, preserve, or restore the health of the individual and is consistent with generally accepted standards of medical practice." 38 C.F.R. § 17.38(b). Care is deemed "to promote health" if "the care will enhance the quality of life or daily

functional level of the veteran," *id.* § 17.38(b)(1), and care is deemed to "preserve health" if the care will maintain the current quality of life or daily functional level of the veteran," including by "extend[ing] lifespan," *id.* § 17.38(b)(2). Notwithstanding its categorical exclusion for some of the most essential medical care for transgender veterans, VHA Directive 2013-003 states that "[i]t is the VHA policy that medically necessary care is provided to enrolled or otherwise eligible intersex and transgender veterans." VHA Directive 2013-003 at 2.²⁹

As discussed above, there is no genuine dispute within the medical community that sex reassignment surgery is a medically necessary component of treatment for some individuals with gender dysphoria. Indeed, the VA implicitly acknowledges the necessity of sex reassignment surgery by providing preoperative assessment and post-operative care to veterans who may undergo, or who have already undergone, such surgery. Not all individuals suffering from gender dysphoria require surgery, yet those who do may be some of the most vulnerable to related complications from lack of access to care—namely, depression and suicide. Transgender individuals who need but do not receive sex reassignment surgery are significantly more susceptible than the general population to depression and suicide.³⁰

Relative to the extraordinarily salubrious effect of providing medically necessary sex reassignment surgery to those in need of it, a change in VA policy would impose an immaterial cost burden on the VA health care system. Only a small absolute number of veterans are

Notably, in addition to preventing transgender veterans from receiving medically necessary care, the VA's exclusion of sex reassignment surgery from coverage appears to be having other unfortunate effects, evidently causing some providers to be skeptical of the medical needs of transgender veterans that are unrelated to gender transition, and outwardly hostile to treating them. *See* Silva Aff. ¶¶ 11-12.

See Ettner Decl. ¶ 15 ("A recent survey shows a 41% rate of suicide attempts among transgender people, far above the baseline rates for North America. (Haas et al., 2014)."); Blosnich et al., Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care," 103 Am. J. Pub. Health e27 (Oct. 2013), available at http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301507 (the "rate of suicide-related events among GID-diagnosed VHA veterans was more than 20 times higher than were rates for the general VHA population.").

transgender, and likely only a fraction of them will require sex reassignment surgery.³¹ And sex reassignment surgery is no more expensive than substantially identical surgeries included in the Medical Benefits Package for cisgender veterans. *See, e.g.*, Bowers Decl. ¶ 20. Moreover, the VA's failure to treat gender dysphoria fully in a given patient leads to collateral consequences, both for the individual veteran who experiences continued mental and physical impairment from his or her partially treated condition, and for the VA health care system itself, which must continue to pay for such veterans' mental health care, sometimes indefinitely. In fact, a recent study shows that the upfront costs of sex reassignment surgery are negligible when compared with the ongoing costs associated with treatment of long-term depression in individuals with cases of gender dysphoria for which surgery is appropriate.³²

The California Department of Insurance likewise recently conducted an assessment of the economic impact of covering transition-related health care and determined that "transgender insureds who have access to treatment see rates of depression drop and anxiety decrease," and that "[t]his overall improvement in mental health and reduction in utilization of mental health

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See supra note 18 and accompanying text. The WPATH Standards of Care reference available studies of individuals who "present for gender-transition-related care at specialist gender clinics," and notes that these studies estimate the prevalence of such individuals in the general population at between "1:11,900 to 1:45,000 for male-to-female individuals ... and 1:30,400 to 1:200,000 for female-to-male ... individuals." Some researchers have suggested that, given the sources of the study participants, the figures in these studies approximate the prevalence of individuals who undergo sex reassignment surgery. See Olyslager & Conway, "On the Calculation of the Prevalence of Transsexualism" (Sept. 2007), at 1 (paper presented at the WPATH 20th International Symposium), available at http://www.changelingaspects.com/ PDF/2007-09-06-Prevalence of Transsexualism.pdf.

The New York Times has reported that a recent yet currently unreleased study commissioned by the Department of Defense and conducted by the RAND Corporation predicted that between only 29 and 129 active service members would seek transition-related medical care annually. The study also found that given these low numbers, the cost of providing transition-related care to active duty service members would be negligible. Editorial Board, *The Military's Transgender Policy, Stalled*, N.Y. Times, Apr. 6, 2016.

Padula et al., Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis, J. of General Internal Medicine (Oct. 19, 2015).

services could be a source of cost savings for employers, insurers, and insureds."³³ Citing the California assessment, HHS agreed in its proposed rule on Section 1557 of the Affordable Care Act that "providing transgender individuals non-discriminatory insurance coverage and treatment ... will have minimal impact on the overall cost of care and on health insurance premiums."³⁴

Finally, offering sex reassignment surgery to transgender veterans is the right thing to do. Offering sex reassignment surgery to transgender veterans can be a life-saving treatment to treat the serious distress associated with gender dysphoria. Bowers Decl. ¶¶ 34-35, 37; Ettner Decl. ¶¶ 15-16, 21. The VA implicitly acknowledges what the broader medical community does not question—that sex reassignment surgery is medically necessary for some patients—yet the VA refuses to provide this medically necessary care to those patients. Our Nation owes transgender veterans this life-changing treatment in the same way it owes all other veterans medically necessary care for their most significant medical conditions. It is time for the VA to take the next step and provide complete treatment to transgender veterans.

VI. THE EXISTING REGULATION IS ARBITRARY AND CAPRICIOUS

Under the Administrative Procedure Act, a court may hold unlawful and set aside final agency action, such as a regulation or a denial of a petition for rulemaking or to amend existing rules, that it finds to be, *inter alia*, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. To comply with the requirements of the Act, the agency "must examine the relevant data and articulate a satisfactory explanation for its action." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 552, (2009) (quoting *Motor Vehicles Mfrs*.

California Department of Insurance, "Economic Impact Assessment of Gender Nondiscrimination in Health Insurance," Reg. File No. REG-2011-00023 (Apr. 13, 2012), *available at* http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.

Notice of Proposed Rulemaking Nondiscrimination in Health Programs and Activities, Medicare & Medicaid Guide 220954, 80 Fed. Reg. 54,171, 54,206 (Sept. 8, 2015).

Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983)). That explanation must "includ[e] a rational connection between the facts found and the choice made." State Farm, 463 U.S. at 42-43. "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise[.]" Fox Television, 556 U.S. at 552 (quoting State Farm, 463 U.S. at 42-43). Moreover, "it is well-established that 'an agency action is arbitrary when the agency offer[s] insufficient reasons for treating similar situations differently." SKF USA Inc. v. United States, 263 F.3d 1369, 1382 (Fed. Cir. 2001) (quoting Transactive Corp. v. United States, 91 F.3d 232, 237 (D.C. Cir. 1996)).

A denial of this petition would be arbitrary and capricious for three reasons: (1) the VA already recognizes that gender dysphoria is a treatable medical condition and currently provides some treatments for it, yet arbitrarily excludes sex reassignment surgery from the covered treatments; (2) the VA covers certain treatments for cisgender and intersex veterans yet arbitrarily denies the same or analogous treatments for transgender veterans; and (3) the VA excluded sex reassignment surgery without examining any relevant data and without giving any public explanation for the exclusion, while the overwhelming medical consensus supports the inclusion of sex reassignment surgery.

It is the height of arbitrary and capricious action to recognize gender dysphoria as a treatable medical condition and provide some treatments for it, while denying other equally necessary medical treatments. The VA's current policy with respect to the provision of medical care to transgender veterans states:

VHA policy [requires] that medically necessary care [be] provided to enrolled or otherwise eligible intersex and transgender Veterans, including hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery. Sex reassignment surgery cannot be performed or funded by VA.

VHA Directive 2013-003 at 2.³⁵ Thus, VA policy clearly recognizes that medically necessary care must be provided to transgender veterans, and also recognizes that some level of care related to sex reassignment surgery is medically necessary. For example, the VA currently provides mental health care coverage and hormonal therapy—which, like surgery, is specifically designed to assist transgender individuals in treating their dysphoria by making their bodies congruent with their gender. VA policy likewise provides transgender individuals with therapies, namely "preoperative evaluation, and medically necessary post-operative and long-term care following sex-reassignment surgery," that are specifically tailored to assist individuals seeking sex reassignment surgery with the pre- and post-surgical aspects of such surgery. And VA policy recognizes as medically necessary evaluations of transgender individuals performed prior to their obtaining sex reassignment surgery (namely, preoperative evaluation). Thus, the VA recognizes the medical necessity of *every aspect of care* for transgender veterans undergoing sex reassignment surgery, except surgery itself. That policy is incoherent because it is internally inconsistent, and therefore arbitrary and capricious.

The arbitrary and capricious nature of the VA's policy is underscored by the fact that the VA offers the same or substantially similar surgeries to cisgender and intersex veterans for other medically necessary conditions. As explained above, sex reassignment surgery is an umbrella term referring to a compliment of surgeries that may include, penectomy, vaginoplasty, chest reconstruction, phalloplasty, hysterectomy, and/or mastectomy.

See also, Dep't of Veterans Affairs, Patient Care Services, (Mar. 3, 2016), available at http://www.patientcare.va.gov/Lesbian Gay Bisexual and Transgender LGBT Veteran Care.asp.

Under the clear language of the VA regulations and directives, each of these surgeries is provided as a matter of VA policy to cisgender and intersex veterans for other conditions that the VA recognizes to be medically necessary. VA policy grants surgery to intersex individuals "to correct inborn conditions related to reproductive or sexual anatomy," and so provides penectomy and vaginoplasty to certain intersex individuals born with ambiguous genitalia. VHA Directive 2013-003 at 2. Hysterectomy and mastectomy are offered to cisgender females for, among other reasons, reduction of cancer risk, but the same surgeries are denied to transgender males. *See supra*, note 15. The VA offers, and so deems medically necessary, breast reconstruction to cisgender women who have had a mastectomy, but denies a substantially identical surgery, breast augmentation, to transgender women. *See supra*, note 14. The VA offers penile and testicular implants to cisgender males whose penises or testes have been damaged, but refuses very similar treatment to transgender men. *See id*.

In each of these comparisons, the VA offers certain surgeries to cisgender or intersex individuals for their conditions, but refuses to cover the same or substantially similar surgeries to transgender individuals for their conditions. The VA cannot justify this inconsistent treatment by claiming that these surgeries are medically necessary for treatment of some conditions, but not medically necessary for the treatment of gender dysphoria—as explained above, *see supra* Section IV.B, there is no genuine dispute within the medical community that sex reassignment surgery is medically necessary for certain patients. Accordingly, the VA's current policy amounts to offering certain surgeries when they are medically necessary, only not when those surgeries are medically necessary to treat gender dysphoria. This policy is incoherent and unjustifiable, and the VA's action in continuing it would be arbitrary and capricious. *See SKF USA Inc.*, 263 F.3d at 1382.

Finally, the VA has given no public explanation for excluding from coverage sex reassignment surgery for transgender veterans. Neither the proposed nor the final Regulation explained the exclusion or offered any evidence that the VA had "examine[d] the relevant data" in arriving at its decision to exclude this surgery from coverage. *State Farm*, 463 U.S. at 42-43; *see* 63 Fed. Reg. 37,299 (July 10, 1998) (proposed rule); 64 Fed. Reg. 54,207 (Oct. 6, 1999) (final regulation). The subsequent VHA directives that implemented the exclusion of sex reassignment surgery from the Medical Benefits Package likewise contained no explanation. *See* VHA Directive 2011-024 (June 9, 2011); VHA Directive 2013-003 (Feb. 8, 2013). The VA has therefore failed thus far even to attempt to "articulate a satisfactory explanation for its action" in excluding sex reassignment surgery from the Medical Benefits Package, or to offer a "rational connection between [] facts found and the choice made." *State Farm*, 463 U.S. at 42-43; *see also Michigan v. E.P.A.*, 135 S. Ct. 2699, 2706 (2015) ("Federal administrative agencies are required to engage in 'reasoned decisionmaking.'") (citation omitted).

As explained above, if the VA were to examine data relevant to its policy of excluding sex reassignment surgery from the Medical Benefits Package, the VA would find that such data clearly support reversing this exclusion. The medical community has reached consensus that sex reassignment surgery is a medically necessary treatment for a significant number of individuals with gender dysphoria—medically necessary in the same way as any other medical treatment that is required "to promote, preserve, or restore" the well-being of the patient. VHA Directive 1091 (Feb. 21, 2014), at 1; *see also* Bowers Decl. ¶¶ 34-37; Ettner Decl. ¶¶ 21, 23. No major medical association considers sex reassignment surgery to be a form of cosmetic surgery. Bowers Decl. ¶¶ 35; Ettner Decl. ¶¶ 23. As discussed above, the costs of providing sex reassignment surgery are negligible in context. *See supra* Section V at 21-22.

For these reasons, a denial of this petition to amend the Regulation to include sex reassignment surgery in the Medical Benefits Package would constitute unlawful, arbitrary and capricious agency action.

VII. THE EXISTING REGULATION VIOLATES THE EQUAL PROTECTION COMPONENT OF THE FIFTH AMENDMENT

A denial of this petition to amend the Regulation to include sex reassignment surgery in the Medical Benefits Package would also violate the Equal Protection component of the Fifth Amendment. The Federal Circuit is required to "hold unlawful and set aside" any VA regulation "contrary to constitutional right, power, privilege, or immunity." 38 U.S.C. § 7292(d)(1)(B). The Regulation violates those guarantees by discriminating against transgender veterans on the basis of their sex and their transgender status, without any compelling, or even arguably permissible, government interest.

A. Discrimination Against Transgender People Receives Heightened Scrutiny

1. Discrimination Against Transgender People Is Sex Discrimination

It is "firmly established" that laws or policies that discriminate based on sex are evaluated under close scrutiny. *Mississippi Univ. for Women v. Hogan*, 458 U.S. 718, 723 (1982). Discrimination against transgender people receives the same scrutiny. In fact, since *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989), every court of appeals to consider the question has concluded that prohibitions against sex discrimination protect transgender people.

In *Price Waterhouse*, the Supreme Court held that discrimination on the basis of gender stereotypes is sex-based discrimination. In that case, a female employee with the Price Waterhouse firm had been denied partnership in the firm because she was considered too "macho" and was told she needed to "walk more femininely, talk more femininely, dress more femininely, wear make-up, have her hair styled, and wear jewelry." 490 U.S. at 235. Six

members of the Supreme Court agreed that that kind of discrimination due to failure to conform to sex stereotypes constituted sex discrimination. *Id.* at 250-251 (plurality opinion); *id.* at 258-261 (White, J., concurring); *id.* at 272-273 (O'Connor, J., concurring).

Since that decision, federal courts have been nearly unanimous in holding that discrimination against transgender people is also a form of sex discrimination under *Price Waterhouse*. *See, e.g., G.G. ex rel. Grimm v. Gloucester Cnty. Sch. Bd.*, No. 15-2056, __ F.3d __, 2016 WL 1567467, at *4-8 (4th Cir. Apr. 19, 2016); *Glenn v. Brumby*, 663 F.3d 1312, 1316-1320 (11th Cir. 2011); *Smith v. City of Salem*, 378 F.3d 566, 571-575 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-216 (1st Cir. 2000); *Schwenk v. Hartford*, 204 F.3d 1187, 1201-1202 (9th Cir. 2000); *see also Schroer v. Billington*, 577 F. Supp. 2d 293, 303-306 (D.D.C. 2008).

As the Eleventh Circuit observed in *Glenn*, "[a] person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes" and there is therefore "a congruence between discriminating against transgender and transsexual individuals and discrimination on the basis of gender-based behavioral norms." 663 F.3d at 1316.

Schroer offered another formulation of why discrimination against transgender people must be understood as sex discrimination, posing a helpful analogy:

Imagine that an employee is fired because she converts from Christianity to Judaism. Imagine too that her employer testifies that he harbors no bias toward either Christians or Jews but only "converts." That would be a clear case of discrimination "because of religion." No court would take seriously the notion that "converts" are not covered by the statute. Discrimination "because of religion" easily encompasses discrimination because of a *change* of religion.

577 F. Supp. 2d at 306. Applying that logic, the court held that the discrimination against a transgender job applicant because she disclosed her intent to transition from male to female "was *literally* discrimination 'because of ... sex." *Id.* at 308; *see also Fabian v. Hosp. of Cent.*

Conn., No. 3:12-cv-1154, 2016 WL 1089178, at *28 (D. Conn. Mar. 18, 2016) ("[D]iscrimination on the basis of gender stereotypes, or on the basis of being transgender, or intersex, or sexually indeterminate ... is literally discrimination 'because of sex.'").

Recognizing that no responsible argument to the contrary remains, the federal government has adopted the position that discrimination against transgender people is sex discrimination. In *Macy v. Holder*, the Equal Employment Opportunity Commission ("EEOC") held unanimously that discrimination against a transgender person is, "by definition," a form of sex discrimination.³⁶ E.E.O.C. Appeal No. 0120120821, 2012 WL 1435995, at *11 (Feb. 24, 2012); *see also* Memorandum from the Attorney General, Treatment of Transgender Employment Discrimination Claims Under Title VII of the Civil Rights Act of 1964 (Dec. 15, 2014) (announcing that the Department of Justice will take the position that discrimination against transgender people violates Title VII); U.S. Department of Labor, Office of Federal Contract Compliance Programs, Directive 2014-02 (Aug. 19, 2014) (clarifying that sex discrimination "under Executive Order 11246 ... includes discrimination on the bas[is] of ... transgender status").³⁷

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Macy was decided under Title VII, but "the showing a plaintiff must make to recover on a disparate treatment claim under Title VII mirrors that which must be made to recover on an equal protection claim." Smith, 378 F.3d at 577; see also Glenn, 663 F.3d at 1316-1318 (reviewing Title VII precedent to conclude that the Fourteenth Amendment prohibits discrimination against transgender employees).

The U.S. Department of Education also has made clear that "Title IX's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity." Dep't of Educ., Office of Civil Rights, *Questions and Answers on Title IX and Sexual Violence* (Apr. 29, 2014), at 5, *available at* http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf. Numerous federal courts have agreed. *See, e.g., G.G.*, 2016 WL 1567467, at *7; *Pratt v. Indian River Cent. Sch. Dist.*, 803 F. Supp. 2d 135, 151-152 (N.D.N.Y. 2011); *Doe v. Brimfield Grade Sch.*, 552 F. Supp. 2d 816, 823 (C.D. Ill. 2008); *Montgomery v. Independent Sch. Dist. No. 709*, 109 F. Supp. 2d 1081, 1090 (D. Minn. 2000); *see also Rumble v. Fairview Health Servs.*, No. 14-cv-2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (holding that Section 1557 of the Affordable Care Act, which incorporates Title IX's prohibition on sex-based discrimination, "protects plaintiffs ... who allege discrimination based on 'gender identity'").

2. Discrimination Based on Transgender Status Also Receives Heightened Scrutiny

Even aside from its inextricable connection to sex discrimination, discrimination based on transgender status is separately entitled to heightened scrutiny. If a classification disadvantages certain groups, it may be considered "suspect" or "quasi-suspect," and therefore scrutinized with extra care. The Supreme Court consistently has applied heightened scrutiny where the classified group has suffered a history of discrimination, and the classification has no bearing on a person's ability to perform in society. See, e.g., Massachusetts Bd. of Ret. v. Murgia, 427 U.S. 307, 313 (1976) (heightened scrutiny is warranted where a classified group has "experienced a 'history of purposeful unequal treatment' or been subjected to unique disabilities on the basis of stereotyped characteristics not truly indicative of their abilities"). In addition, the Supreme Court has sometimes considered whether the group is a minority or relatively politically powerless, and whether the characteristic is defining or "immutable" in the sense of being beyond the group member's control or not one the government has a right to insist an individual try to change. See, e.g., Lyng v. Castillo, 477 U.S. 635, 638 (1986); see also Kerrigan v. Comm'r of Pub. Health, 957 A.2d 407, 425-28 (Conn. 2008) (analyzing federal equal protection law to conclude that history of discrimination and ability to contribute to society are the two central considerations, and collecting authorities). While not all considerations need point toward heightened scrutiny, Plyler v. Doe, 457 U.S. 202, 216 n.14, (1982); Golinski v. Office of Pers. Mgmt., 824 F. Supp. 2d 968, 983 (N.D. Cal. 2012), here all demonstrate that laws that discriminate based on transgender status should be subjected to heightened review.

Under any faithful application of that standard, discrimination against transgender people must receive heightened review. In recent decisions, federal courts have recognized that discrimination against transgender people—beyond its connection to discrimination based on

sex—must be evaluated under heightened scrutiny. *See, e.g., Adkins v. City of New York*, ___ F. Supp. 3d ___, No. 14 Civ. 7519, 2015 WL 7076956, at *3-4 (S.D.N.Y. Nov. 16, 2015); *Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1119 (N.D. Cal. 2015). In *Adkins*, the court found that all four of the hallmarks of heightened scrutiny were present with respect to the transgender community. It found that "transgender people have [inarguably] suffered a history of persecution and discrimination," 2015 WL 7076956, at *3;³⁸ that "transgender status bears no relation to ability to contribute to society," *id.*; that "transgender status is a sufficiently discernible characteristic to define a discrete minority class," *id.*; and that "transgender people are a politically powerless minority," noting that "there have [n]ever been any transgender members of the United States Congress or the federal judiciary," *id.* at *4. The court therefore concluded that transgender people constituted a "quasi-suspect class" entitled to intermediate scrutiny. *Id.* at *4.

Another federal court examined the same question in a case challenging a health care policy—like the VA's here—that denied transgender people access to sex reassignment surgery. *Norsworthy*, 87 F. Supp. 3d at 1119. That court noted the recent federal decisions indicating that discrimination based on sexual orientation must be evaluated with heightened scrutiny, holding that such conclusion "applies with at least equal force to discrimination against transgender people, whose identity is equally immutable and irrelevant to their ability to contribute to society, and who have experienced even greater levels of societal discrimination and marginalization." *Id.* at 1119 n.8. As a result, the court held squarely that "discrimination based

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See also Sears et al., Documenting Discrimination on the Basis of Sexual Orientation and Gender Identity in State Employment, Williams Institute (2009), available at http://williamsinstitute.law.ucla.edu/research/workplace/documenting-discrimination-on-the-basis-of-sexual-orientation-and-gender-identity-in-state-employment; Grant et al., Injustice at Every Turn: A Report of the National Transgender Discrimination Survey (2011), available at http://www.thetaskforce.org/downloads/reports/reports/ntds_full.pdf.

on transgender status ... qualifies as a suspect classification under the Equal Protection Clause." *Id.* at 1119.

B. The Regulation Cannot Survive Any Level of Review

The Regulation is plainly discriminatory: It denies transgender veterans treatments critical for their health, while providing the same treatments for other veterans. To state the obvious, an exclusion of coverage for surgeries related to "gender alteration," which the VA applies *only* to transgender veterans, targets transgender veterans for differential treatment.

38 C.F.R. § 17.38(c)(4); VHA Directive 2013-003 at 2 (defining the prohibited surgery to apply to transgender, but not intersex, veterans). That is facial discrimination based on sex and transgender status. Because there is no permissible justification for that exclusion, the Regulation is unconstitutional.

Under the heightened scrutiny standard applicable to claims of discrimination based on sex or transgender status, the challenged action must "serve important governmental objectives" and be "substantially related to the achievement of those objectives." *Craig v. Boren*, 429 U.S. 190, 197 (1976); *see also United States v. Virginia*, 518 U.S. 515, 531, 533 (1996) (under intermediate scrutiny, government "must demonstrate an exceedingly persuasive justification for that action," the burden for which "is demanding and ... rests entirely on the state") (internal quotation marks and citations omitted).

No such "important" objective can be advanced by denying transgender veterans the same medically necessary treatments that are provided to other veterans. For example, the facts of this case are nearly identical to those in *Norsworthy*. That case challenged the policy of a state prison that sex reassignment surgery could never be provided to transgender people in prison, although the prison did provide the same treatments for non-transgender individuals, and it did provide mental health and hormone treatments to transgender individuals. The state was

unable to identify any "important governmental interest, much less describe how their gender classification—which makes it more difficult for a transgender person to receive vaginoplasty than it is for a cisgender woman—[could be] substantially related to that interest." 87 F. Supp. 3d at 1120. The court therefore concluded that a state policy of "treat[ing a transgender woman] differently from a similarly situated non-transgender woman in need of [the same] medically necessary surgery" would violate her right to equal protection. *Id*.

Even under the most deferential standard of review, however, the policy cannot stand. Governmental action that "neither burdens a fundamental right nor targets a suspect class" will be upheld only "so long as it bears a rational relation to some legitimate end." *Romer v. Evans*, 517 U.S. 620, 631 (1996). That test is not "toothless." *Mathews v. Lucas*, 427 U.S. 495, 510 (1976). In particular, the review must be meaningful when the policy at issue targets a vulnerable group. *See Romer*, 517 U.S. at 634-635 (invalidating law that burdened the "politically unpopular group" of lesbian, gay, and bisexual people); *Lawrence v. Texas*, 539 U.S. 558, 580 (2003) (O'Connor, J., concurring) ("When a law exhibits such a desire to harm a politically unpopular group, we have applied a more searching form of rational basis review to strike down such laws under the Equal Protection Clause."); *Kelo v. City of New London*, 545 U.S. 469, 490-491 (2005) (Kennedy, J., concurring) (distinguishing between the rational basis test applied to "economic regulation" versus classifications discriminating against a particular group of people).

As discussed above, because the VA already provides the same or similar treatments to non-transgender and intersex veterans, there is no conceivable non-discriminatory basis for excluding coverage for transgender veterans alone. The Regulation and its implementing directives do not deny transgender veterans surgical treatments for gender dysphoria because of

concerns about medical necessity, or because it is expensive (which it is not),³⁹ or because it is impractical or difficult to provide—if any of those were the case, the VA would bar provision of those treatments for *any* veteran, not just transgender veterans. And the reason cannot be that the VA disagrees with the necessity of medical treatments for gender dysphoria generally—because if that were the case, the VA would not provide the many other medical treatments it *does* provide for transgender veterans, such as hormone therapy and pre- and post-operative care.

Accordingly, the only conceivable explanation for the transgender-specific surgery exclusion appears to be the fear of potential political controversy that could result from extending care to this vulnerable minority, which is not a permissible consideration under any standard of review. *See U.S. Dep't of Ag. v. Moreno*, 413 U.S. 528, 534 (1973) (intention to exclude a "politically unpopular group" from receiving benefits "cannot constitute a legitimate governmental interest"); *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 448 (1985) ("mere negative attitudes, or fear, unsubstantiated by factors which are properly cognizable ... are not permissible bases" for differential treatment of a vulnerable group).

VIII. CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Secretary of Veterans Affairs amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4), that exclude sex reassignment surgery for transgender veterans from the Medical Benefits Package provided to veterans under the Veterans Affairs health system, and promulgate regulations expressly

Because the population of transgender veterans affected by the Regulation is small compared to the overall population, cost concerns have no basis in reality. But regardless, the Fifth Amendment does not safeguard equality only when it is costless. Seeking to justify the Regulation as a budgetary matter would do what the Supreme Court has condemned: attempt to "protect the public fisc by drawing an invidious distinction between classes of its citizens." *Memorial Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 263 (1974); *see also Graham v. Richardson*, 403 U.S. 365, 374-375 (1971).

including sex reassignment surgery for transgender veterans within that Medical Benefits

Package.

Dated: May 9, 2016

By: Man Schomfell / APV

Alan Schoenfeld

Austin Van WILMER CUTLER PICKERING

HALE AND DORR LLP

7 World Trade Center

250 Greenwich Street New York, NY 10007

Telephone: (212) 937-7294

Facsimile: (212) 230-8888

Paul R.Q. Wolfson

Andrew Jaco

WILMER CUTLER PICKERING

HALE AND DORR LLP

1875 Pennsylvania Avenue

Washington, DC 20006

Telephone: (202) 663-6390

Facsimile: (202) 663-6363

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Respectfully submitted,

M. Dru Leyasseur

LAMBDA LEGAL DEFENSE AND

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EDUCATION FUND, INC.

120 Wall Street, 19th Floor

New York, NY 1005

Telephone: (212) 809-8585

Facsimile: (212) 809-0055

Tara L. Borelli

LAMBDA LEGAL DEFENSE AND

EDUCATION FUND, INC.

730 Peachtree Street NE, Suite 1070

Atlanta, GA 30308-1210

Telephone: (404) 897-1880

Facsimile: (404) 897-1884

Sam 1/2 7

Ilona Turner

Sasha Buchert

TRANSGENDER LAW CENTER

1629 Telegraph Avenue, Suite 400

Oakland, CA 94612

Telephone: (415) 865-0176

Facsimile: (877) 847-1278

Attorneys for Petitioners

Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA DIRECTIVE 2013-003

February 8, 2013

PROVIDING HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. **PURPOSE:** This Veterans Health Administration (VHA) Directive establishes policy regarding the respectful delivery of health care to transgender and intersex Veterans who are enrolled in the Department of Veterans Affairs (VA) health care system or are otherwise eligible for VA care.

- **2. BACKGROUND:** In accordance with the medical benefits package (title 38 Code of Federal Regulations (CFR) section 17.38), VA provides care and treatment to Veterans that is compatible with generally accepted standards of medical practice and determined by appropriate health care professionals to promote, preserve, or restore the health of the individual.
- a. VA provides health care for transgender patients, including those who present at various points on their transition from one gender to the next. This applies to all Veterans who are enrolled in VA's health care system or are otherwise eligible for VA care, including those who have had sex reassignment surgery outside of VHA, those who might be considering such surgical intervention, and those who do not wish to undergo sex reassignment surgery but self-identify as transgender. Intersex individuals may or may not have interest in changing gender or in acting in ways that are discordant with their assigned gender.
- b. VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes.

c. Definitions

- (1) **Sex.** Sex refers to the classification of individuals as female or male on the basis of their reproductive organs and functions.
- (2) **Gender.** Gender refers to the behavioral, cultural, or psychological traits that a society associates with male and female sex.
- (3) **Transgender.** Transgender is a term used to describe people whose gender identity (sense of themselves as male or female) or gender expression differs from that usually associated with their sex assigned at birth.
- (a) <u>Transsexual (Male-to-Female)</u>. Male-to-female (MtF) transsexuals are a subset of transgender individuals who are male sex at birth but self-identify as female and often take steps to socially or medically transition to female, including feminizing hormone therapy, electrolysis, and surgeries (e.g., vaginoplasty, breast augmentation).

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(b) <u>Transsexual (Female-to-Male)</u>. Female-to-male (FtM) transsexuals are a subset of transgender individuals who are female sex at birth but self-identify as male and often take steps to socially or medically transition to male, including masculinizing hormone therapy and surgeries (e.g., phalloplasty, mastectomy).

- (4) **Sex reassignment surgery.** Sex reassignment surgery includes any of a variety of surgical procedures (including vaginoplasty and breast augmentation in MtF transsexuals and mastectomy and phalloplasty in FtM transsexuals) done simultaneously or sequentially with the explicit goal of transitioning from one sex to another. This term includes surgical revision of a previous sex reassignment surgery for cosmetic purposes. **NOTE:** This term does not apply to non-surgical therapy (e.g., hormone therapy, mental health care, etc.) or intersex Veterans in need of surgery to correct inborn conditions related to reproductive or sexual anatomy or to correct a functional defect.
- (5) **Gender Identity Disorder (GID).** GID is a conflict between a person's physical sex and the gender with which the person identifies.
- (6) **Intersex.** Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female. People with intersex conditions are often assigned male or female gender by others at birth (e.g., parents), although the individual may or may not later identify with the assigned gender.
- **3. POLICY:** It is VHA policy that medically necessary care is provided to enrolled or otherwise eligible intersex and transgender Veterans, including hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery. Sex reassignment surgery cannot be performed or funded by VA.

4. ACTION

- a. <u>Veterans Integrated Service Network (VISN) Director.</u> Each VISN Director must ensure that necessary and appropriate health care is provided to all enrolled or otherwise eligible Veterans based on the Veteran's self-identified gender, regardless of sex or sex reassignment status.
- b. <u>Medical Facility Director, Chief of Staff, and Associate Director for Patient Care</u> <u>Services or Nurse Executive</u>. The medical facility Director, Chief of Staff, and Associate Director for Patient Care Services or Nurse Executive are responsible for ensuring:
- (1) Transgender patients and intersex individuals are provided all care included in VA's medical benefits package including but not limited to: hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery to the extent that the appropriate health care professional determines that the care is needed to promote, preserve or restore the health of the individual and is in accord with generally-accepted standards of medical practice.

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- (a) Patients will be addressed and referred to based on their self-identified gender. Room assignments and access to any facilities for which gender is normally a consideration (e.g., restrooms) will give preference to the self-identified gender, irrespective of appearance and/or surgical history, in a manner that respects the privacy needs of transgender and non-transgender patients alike. Where there are questions or concerns related to room assignments, an ethics consultation may be requested.
- (b) The documented sex in the Computerized Patient Record System (CPRS) needs to be consistent with the patient's self-identified gender. In order to modify administrative data (e.g., name and sex) in CPRS, patients must provide official documentation as per VHA guidance and policy on <u>Identity Authentication for Health Care Services</u> and <u>Data Quality Requirements for Identity Management and Master Patient Index Functions</u>.
- (c) Sex reassignment surgery as defined in subparagraph 2c(4), will not be provided or funded
- (d) Non-surgical, supportive care for complications of sex-reassignment surgery must be provided. For example, a MtF patient over the age of 50 may be offered breast cancer screening and may wish to discuss the benefits and harms of prostate cancer screening with her provider. A FtM transsexual patient may be offered screening for breast and cervical cancer.
- (e) A diagnosis of GID, or other gender dysphoria diagnoses, is not a pre-condition for receiving care consistent with the Veteran's self-identified gender.
- (2) All other health services are provided to transgender Veterans without discrimination in a manner consistent with care and management of all Veteran patients.
- (3) All staff, including medical and administrative staff, are required to treat as confidential any information about a patient's transgender status or any treatment related to a patient's gender transition, unless the patient has given permission to share this information.
- (4) VA Mandates diversity awareness and maintains a zero-tolerance standard for harassment of any kind.

5. REFERENCES

Title 38 CFR § 17.38 (c).

- **6. FOLLOW-UP RESPONSIBILITY:** The Office of Patient Care Services (10P4) is responsible for the contents of this Directive. Questions related to medical care may be referred to Specialty Care Services (10P4E) at (202) 461-7120. Questions related to mental health care may be referred to the Office of Mental Health Services (10P4M) at (202) 461-7310.
- **7. RESCISSIONS:** VHA Directive 2011-024, Providing Health Care for Transgender and Intersex Veterans, is rescinded. This VHA Directive expires February 28, 2018.

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February 8, 2013

Robert A. Petzel, M.D. Under Secretary for Health

Attachment

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 2/11/2013

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Attachment A

FREQUENTLY ASKED QUESTIONS (FAQ) REGARDING THE

PROVISION OF HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

- 1. What is the prevalence of transgender individuals? Is there a difference between transgender and transsexual individuals?
- a. The prevalence of transgender individuals is not known in general or in the Veteran population. This is because of challenges in defining gender identity, the reluctance of individuals to identify themselves to others as transgender, and measures that are narrowly focused on subsets of individuals who either have been diagnosed with gender identity disorder (GID) or have had sex reassignment surgery. It is for these reasons that the Institute of Medicine issued their report "The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding" (March 31, 2011) and called on Health and Human Services (HHS) and other Federal agencies to "implement a research agenda designed to advance knowledge and understanding of Lesbian, Gay, Bisexual, and Transgender (LGBT) health. This agenda includes appropriate data gathering on sexual orientation and gender identity in public health research tools and electronic health records.
- b. Current estimates of the prevalence of transsexual individuals with GID are approximately 1:11,000 natal males and 1:30,000 natal females. The prevalence of all transgender individuals is much higher since "transgender" is an umbrella term that includes individuals who do not have GID.
- c. Based on these data, the estimated prevalence of Male-to-Female (MtF) to Female-to-Male (FtM) transsexual individuals is approximately 3:1 in the general population. This prevalence ratio is likely to be higher in the predominantly male Veteran population. It is important to note that FtM transsexual individuals are also part of the Veteran population.
- d. Intersex Veterans, that is, individuals who are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female, may or may not identify as transgender.

2. Is transgender the same as being "gay" or "lesbian?"

No. The term "transgender" refers to gender identity or the sense of oneself as male, female, or other, (e.g., androgynous, eunuch, etc.). The terms "gay" (in the case of men) and "lesbian" (in the case of women) refer to sexual orientation. The sexual orientation of gay and lesbian persons is attraction to the same gender whereas heterosexual persons are attracted to the opposite gender. A transgender Veteran may identify as heterosexual ("straight"), gay, lesbian, bisexual (i.e., attracted to both genders), queer, pansexual, asexual, etc. Knowing someone's gender identity gives you no information about their sexual orientation.

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3. What is intersex?

Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female. People with intersex conditions are often assigned male or female gender by others at birth (e.g., parents), although the individual may or may not later identify with the assigned gender.

4. Do all intersex individuals identify as transgender?

No. For example, an individual may be assigned the physical status of "female" at birth and identify as female throughout her lifetime, with or without knowledge of an intersex condition. Some intersex persons with male chromosomes who have been assigned female become gender dysphoric even without knowing that they were "reassigned" at, or near, birth. Knowing someone has an intersex condition gives you no information about their gender identity or sexual orientation

5. What is sex reassignment surgery?

Sex reassignment surgery includes any of a variety of surgical procedures done simultaneously or sequentially with the explicit goal of transitioning from one gender to another. This term includes surgical revision of a previous sex reassignment surgery for cosmetic purposes. This term does not apply to non-surgical therapy (e.g., hormone therapy, mental health care, etc.) or to intersex Veterans in need of surgery to correct inborn conditions related to reproductive or sexual anatomy or to correct a functional defect.

6. Will VA provide sex reassignment surgery and plastic reconstructive surgery if needed?

VA does not provide sex reassignment surgery in VA facilities or through non-VA care. In addition, VA does not provide plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. However, patients with GID or other gender dysphoria conditions may elect to have one or more medical or surgical procedures over their lifetime to bring their bodies into a closer alignment with their perceived gender. *NOTE:* Only a minority of transgender Veterans will undergo sex reassignment surgery, as their symptoms may often be adequately treated with other therapeutic interventions. Some Veterans receiving care at the VA may have had sex reassignment surgery somewhere else. The VA does provide health care to pre- and post-operative transsexual Veterans, including treatment of surgical complications.

7. Will the VA provide for electrolysis through non-VA care for male-to-female transsexual (MtF) Veterans?

No. VA will not provide electrolysis as this is considered by VHA to be cosmetic rather than medically necessary to promote, preserve, or restore health of the Veteran.

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8. What are the guidelines for clinical care and the informed consent process?

a. Effective clinical care for transgender and intersex patients ideally involves an interdisciplinary, coordinated treatment approach with special attention to the needs of the individual patient and collaboration among multiple specialties, notably: gynecology, mental health, primary and specialty care, women's health, pharmacy, and urology. For all treatments and procedures, informed consent and shared decision-making needs to be the basis for individualized care that weighs the possible benefits and harms, with an emphasis on the lowest (safest) dose to achieve benefits. **NOTE:** Procedures regarding informed consent can be found in VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures at: http://www1.va.gov/vhapublications/ViewPublication.asp?pub ID=2055.

b. For treatment plans that include cross-sex hormone therapy, VA clinicians must, consistent with requirements of informed consent (VHA Handbook 1004.01), discuss the risks, benefits, and limitations of cross-sex hormone therapy with the patient. Signature consent is <u>not</u> required for cross-sex hormone therapy. Ongoing monitoring of treatment is required.

9. Will VA provide feminizing or masculinizing hormone therapy?

Yes, if it is consistent with the patient's wishes, the treatment team's clinical recommendations, and VA treatment guidance.

10. What guidance is available to clinicians regarding hormone therapy?

VA Pharmacy Benefits Management Services has developed guidance for the use of hormone therapy in transgender and intersex patients in VA. This guidance is located at: http://vaww.national.cmop.va.gov/PBM/default.aspx. *NOTE:* This is an internal Web site and is not available to the public.

11. What are the goals of cross-sex hormonal treatment? What effects and risks are associated with hormonal treatment?

- a. Cross-sex hormonal treatment is used to reduce or eliminate gender dysphoria and other symptoms related to the discordance between a transgender or intersex individual's gender identity and their biological sex at birth or the gender they were assigned at birth. The treatment produces changes in hormonally-sensitive sex characteristics (i.e., reducing characteristics of the original sex and inducing those of the opposite sex). VA clinicians need to provide transgender and intersex patients with a careful evaluation prior to providing a prescription for cross-sex hormonal therapy.
- b. The goal of cross-sex hormone therapy in treatment of MtF transgender patients is to suppress testosterone levels and introduce estrogen to achieve a pre-menopausal female hormonal range. The effects are decreased facial and body hair, redistribution of fat, breast development and prostate and testicular atrophy. Risks include venous thromboembolism, liver dysfunction, hypertension, and cardiovascular disease. As with any medical therapy, benefits

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and harms of treatment need individualization using principles of shared decision-making, with an emphasis upon the lowest (safest) dose to achieve benefits.

c. The goal of cross-sex hormone therapy in treatment of FtM transgender patients is to maintain testosterone and estrogen levels in the normal male range, generally through testosterone supplementation and sometimes in combination with a Gonadotropin Releasing Hormone (GnRH) agonist or progestins to suppress menses. The effects are increased facial and body hair and muscle, acne, permanent deepening of the voice, cessation of menses, redistribution of fat mass, and clitoral enlargement. Risks include hypertension, erythrocytosis, liver dysfunction, lipid changes, weight gain, and sodium retention.

12. Are there specific diagnostic criteria to consider in prescribing cross-sex hormone therapy?

- a. A diagnosis of GID or other dysphoria condition should be the basis for prescription for cross-sex hormonal therapy for transgender patients. There may be clinical exceptions to the diagnosis for prescribing cross-sex hormone therapy (e.g., transgender individuals with "GID not otherwise specified").
- b. Intersex patients are excluded from the GID diagnosis by DSM IV criteria. Transgender patients with intersex conditions who are seeking hormonal treatment need to fulfill DSM IV criteria for "GID not otherwise specified." Intersex and transgender individuals may have different mental health considerations.
- 13. Transgender and intersex Veterans are presenting to VA providers with prescriptions for hormones from outside sources, such as from another provider, the internet, or illicit sources. Should we stop these medications while we do a full evaluation or should a VA provider rewrite the prescriptions so they can be filled in a VA pharmacy and continued?

Under current VHA National Dual Care Policy, VA providers are not permitted to simply rewrite prescriptions from an outside provider, unless the VA provider has first made a professional assessment that the prescribed medication is medically appropriate. However, cross sex hormones cannot generally be stopped abruptly without negative physical and psychiatric consequences. If the patient has records that support a thorough evaluation and psychotherapy prior to initiation of hormones, then it may be appropriate for a VA provider to rewrite the prescriptions so they can be filled in a VA pharmacy and continued while the evaluation is in progress and to monitor hormone levels. A mental health exam in this situation is not required and is based on the clinical situation. Very high doses of cross-sex hormones are associated with a greater likelihood of side effects, and a reduction in dose may be required. Additionally, the benefits and harms of hormonal therapy differ based upon the presence or absence of risk factors for, or occurrence of, serious complications (cardiovascular, thrombotic-embolic) and thus dosage needs to be individualized.

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14. What if a transgender or intersex Veteran presents to VA and self-reports that they have been taking cross sex hormones that they would like to continue but can provide no supportive documentation from a physician?

Consistent with the VHA National Dual Care Policy, VA clinicians need to provide transgender patients with a careful medical and mental health evaluation <u>prior</u> to providing a prescription for cross-sex hormonal therapy.

15. Is a mental health evaluation necessary or required?

A thorough and careful mental health evaluation needs to be completed prior to provision of hormone therapy and needs to include evaluation and treatment for psychiatric comorbidities that may have overlapping presentations, such as depression, anxiety, Post Traumatic Stress Disorder (PTSD) or substance use disorders. The presence of other psychiatric and physical conditions is not necessarily a barrier to initiating treatment. For patients who enter VA with well-documented cross-sex hormone therapy from outside clinicians, mental health evaluations are optional based on the clinical presentation.

16. I understand that VA does not provide sex reassignment surgery, but are there any special considerations regarding a mental health evaluation prior to sex reassignment surgery?

Mental health evaluation prior to surgery includes specialized exams by knowledgeable doctoral level clinicians. Some professional associations with expertise on transgender issues (see resources in paragraph 28 of this Attachment) recommend that individuals contemplating genital surgery need to participate in a minimum of a 1-year "real life experience" i.e., living full time in the preferred gender role, prior to any genital surgical intervention.

17. In what ways would a pre-operative medical evaluation differ for these Veterans?

Medical evaluation prior to surgery includes pre-operative cardiac risk assessment and careful evaluation of current medications including hormone dosing.

18. What types of surgeries might transgender Veterans consider?

- a. As part of their transition, FtM patients might consider undergoing several types of surgery including mastectomy, hysterectomy or oopherectomy, and neophallus construction. The common complications of neophallus construction include flap or graft necrosis, fistulae, urinary tract infection, donor site scarring, and infections. Mastectomy and hysterectomy have far fewer complications. Clinicians need to be aware that VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care.
- b. As part of their transition, MtF patients might consider undergoing several types of surgery including orchiectomy, penectomy, vaginoplasty, breast implants, laryngeal shave, and facial feminization procedures. Common complications of genital surgeries include strictures,

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infections, fistulae, urinary tract complications and loss of genital sensation. Clinicians need to be aware that VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. MtF patients may consider undergoing electrolysis for hair removal. Clinicians need to be aware that VA does not provide electrolysis as this is considered a cosmetic rather than a medically necessary procedure.

19. If a patient has had sex reassignment surgery, how do we handle preventive screening requirements?

In addition to treatments related to their new gender identity, transgender patients need appropriate medical screening and/or treatment specific to their birth sex. This includes prostate exams and mammograms for MtF patients and vaginal exams and mammograms for FtM patients, as indicated.

20. Can a transgender Veteran request a change of gender or sex in Computerized Patient Record System (CPRS) before having sex reassignment surgery?

Amending the gender or sex of the Veteran in CPRS is based on the Veteran making a request to the facility Privacy Officer and providing the official documentation as required by VHA policies. Sex reassignment surgery is not a prerequisite for amendment of gender or sex in the Veteran's record.

21. What constitutes "official documentation" in order for gender or sex to be changed in CPRS?

A Veteran's request for amendment to gender or sex in the record is considered a Privacy Act "amendment request."

- a. One of the following is required as supporting documentation: Legal documentation (i.e., amended birth certificate or court order), passport or a signed original statement on office letterhead, from a licensed physician. Sex reassignment surgery is not a prerequisite for amendment of gender/sex in the Veteran's record.
 - b. The licensed physician's statement must include <u>all</u> of the following information:
 - (1) Physician's full name:
 - (2) Medical license or certificate number:
 - (3) Issuing state of medical license or certificate;
- (4) Drug Enforcement Administration (DEA) registration number assigned to the physician or comparable foreign designation, if applicable;
 - (5) Address and telephone number of the physician;

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(6) Language stating that the physician has treated the patient or reviewed and evaluated the medical history of the applicant. The physician also has a doctor patient relationship with the applicant, which is evident in having one or more clinical encounters between doctor and patient;

- (7) Language stating that the patient has had appropriate clinical treatment for gender transition to the new gender (specifying male or female); and
- (8) Language stating, "I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct."

22. Do I need to become an expert in treating transgender Veterans?

- a. All clinicians and staff who provide clinical services to transgender Veterans need to become more knowledgeable about transgender health issues. Everyone needs to be aware that transgender Veterans deserve to receive health care at VA and need to be treated with dignity and respect. Primary Care and Mental Health providers need to be encouraged to consult with specialty physicians on any aspect of management for which they need advice or for ongoing management, as they would for any other complex patient. The initial VA prescription for cross-sex hormone therapy need to be restricted to facility-designated providers experienced with the use of cross-sex hormone therapy (e.g., women's health specialist, endocrinologist, psychiatrist, or other local designee).
- b. The potential lack of clinical expertise in specialties such as endocrinology, mental health, and surgery regarding clinical care of transgender and intersex Veterans, may necessitate establishing a mechanism for timely expert consultation on complicated cases within Veterans Integrated Service Networks (VISN) or facilities.

23. What education will be provided to VA staff?

Cultural awareness and sensitivity education for field staff was developed and implemented in fiscal year 2012. The VA standard of zero tolerance for discrimination, harassment, or abuse of Veterans applies to VHA treatment of transgender and intersex Veterans.

24. What is the correct pronoun to use when speaking with a transgender Veteran and in documentation of the clinical encounter in a progress note?

Transgender Veterans should always be addressed and referred to based on their self-identified gender, in conversation and in documentation in the patient record, irrespective of the Veteran's appearance. Neither sex reassignment surgery nor official documentation of change in sex is required for Veterans to be identified by their preferred gender or for documentation of preferred gender in the patient record.

25. Are transgender Veterans allowed to use the bathroom of their choice?

Transgender Veterans who presently self-identify as female are allowed to use bathrooms for women. Likewise, those who presently self-identify as males are allowed to use bathrooms for

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men. This is irrespective of the Veteran's appearance or whether the Veteran has had sex reassignment surgery. The privacy needs of other patients must also be considered; availability of "unisex" bathrooms (for men and women) throughout facilities is a practical approach to this issue and is common practice in some facilities.

26. What about room assignments?

Patient room assignments are made in accordance with the patient's self-identified gender irrespective of the Veteran's appearance or whether the Veteran has had sex reassignment surgery, and in consideration of the needs of other patients. *NOTE:* Ethics consultations are encouraged when concerns arise related to the provision of respectful care for transgender and intersex Veterans and other patients.

27. In situations where shared inpatient rooms are common, might assignments be made such that a MtF transsexual patient and a biologic female would be assigned to share a room or a FtM transsexual patient and a biologic male would be assigned to share a room?

Yes. According to current VHA policy, "room assignments will give preference to the self-identified gender, irrespective of appearance and/or surgical history, in a manner that respects the privacy needs of transgender and non-transgender patients alike." Privacy and confidentiality dictate that staff may not share any information about one patient with another without express permission. If a room assignment leads to distress for either patient, then efforts need to be made to assign one of them to a private room. When this cannot be accommodated or when there are questions or concerns related to room assignments, an ethics consultation needs to be requested.

28. Are there any recommended resources for further information?

VA does not currently have clinical practice guidelines for the care of transgender and intersex Veterans. While VA does not endorse the following private sector guidelines, they may serve to provide information and education about the complexities of caring for this patient population.

- a. World Professional Association for Transgender Health's Standards of Care for Gender Identity Disorders, Version 7, 2011. Available from www.WPATH.org
- b. Endocrine Society Guidelines http://www.endo-society.org/guidelines/final/upload/Endocrine-Treatment-of-Transsexual-Persons.pdf
- c. Clinical Protocol Guidelines for Transgender Care http://www.vch.ca/transhealth or http://transhealth.vch.ca/resources/careguidelines.html
- d. The Joint Commission: Advancing Effective Communication, Cultural Competence and Patient-and-Family Centered Care for the Lesbian, Gay, Bisexual and Transgender (LGBT) Community: A Field Guide. Oak Brook, IL, Oct. 2011. http://www.jointcommission.org/lgbt/

> VHA DIRECTIVE 2013-003 February 8, 2013

29. REFERENCES

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- b. Institute of Medicine. (2011). *The health of lesbian, gay, bisexual, and transgender people: Building a foundation for better understanding.* Washington, DC: The National Academies Press: http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.
- c. Murad, M. H., Elamin, M. B., Garcia, M. Z., Mullan, R. J., Murad, A., Erwin, P. J., &Montori, V. M. (2010). Hormonal therapy and sex reassignment: A systematic review and meta-analysis of quality of life and psychosocial outcomes. *Clinical Endocrinology*, 72(2), 214-231. doi:10.1111/j.1365-2265.2009.03625.x.

Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA DIRECTIVE 1341(3) Transmittal Sheet May 23, 2018

PROVIDING HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive revises VHA policy for the respectful delivery of health care to transgender and intersex Veterans who are enrolled in the Department of Veterans Affairs (VA) health care system or are otherwise eligible for VA care.

2. SUMMARY OF MAJOR CHANGES:

Amendment dated, June 1, 2023:

- a. Includes updates in language to be more inclusive, such as the addition of queer and other identities reflected by "Q+". **NOTE:** The '+' symbol captures identities beyond LGBTQ, including pansexual and asexual and those who are questioning their sexual orientation identity. The '+' symbol is used throughout the directive but is not in the directive title due to assistive technology accessibility needs. See paragraph 5 for additional information regarding terminology.
- b. Paragraph 5.e.: Specifies a minimum number of working hours for Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ+) Veterans Integrated Services Network (VISN) Leads based on current VISN Lead activities.
- c. Paragraph 5.f.(1): Increases the recommended minimum number of hours for VA medical facility LGBTQ+ Veteran Care Coordinators (VCCs) and clarifies current duties, which have expanded since the inception of the program.
- d. Paragraphs 5.f.(7) and 5.g.(2): Strengthens the recommendation to collect Veteran gender identity information during clinical encounters to improve individual Veteran care and aid analyses of LGBTQ+ Veteran population needs.
- e. Paragraph 3: Replaces definition for gender non-conforming with definition for gender diverse.
- f. Appendix A: Adds qualifications for LGBTQ+ VISN Leads and VA medical facility VCCs.
 - g. Appendix B: Adds additional information for LGBTQ+ VCCs.

Amendment dated, June 26, 2020, incorporates Appendix B which includes additional guidance for LGBTQ+ Veteran Care Coordinators (VCCs).

Amendment dated May 24, 2019, updates language to Appendix A in paragraph 22.

Major changes as published on May 23, 2018 included:

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- a. Updates to language and definitions to reflect current nomenclature.
- b. Removal of content which conflicts with changes to the Computerized Patient Record System (CPRS).
- c. Additional oversight responsibilities for the Under Secretary for Health and the Deputy Under Secretary for Health for Operations and Management.
- d. Delineated responsibilities for the Veterans Integrated Service Network (VISN) Lesbian, Gay, Bisexual, and Transgender, Queer, and associated identities (LGBTQ+) Lead and LGBTQ+ Veteran Care Coordinator.
 - e. Updates to the Frequently Asked Questions.
- f. Inclusion of sections on Training and Records Management, in accordance with VHA Directive 6330(3), Controlled National Policy/Directives Management System, dated June 24, 2016. **NOTE:** VHA Directive 0999, VHA Policy Management, dated March 29, 2022 rescinded VHA Directive 6330.
- 3. RELATED ISSUES: None.
- **4. REPONSIBLE OFFICE:** The LGBTQ+ Health Program, Office of Patient Care Services (12PCS), is responsible for the content of this VHA directive. Questions may be referred to LGBTQ+ Health Program at VHALGBTQ+HEALTH@va.gov.
- **5. RESCISSIONS:** VHA Directive 2013-003, Providing Health Care for Transgender and Intersex Veterans, dated February 8, 2013, is rescinded.
- **6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of May 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

/s/ Carolyn M. Clancy, M.D. Executive in Charge

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publication Distribution List on 6/1/2018. **Substantive amendment** dated, June 1, 2023 was emailed to the VHA Publications Distribution List on June 6, 2023.

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PROVIDING HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. PURPOSE

This Veterans Health Administration (VHA) directive states policy regarding the respectful delivery of health care to transgender and intersex Veterans who are enrolled in the Department of Veterans Affairs (VA) health care system or are otherwise eligible for VHA care. In accordance with the medical benefits package, VA provides care and treatment to Veterans that is compatible with generally accepted standards of medical practice and determined by appropriate health care professionals to promote, preserve, or restore the health of the individual. **AUTHORITY:** 38 U.S.C. § 7301(b); 38 C.F.R. § 17.38.

2. BACKGROUND

- a. VA is committed to addressing health disparities, including disparities among our transgender and intersex Veterans.
- b. VHA provides health care for transgender and intersex Veterans, no matter how they present. Not all Veterans who identify as transgender or intersex undergo a transition process. For those who do, they may present to VHA at various points in their gender transition. VHA does not discriminate based on state of gender transition. This applies to all Veterans who are enrolled in VHA's health care system or are otherwise eligible for VHA care.
- c. VHA will provide care to all transgender and intersex Veterans in a manner that is consistent with their self-identified gender identity.
- d. VA does not provide gender confirming/affirming surgeries because VA regulation excludes them from the medical benefits package.
 - e. VA does not provide plastic reconstructive surgery for strictly cosmetic purposes.

3. DEFINITIONS

- a. <u>Birth Sex.</u> Birth sex refers to the classification of individuals as female or male, most often on the basis of their external genitalia at birth. In VA records, this information is the sex recorded on the Veteran's original birth certificate.
- b. **Gender.** Gender refers to the behavioral, cultural, or psychological traits that a society associates with birth sex or gender expression. Common gender categories are man and woman.
- (1) **Gender Expression.** Gender expression is the external display of one's gender, through a combination of dress, social behavior, and other factors. Gender expression is sometimes (but not always) consistent with gender identity.

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(2) **Gender Identity.** Gender identity refers to how an individual identifies the self as belonging to the male (that is, boy or man), female (that is, girl or woman), or some other gender category (for example, gender non-conforming – see definition below). In VA, administrative staff record this information as self-identified gender identity (SIGI).

- c. <u>Gender Confirming/Affirming Surgeries</u>. Gender confirming/affirming surgeries (also referred to as sex reassignment surgeries) include any of a variety of surgical procedures (including but not limited to vaginoplasty and breast augmentation in transgender women and mastectomy and phalloplasty in transgender men) done simultaneously or sequentially with the explicit goal of gender transitioning. Not all transgender or intersex individuals want gender confirming/affirming surgeries.
- d. <u>Gender Dysphoria.</u> Gender Dysphoria is the diagnosis in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) for persons who experience distress related to an incongruence between the gender with which the person identifies and their birth sex. Not all transgender people meet full criteria for this diagnosis.
- e. <u>Intersex.</u> Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that does not fit typical definitions of male or female birth sex. People with intersex conditions are often assigned male or female birth sex by others (for example, by parents or doctors). The individual's gender identity may or may not be consistent with the sex assigned at birth.
- f. <u>Self-Identified Gender Identity.</u> Self-Identified Gender Identity (SIGI) is a field in the VA records which refers to how Veterans think about their gender. Veterans may choose from a set of responses which include male, female, transman, transwoman, other, or the individual chooses not to answer. For more information, see https://dvagov.sharepoint.com/sites/vhava-lgbt-resources/HealthCareTopics/SitePages/SIGI.aspx. **NOTE:** This is a VA internal Web site that is not available to the public.
- g. <u>Transgender</u>. A transgender person is someone whose gender identity differs from their birth sex.
- (1) **Transgender Woman.** Transgender women are a subset of transgender individuals who are assigned male sex at birth but self-identify as female and often take steps to socially or medically transition to live as women. This may include feminizing hormone therapy, electrolysis, and surgeries (for example, vaginoplasty, facial feminization, or breast augmentation). Generally, the pronouns these individuals use are "she," "her," or "hers," unless the Veteran requests different pronouns.
- (2) **Transgender Man**. Transgender men are a subset of transgender individuals who are assigned female sex at birth but self-identify as male and often take steps to socially or medically transition to live as men. This may include masculinizing hormone therapy and surgeries (for example, phalloplasty, metoidioplasty, or mastectomy with

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chest reconstruction). Generally, the pronouns these individuals use are "he," "him," or "his," unless the Veteran requests different pronouns.

(3) **Gender Diverse.** Individuals whose gender identity falls outside of the gender binary structure (e.g., non-binary, genderqueer, agender).

4. POLICY

It is VHA policy that staff provide clinically appropriate, comprehensive, Veterancentered care with respect and dignity to enrolled or otherwise eligible transgender and intersex Veterans, including but not limited to hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following gender confirming/affirming surgery. It is VHA policy that Veterans must be addressed based upon their self-identified gender identity; the use of Veteran's preferred name and pronoun is required. *NOTE:* VA does not provide or fund gender confirming/affirming surgeries because VA regulation excludes them from the medical benefits package. In addition, VA does not provide plastic reconstructive surgery, in accordance with the medical benefits package and VHA Directive 1091, Plastic Reconstructive Surgery, dated February 28, 2020.

5. RESPONSIBILITIES

- a. <u>Under Secretary for Health.</u> The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.
- b. <u>Assistant Under Secretary for Health for Patient Care Service/Chief Nursing Officer.</u> The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer is responsible for supporting the LGBTQ+ Health Program with implementation and oversight of this directive.
- c. <u>Assistant Under Secretary for Health for Operations.</u> The Assistant Under Secretary for Health for Operations is responsible for:
- (1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).
- (2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.
- (3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.
- d. <u>Executive Director, LGBTQ+ Health Program.</u> The Executive Director, LGBTQ+ Health Program, is responsible for:
- (1) Providing oversight for VISN and VA medical facility compliance with this directive by communicating with LGBTQ+ VISN Leads about continuous quality improvement activities, reviewing VA medical facility reports and surveys regarding

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LGBTQ+ populations, raising awareness about complaints or problems from VISNs and VA medical facilities and ensuring corrective action is taken when non-compliance is identified, including sharing challenges and needs with Clinical Informatics, Office of Information and Technology, and other offices as appropriate.

- (2) Disseminating this directive to VISNs and VA medical facilities and responding to staff questions, concerns and educational needs regarding its implementation.
- (3) Facilitating connections between VA medical facility and VISN stakeholders as needed.
- (4) Conducting national LGBTQ+-specific monitoring and reporting on prevalence of LGBTQ+ Veterans, health services utilization and health care needs.
 - (5) Communicating with the LGBTQ+ VISN Leads, on a minimum quarterly basis.
- e. <u>Veterans Integrated Service Network Director</u>. Each VISN Director is responsible for:
- (1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.
- (2) Ensuring that necessary and appropriate health care is provided at all VA medical facilities within the VISN to all enrolled or otherwise eligible Veterans based on the Veteran's self-identified gender, regardless of birth sex, status of medical/surgical interventions, or appearance.
- (3) Appointing a LGBTQ+ VISN Lead, ensuring sufficient allocated time to meet their responsibilities, meeting at least quarterly, and supporting the LGBTQ+ VISN Lead in their work with the VA medical facility LGBTQ+ Veteran Care Coordinators (VCCs) in their region.
- (4) Ensuring a minimum of quarterly attendance by the LGBTQ+ VISN Lead at VISN staff meetings.
- (5) Monitoring vacancies in the VA medical facility LGBTQ+ VCC role and facilitating an appointment if the position is vacant for more than 2 months. **NOTE:** Vacancies for more than 2 months are considered deficiencies.
- (6) Communicating with the LGBTQ+ VISN Lead on a minimum quarterly basis about the LGBTQ+ activities at the VA medical facilities.
- f. <u>LGBTQ+ Veterans Integrated Service Network Lead.</u> *NOTE:* The LGBTQ+ VISN Lead is appointed by and reports to the VISN Director. The role of the LGBTQ+ VISN Lead requires a minimum of 8-12 hours per week. The number of hours allocated for the LGBTQ+ VISN Lead will vary by number of VA medical facilities in the VISN, size of VA medical facilities, number of VA medical facility LGBTQ+ VCCs in the VISN and support needs of the VA medical facility LGBTQ+ VCCs. This can be a collateral

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position. VISN Directors may determine that the LGBTQ+ VISN Lead work be assigned as part of regular duties (i.e., full or part time). The LGBTQ+ VISN Lead is responsible for:

- (1) Assisting VA medical facility Directors in their VISN with identifying and appointing VA medical facility LGBTQ+ VCCs and allocating sufficient time for their responsibilities, as well as working collaboratively on any remediation needed with VA medical facility LGBTQ+ VCC performance or time allocation.
- (2) Serving as a reliable source of information regarding the appropriate amount of time a VA medical facility LGBTQ+ VCC may need to perform their duties above the suggested minimum, as well as the need for local resources to support their work.
- (3) Supporting the LGBTQ+ Health VCC program by orienting newly appointed VA medical facility LGBTQ+ VCCs to their roles and responsibilities.
 - (4) Attending the VISN staff meetings at least quarterly.
- (5) Assisting VA medical facility LGBTQ+ VCCs across the VISN with development and coordination of strategic plans and program activities, local problem solving and engagement of VA medical facility leadership when necessary.
- (6) Communicating with the Executive Director, LGBTQ+ Health Program, on a minimum quarterly basis, about activities in their VISN to ensure ongoing quality improvement with measurable gains and to monitor compliance with this directive.
- (7) Communicating with the VISN Director on a minimum quarterly basis about the LGBTQ+ VISN Lead's activities and activities at the VA medical facilities, including sharing results of VA medical facility LGBTQ+ VCC activities (e.g., training and education initiatives, outreach efforts, LGBTQ+ awareness campaigns, Pride events).
- (8) Communicating on a minimum of monthly basis with VA medical facility LGBTQ+ VCCs in the VISN to ensure quality improvement within VA medical facilities, including but not limited to conducting an annual survey of VA medical facility LGBTQ+ VCCs to gather information about VA medical facility initiatives.
- (9) Conducting an annual meeting with each VA medical facility Director and VA medical facility LGBTQ+ VCCs to review the strategic plan progress, as well as review VA medical facility data collection progress for Veteran's sexual orientation identity and self-identified gender identity in the electronic health record (EHR).
 - g. **VA Medical Facility Director.** The VA medical facility Director, is responsible for:
- (1) Appointing at least one designated VA medical facility LGBTQ+ VCC who dedicates non-clinical time (that is, dedicated administrative time and labor mapped appropriately) to fulfill the responsibilities of the role. **NOTE:** The VA medical facility LGBTQ+ VCC reports to the VA medical facility Director.

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- (a) VA medical facility LGBTQ+ VCC positions can be ancillary duty assignments, but increasingly are full-time positions in combination with delivery of LGBTQ+ Veteran direct care or serving as a LGBTQ+ Special Emphasis Program Manager for Equal Employment Opportunity. (See Distinctions Between the Roles and Responsibilities of the VA medical facility LGBTQ+ Veteran Care Coordinators and LGBTQ+ Special Emphasis Program Managers in VA Handbook 5975.5, Special Emphasis Program Management, dated December 28, 2017.) LGBTQ+ Veteran needs may vary across settings for multiple reasons. Based on data from currently serving VA medical facility LGBTQ+ VCCs, it is recommended to allocate the following minimum number of hours for the LGBTQ+ VCC role relative to VA medical facility complexity and enrollment:
- 1. For VA medical facilities with less than 25,000 Veterans enrolled, a minimum of 12 hours per week (or.30 full-time employee equivalent (FTEE)).
- 2. For VA medical facilities with 25,000 to 75,000 Veterans enrolled, a minimum of 16 hours per week (or.40 FTEE).
- 3. For VA medical facilities with over 75,000 Veterans enrolled, a minimum of 20 hours per week (or.50 FTEE).
- (b) Determining, based on VA medical facility needs, whether to assign more than one VA medical facility LGBTQ+ VCC or to increase the minimum number of hours necessary for this role at the VA medical facility. Need for more than one VA medical facility LGBTQ+ VCC or creation of a full-time LGBTQ+ VCC position may be due to:
 - 1. The size of the VA medical facility.
- 2. A high number of community-based outpatient clinics (CBOCs) or multiple campuses.
- 3. A high number of anticipated LGBTQ+ Veterans receiving care in the health care system.
 - 4. A great distance between sites.
 - 5. Minimal existing services for LGBTQ+ Veterans.
- (2) Meeting with the VA medical facility LGBTQ+ VCCs at least twice annually to ensure that responsibilities are being fulfilled, ensure sufficient time is allocated to meet their responsibilities, and develop improvement plans as needed.
- (3) Overseeing the VA medical facility LGBTQ+ VCCs and supporting staff, education and training to promote an affirming clinical environment.
- (4) Maintaining an environment free from harassment of any kind. The LGBTQ+ Veteran Care Coordinator (VCC) is a resource for the medical facility Director in implementing corrective actions and training. **NOTE:** For more information, see LGBT VCC section below.

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(5) Meeting with the LGBTQ+ VISN Lead and VA medical facility LGBTQ+ VCC at least once a year to review the strategic plan progress, as well as reviewing VA medical facility data collection progress for Veteran's sexual orientation identity and self-identified gender identity in the EHR.

- (6) Ensuring the VA medical facility has the mechanisms available for staff and Veterans to bring concerns about interactions that are disrespectful, biased or discriminatory (e.g., Patient Advocate, staff member's supervisor, EEO Office, Disruptive Behavior Committee).
- (7) Ensuring transgender and intersex individuals are provided all care in VA's medical benefits package, including but not limited to: hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following gender confirming surgeries to the extent that the appropriate health care professional determines that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice. *NOTE:* VA will not provide or fund gender confirming/affirming surgeries because VA regulation excludes them from the medical benefits package. In addition, VA does not provide plastic reconstructive surgery, in accordance with the medical benefits package and VHA Directive 1091, Plastic Reconstructive Surgery, dated February 18, 2020.
- (8) Adhering to VA's values of diversity, inclusion, and commitment to increasing awareness about the health care needs of Veterans by assuring transgender and intersex Veterans receive culturally appropriate, confidential care in a welcoming environment.
- (9) Addressing and referring to Veterans (even when they are not present) based on the Veteran's self-identified gender identity and preferred name, including in conversation and clinical notes, even when this is not their legal name. Pronouns used must be consistent with the Veteran's preferences.
- (10) Offering patients appropriate clinical health screens. Birth sex, gender identity, hormone therapy, surgical status, and current treatments determine which clinical health screens are appropriate. For example, a transgender man should receive breast and cervical cancer screening, if that anatomy is present, and a transgender woman should receive prostate cancer screening.
- (11) Modifying administrative data (including name and birth sex) in the electronic health record, as specified in VHA Directives 1907.09, Identity Authentication for Health Care Services, dated June 6, 2019, and VHA Directive 1906, Data Quality Requirements for Identity Management and Master Patient Index Functions, dated April 10, 2020. Additional guidance is offered in the Identity Management Fact Sheet. For more information see the HC IdM website:

http://vaww.vhadataportal.med.va.gov/PolicyAdmin/HealthcareIdentityManagement.asp x. **NOTE:** This is an internal VA website that is not available to the public.

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(12) Informing Veterans about how birth sex and gender identity will be included in the patient's health record and the procedure to request a change to the record (VHA Directive 1907.01, Health Information Management and Health Records, dated April 5, 2021). The Veteran has a right to not be identified as "transgender" or any other label, unless omitting this information would compromise medically necessary care.

- (13) Room assignments and access to facilities for which gender is a consideration (for example, restrooms) in a manner which gives preference to self-identified gender, irrespective of appearance and/or surgical status. Where there are questions related to room assignments or other concerns or conflicts about values, an ethics consultation may be requested. **NOTE:** Federal policy and law supersedes state law on Federal grounds property or in federally leased space.
- (14) Providing all health services to transgender and intersex Veterans without discrimination in a manner consistent with care and management of all Veterans.
- (15) Requiring all staff, including medical and administrative staff, to treat as confidential any information about a Veteran's transgender or intersex identity or any treatment related to a Veteran's gender transition, unless relevant to medical care, consistent with VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016. For example, casual conversation about a Veteran's identity is inappropriate.
- h. VA Medical Facility Chief of Staff or Associate Director for Patient Care Services. The VA medical facility CoS or Associate Director for Patient Care Services (ADPCS) is responsible for:
- (1) Ensuring clinically appropriate, comprehensive, Veteran-centered care is provided with respect and dignity to all Veterans in an affirming environment, regardless of their gender identity or gender expression.
- (2) Monitoring completion rates of the sexual orientation and gender identity data fields in the EHR by staff and clinicians to ensure that this information is available on all Veterans.
- (3) Ensuring all staff members, including medical and administrative staff, treat as confidential any information about a Veteran's gender identity.
- (4) Ensuring VA health care providers ask Veterans about their gender identity, discuss with the Veteran how information about gender identity will be included in the Veteran's EHR and populate the gender identity field. **NOTE:** VA will comply with the Veteran's decision not to be identified as "transgender" or another label as long as the omission of this information does not compromise medically necessary care.
- (5) Educating Veterans about the need for open communication with VA health care providers about gender identity as part of routine care that is delivered with respect and without judgment or bias.

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i. <u>VA Medical Facility LGBTQ+ Veteran Care Coordinator</u>. *NOTE:* The VA medical facility LGBTQ+ VCC coordinator is appointed by and reports to the VA medical facility Director and coordinates activities with the LGBTQ+ VISN Lead. The VA medical facility LGBTQ+ VCC plays a critical role in ensuring culturally competent, Veterancentered and effective care for LGBTQ+ Veterans because LGBTQ+ Veterans are seen at every VA medical facility. See Appendix B for additional guidance for LGBTQ+ VCCs. **NOTE:** See Appendix B for additional guidance for LGBTQ+ VCCs. The LGBTQ+ VCC is responsible for:

- (1) Supporting the implementation of national policies related to LGBTQ+ Veteran health at the VA medical facility to ensure consistent access to culturally competent care for LGBTQ+ Veterans.
- (2) Investigating and recommending corrective action upon awareness of an issue and, as appropriate, offering recommendations to the VA medical facility Director for further action to assist the VA medical facility in educating staff and creating an affirming environment (for example, providing education to staff about treatment of Veterans based upon their self-identified gender identity and assuring facilities are inclusive and welcoming).
- (3) Communicating with individual facility services (for example, prosthetics, endocrinology, social work, etc.) to provide tailored guidance and education as needed. This includes working with the clerical staff who may need training in asking about birth sex and self-identified gender identity in a respectful manner, and/or working with local Master Veteran Index coordinators (typically the Privacy Officer) for Veterans making changes to name and/or birth sex fields in the record system.
- (4) Serving as a point-person, source of information, Veteran advocate and problemsolver for LGBTQ+ Veteran-related health care issues at the VA medical facility.
- (5) Identifying the needs of LGBTQ+ Veterans within the VA medical facility (e.g., town hall meetings, needs assessment) and assisting the VA medical facility in developing needed care.
 - (6) Serving as a liaison with external LGBTQ+ community organizations.
- (7) Developing relationships with internal VA medical facility stakeholders, such as primary care, mental health, women's health, police, eligibility and enrollment.
- (8) Ensuring coverage of VA medical facility LGBTQ+ VCC duties during absences and coordinating with the VA medical facility Director to determine a backfill when needed.
- (9) Communicating to the public via outreach measures, for example, sustainment of a dedicated website for the VA medical facility's LGBTQ+ Veteran care resources.
- (10) Participating in community events such as Veteran outreach activities, Transgender Day of Remembrance and LGBTQ+ Pride events.

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(11) Promoting an affirming environment for LGBTQ+ Veterans (e.g., VA medical facility LGBTQ+ resource webpage, advisory council, LGBTQ+ awareness posters, Pride events) that directly counteracts any potential expectations of discrimination. These activities occur in coordination with the VA medical facility's Public Affairs Office.

- (12) Conducting LGBTQ+-specific monitoring and reporting in their VA medical facility and related CBOCs, including strategic planning.
- (13) Serving as the primary designee of the VA medical facility Director for monitoring and reporting on LGBTQ+ Veterans in the catchment area.
- (14) Participating in strategic planning processes and responding to the annual national survey of VA medical facility LGBTQ+ VCC activities.
- (15) Ensuring LGBTQ+ VCC contact information on the VA medical facility LGBTQ+ website is accurate and current.
- (16) Creating local educational materials (e.g., fliers and brochures) and confirming the accuracy of information on the national LGBTQ+ VCC directory.
- (17) Meeting with the VA medical facility Director at least twice a year to ensure that responsibilities are being fulfilled and developing improvement plans as needed.
- (18) Meeting with the LGBTQ+ VISN Lead and VA medical facility Director once a year to review the strategic plan progress, as well as review VA medical facility data collection progress for Veteran's sexual orientation identity and gender identity in the EHR.
- (19) Communicating at least once a month with the LGBTQ+ VISN Lead to ensure quality improvement within the VA medical facility through existing formal quality improvement projects or through informal changes in VA medical facility processes, including but not limited to the annual survey of LGBTQ+ VCCs.
- (20) Communicating to the VA medical facility Director if insufficient time has been allocated to ensure the responsibilities of the VA medical facility LGBTQ+ VCC are fulfilled. **NOTE:** For more information on time allocation, see paragraph 2.f.(1)(a) and (b).

6. TRAINING

Recommended staff training on transgender and intersex health and other educational and clinical resources may be accessed through the LGBTQ+ Health Resources SharePoint https://dvagov.sharepoint.com/sites/vhava-lgbt-resources, which includes direct links to the Talent Management System (TMS) trainings. **NOTE:** This is an internal VA website that is not available to the public. These trainings cover general information for non-clinical staff and brief, topic-focused modules for clinicians.

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7. RECORDS MANAGEMENT

All records regardless of medium (paper, electronic, electronic systems) created by this directive shall be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

8. REFERENCES

- a. 38 U.S.C. § 7301(b).
- b. 38 C.F.R. § 17.38.
- c. VHA Directive 0999, VHA Policy Management, dated March 21, 2022.
- d. VHA Directive 1906, Data Quality Requirements for Identity Management and Master Veteran Index Functions, dated April 10, 2020.
- e. VHA Directive 1907.09, Identity Authentication for Health Care Services, dated June 6, 2019.
- f. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.
- g. VHA Directive 1310, Medical Management of Enrolled Veterans Receiving Self-Directed Care from External Health Care Providers, dated October 4, 2021.
- h. VHA Directive 1907.01, Health Information Management and Health Records, dated April 5, 2021.
- i. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.
- j. Identity Management Fact Sheet, VHA Office of Informatics and Information Governance Data Quality, Healthcare Identity Management (HC IdM), available at: http://vaww.vhadataportal.med.va.gov/PolicyAdmin/HealthcareIdentityManagement.asp
 x.z.gov/PolicyAdmin/HealthcareIdentityManagement.asp
- k. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), American Psychiatric Association (2013).

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APPENDIX A

FREQUENTLY ASKED QUESTIONS (FAQ) REGARDING THE PROVISION OF HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. How can a Department of Veterans Affairs (VA) employee know a Veteran's gender identity?

VA record systems now have both a "birth sex" field and a "self-identified gender identity" (SIGI) field. Birth sex is used for determining sex-based medical health screenings, and SIGI is used for addressing the Veteran based upon the Veteran's self-identified gender identity. For information about how to ask about birth sex and SIGI, see: https://dvagov.sharepoint.com/sites/vhava-lgbt-resources/HealthCareTopics/SitePages/SIGI.aspx. **NOTE:** This is an internal VA website that is not available to the public.

2. Is being transgender the same as being "gay", "lesbian", or "bisexual"?

No. Being transgender is not the same as being gay, lesbian, or bisexual. The term "transgender" refers to gender identity or the sense of oneself as a man, woman, or something else (for example, gender non-conforming). Gay, lesbian, and bisexual refer to sexual orientation identities. Sexual orientation identities are the terms one uses to describe sexual and romantic attractions. Transgender people, like all people, can identify with any sexual or romantic identity. A transgender Veteran may identify as heterosexual ("straight"), gay, lesbian, bisexual, queer, pansexual, asexual, etc. Knowing someone's gender identity gives you no information about their sexual orientation. The best practice is to ask Veterans how they identify and use those terms. For more information about sexual orientation terms and uses, see the Glossary on the LGB SharePoint: http://vaww.infoshare.va.gov/sites/LGBEducation/GLOSSARY (sharepoint.com)sitefiles/LGBT%20Veteran%20Health%20glossary.pdf. NOTE: This is an internal VA Web site that is not available to the public.

3. Do all intersex individuals identify as transgender?

No. For example, an individual may be assigned a "female" birth sex and identify as female throughout her lifetime, with or without knowing about her intersex condition. Some intersex persons with male chromosomes, who have been assigned "female" sex at birth, may experience gender dysphoria even without knowing that they were "reassigned" at, or near, birth. Knowing someone has an intersex condition gives you no information about their gender identity or sexual orientation.

4. I have heard the term transsexual - what does that term mean?

Transsexual is an older term that refers to a subset of transgender individuals who often take steps to socially or medically transition to their preferred gender.

Transgender women are sometimes referred to as male-to-female transsexuals.

Transgender men are sometimes referred to as female-to-male transsexuals. In

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general, it is best practice to use the term that the Veteran uses to refer to themselves as a way to be respectful.

5. Where can we refer transgender Veterans?

It is always the preference for Veterans to be treated at their nearest VA facility when they are eligible for care, since that is less expensive and more culturally appropriate. Transgender and intersex Veterans are no different. Since 2011, all VA facilities are required to either provide care or pay for care in the local community for enrolled Veterans who identify as transgender. Treatment plans are individualized and based upon the Veteran's unique treatment goals and circumstances. The local LGBTQ+ Veteran Care Coordinator can assist in identifying training resources for providers to treat transgender or intersex Veterans.

6. What is the correct pronoun to use when speaking with a transgender Veteran or documenting the clinical encounter in a progress note?

You should always address and refer to a transgender Veteran by the Veteran's preferred name and self-identified gender. This is true in conversation and in documentation in the medical record, irrespective of the Veteran's appearance. Official documents are not needed (for example, legal name change or changed birth certificate) nor are surgical or medical interventions required for Veterans to be identified by their preferred gender or name. For more information about how to ask about birth sex and self-identified gender identity (SIGI), see: https://dvagov.sharepoint.com/sites/vhava-lgbt-resources/HealthCareTopics/SitePages/SIGI.aspx. **NOTE:** This is an internal VA website that is not available to the public.

7. Are transgender Veterans allowed to use public accommodations of their choice?

Yes. VA policies on access to facilities (for example, bathrooms, locker rooms, or room assignments) apply to all VA facilities across the country, regardless of local or state laws or regulations regarding use of facilities based on birth sex. To ensure the safety and respect of Veterans in cities and states with policies restricting access to bathrooms, locker rooms, etc., extra education, signage, and safety precautions could be needed to guarantee the safety of transgender people using the facilities of their choosing.

8. Are transgender Veterans allowed to use the bathroom of their choice?

Yes. Transgender Veterans who self-identify as women are allowed to use bathrooms for women. Likewise, those who self-identify as men are allowed to use bathrooms for men. This is irrespective of the Veteran's appearance or whether the Veteran has had surgical interventions. Some transgender people may prefer to use single stall bathrooms, typically labeled "unisex," or something similar. If a transgender person requests a single stall bathroom, they should be directed accordingly, though

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they remain welcome to use any and all facilities that correspond to their self-identified gender identity.

9. What about room assignments, including shared rooms?

Room assignments are made in accordance with the Veteran's self-identified gender, irrespective of the Veteran's appearance or whether the Veteran has had surgical interventions, and in consideration of the needs of other Veterans. Privacy and confidentiality dictate that staff may not share any information about one Veteran with another Veteran without express permission. If a room assignment leads to distress for either Veteran, then efforts need to be made to move the distressed Veteran to a different semi-private room. If both Veterans are distressed, staff should use current policies about resolving roommate disputes to determine if/when and how a room change should happen. **NOTE:** Ethics consultations are encouraged when concerns arise related to the provision of respectful care for transgender and intersex Veterans and other Veterans.

10. What is sex reassignment surgery?

Sex reassignment surgery is an older term for gender confirming/affirming surgeries or procedures.

11. Will VA provide gender confirming/affirming surgeries or plastic reconstructive surgery if needed?

VA does not provide gender confirming/affirming surgeries in VA facilities or through non-VA care. In addition, VA does not provide plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. However, transgender Veterans cannot be denied access to surgical interventions that are medically indicated for other medical conditions simply because the procedure is also consistent with transition goals. *NOTE:* Some transgender Veterans may elect to have one or more medical or surgical procedures over their lifetime to bring their bodies into a closer alignment with their experienced gender. Only a minority of transgender Veterans will undergo gender confirming/affirming surgeries outside VA. Some Veterans receiving care at a VA medical facility may have had gender confirming/affirming surgeries somewhere else. VA does provide health care to pre- and post-operative transgender Veterans, including treatment of surgical complications.

12. How do pre-operative medical and mental health evaluations differ for transgender Veterans?

VA provides pre-operative medical and mental health evaluations for Veterans who receive surgeries outside VA. Medical evaluation prior to any surgery includes pre-operative cardiac risk assessment and careful evaluation of current medications, including hormone dosing. Providers may recommend that Veterans on hormone therapy taper off prior to surgery to reduce risks and reinitiate hormone treatment post-surgery.

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13. Will VA provide feminizing or masculinizing hormone therapy?

Yes, if it is consistent with the Veteran's wishes, the treatment team's clinical recommendations, and VA treatment guidance.

14. What guidance is available to clinicians regarding hormone therapy?

VA Pharmacy Benefits Management Services has developed guidance for the use of hormone therapy in transgender and intersex Veterans in VA. This guidance is located at: https://dvagov.sharepoint.com/sites/vhava-lgbtresources/HealthCareTopics/Transgender%20Care/Forms/AllItems.aspx?id=%2Fsites %2Fvhava%2Dlgbt%2Dresources%2FHealthCareTopics%2FTransgender%20Care%2 FCFU%20PBM%20Guidelines%2FCFU%20Masculinizing%20Hormone%20Therapy%2 0%28Testosterone%29%20Transgender%20%26%20Gender%20Diverse%20Patients %20%20%28Rev%20Apr%202021%29%5F508%2Epdf&parent=%2Fsites%2Fvhava% 2Dlqbt%2Dresources%2FHealthCareTopics%2FTransgender%20Care%2FCFU%20PB M%20Guidelines and https://dvagov.sharepoint.com/sites/vhava-lgbtresources/HealthCareTopics/Transgender%20Care/Forms/AllItems.aspx?id=%2Fsites %2Fvhava%2Dlgbt%2Dresources%2FHealthCareTopics%2FTransgender%20Care%2 FCFU%20PBM%20Guidelines%2FCFU%20Feminizing%20Hormone%20Therapy%20 %28Estrogens%29%20for%20Transgender%20%26%20Gender%20Diverse%20Patien ts%20%28Rev%20Apr%202021%29%5F508%2Epdf&parent=%2Fsites%2Fvhava%2DI gbt%2Dresources%2FHealthCareTopics%2FTransgender%20Care%2FCFU%20PBM %20Guidelines. NOTE: This is an internal Web site and is not available to the public. Training in prescribing hormone therapy is available TMS courses: VA 39646, 39647. 39648, 39649, and 39644. NOTE: This is an internal Web site and is not available to the public. This training is also available on an external Web site at: https://www.train.org/vha/welcome, TRAIN course: 1066855.

15. What is the process for informed consent for hormone therapy?

- a. For treatment plans that include hormone therapy or surgical interventions, VA clinicians should follow the requirements for informed consent as outlined in VHA Handbook 1004.01(5), Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009. This includes discussing the indication for the treatment, the risks, benefits, and limitations of the therapy with the Veteran, as well as the risks and benefits of the alternative treatments, including no treatment. Signature consent is not required for hormone therapy; oral informed consent is sufficient. **NOTE:** Policy regarding informed consent can be found in VHA Handbook 1004.01(5).
- b. Obtaining the patient's consent for treatments and procedures promotes the Veteran's involvement in decisions about their care. Shared decision-making combines the provider's medical knowledge and expertise with the Veteran's preferences about care. Using shared decision-making for decisions about hormone therapy will help identify a medically appropriate treatment option that promotes the Veteran's preferences about treatment (for example, desired feminizing or masculinizing

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outcomes) and incorporate the provider's knowledge and experience about the risks and benefits of the treatment.

16. What are the goals of hormone therapy? What effects and risks are associated with hormone therapy?

- a. Hormone therapy is used to reduce or eliminate gender dysphoria and other symptoms related to the discordance between a transgender or intersex individual's gender identity and their sex assigned at birth. The treatment produces changes in hormonally-sensitive sex characteristics (that is, reducing characteristics of the birth sex and inducing those of the opposite sex). VA clinicians need to provide transgender and intersex Veterans with a careful evaluation prior to providing prescriptions for hormone therapy. Not all transgender or intersex Veterans will want hormone treatment.
- b. The goal of feminizing hormone therapy is to suppress testosterone levels and introduce estrogen to achieve a pre-menopausal female hormonal range. The effects are decreased facial and body hair, redistribution of fat, breast development, and prostate and testicular atrophy. Risks include infertility, venous thromboembolism, liver dysfunction, hypertension, and cardiovascular disease. As with any medical therapy, benefits and harms of treatment need individualization using principles of shared decision-making, with an emphasis upon the lowest (safest) dose to achieve benefits. VA does not encourage the imposition of "menopausal" state in elder transgender women. Hormone treatments should be consistent with the Veteran's treatment goals and can include feminizing hormone therapy in older transgender women.
- c. In cases when anti-androgens and/or doses of estrogens cannot be tolerated by the patient, are ineffective, or if the Veteran would be at increased risk for adverse effects, such as cardiovascular or other thrombotic events, and when an appropriate medical provider has determined that there are no other standard medical options for hormone management, surgical orchiectomy is an acceptable treatment recommendation. In these select Veterans, orchiectomy can be considered medically necessary as part of their hormone management, and not gender confirming/affirming surgery. Decisions about the appropriate use of orchiectomy should be made on a case-by-case basis as determined by the treatment team, and should include a medical provider who has expertise in the management of hormone therapy. **NOTE:** Transgender E-consultations and/or ethics consultations are available for case-specific consultation.
- d. The goal of masculinizing hormone therapy is to maintain testosterone and estrogen levels in the typical male range, generally through testosterone supplementation and sometimes in combination with a Gonadotropin Releasing Hormone (GnRH) agonist or progestins to suppress menses. The effects are increased facial and body hair and muscle, acne, permanent deepening of the voice, cessation of the menses, redistribution of fat mass, and clitoral enlargement. Risks include hypertension, erythrocytosis, liver dysfunction, lipid changes, weight gain, and sodium retention.

17. Can hormone therapy cause infertility?

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Yes. This should be discussed with the prescribing provider as a part of medical decision making. Transgender and intersex Veterans are eligible for the same fertility preservation services as other Veterans about to undergo treatment that can alter fertility. For more information about VA's coverage of fertility services, please see: https://vaww.infoshare.va.gov/sites/LGBEducation/Pages/FAQ.aspx. **NOTE:** This is an internal Web site and is not available to the public.

18. Are there specific diagnostic criteria to consider in prescribing hormone therapy?

A diagnosis is required to prescribe medications. A DSM-5 diagnosis of Gender Dysphoria or other gender dysphoria condition should be the basis for prescription for hormone therapy for transgender Veterans. There may be clinical exceptions to the diagnosis for prescribing hormone therapy (for example, transgender individuals diagnosed as having "Other Specified Gender Dysphoria" who are post-transition and still require medications). **NOTE:** Gender Identity Disorder (GID) is an outdated diagnosis from DSM-IV that described a conflict between a person's birth sex and the gender with which the person identifies. With regard to encounter codes, the term GID may be listed if Gender Dysphoria is not available.

19. Transgender and intersex Veterans are presenting to VA providers with prescriptions for hormones from outside sources, such as from another provider, the Internet, or illicit sources. Should we stop these medications while we do a full evaluation or should a VA provider rewrite the prescriptions so they can be filled in a VA pharmacy and continued?

Under VHA Directive 1310(1), Medical Management of Enrolled Veterans Receiving Self-Directed Care form External Health Care Providers, October 4, 2021, VA providers are not permitted to simply rewrite prescriptions from an outside provider, unless the VA provider has first made a professional assessment that the prescribed medication is medically appropriate. *NOTE:* It may be appropriate for a VA provider to provide temporary prescriptions based on each Veteran's unique situation and a weighing of risks/benefits in order to avoid negative physical and psychiatric consequences while a VA evaluation is in progress.

20. What evaluation is necessary prior to initiation of hormone therapy?

Because the provision of hormone therapy in transgender Veterans is designed to treat the gender incongruence and dysphoria, a diagnosis must be established before hormone therapy can begin. A mental health professional generally establishes a Gender Dysphoria diagnosis prior to provision of hormone therapy. Additionally, the provider who prescribes the hormone therapy must obtain informed consent for that treatment, as described in FAQ #15. The presence of other psychiatric and physical conditions is not necessarily a barrier to initiating treatment. Treatment for comorbid conditions can be recommended in the evaluation, but cannot create a barrier to access for hormone treatment, except where medically contraindicated. For Veterans who enter VA with well documented hormone therapy from outside clinicians, the diagnosis

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of Gender Dysphoria is still required, and should be confirmed. In such cases, a mental health evaluation may help to both confirm the diagnosis and address other potential mental health needs of the Veteran.

21. How do we handle preventive screening requirements?

In addition to treatments related to their new gender identity, transgender Veterans need appropriate medical screening and/or treatment specific to their birth sex. Clinical reminders are cued to birth sex. Important screening reminders include prostate exams and mammograms for transgender women and vaginal exams and mammograms for transgender men, as indicated. Some transgender Veterans will change the birth sex in their records. For these Veterans, their clinical reminders will not be cued to their natal sex but to the sex listed in the birth sex field. Providers and Veterans will need to remember to do preventive screens as needed.

22. Is hair removal (electrolysis/laser hair removal) covered by the VA for transgender Veterans?

Permanent hair removal can be medically necessary, such as for pre-surgical hair removal for genital surgery. VA provides pre-operative and long term post-operative care for gender affirming surgeries. For non-cosmetic medically necessary hair removal, laser hair removal is appropriate to prevent major complications following genital surgery. For Veterans who are not candidates for laser hair removal due to hair color (white/gray/ blonde), electrolysis may be provided. Currently, each VA decides if hair removal is indicated on a case-by-case basis after an evaluation of medical necessity. Some VA facilities have the equipment to perform laser hair removal and/or electrolysis, while others will need to access community care when this procedure is medically indicated.

23. Will VA provide medically necessary prosthetics (e.g., wigs, chest binders, dilators, etc.) to eligible transgender and intersex Veterans?

Yes. For more information on prosthetics, see the Prosthetic & Sensory Aids Service Policy SharePoint at https://vaww.infoshare.va.gov/sites/prosthetics/Policy%20Questions/Forms/Answer.aspx. NOTE: This is a VA internal Web site that is not available to the public.

24. Will VA provide medically necessary vocal coaching to transgender and intersex Veterans?

Yes. VA speech pathologists can offer this care, or if this service is not available at your facility, it can be offered through non-VA community-based care.

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25. Can a transgender Veteran request a change of birth sex in Computerized Patient Record System (CPRS) before having gender confirming/affirming surgery?

Yes. Surgery is not a prerequisite for amendment of birth sex in the Veteran's record. Amending the birth sex of the Veteran in CPRS is based on the Veteran making a written amendment request to the facility's Master Veteran Index Coordinator (often the Privacy Officer). The request must be accompanied by official documentation as described in the Identity Management Fact Sheet, dated November 2016. However, self-identified gender identity can be changed without documentation by the Veteran or by any VA staff who routinely update demographic data. Changing birth sex will result in loss of information for preventive health screenings, and may complicate medication dosing and medical reports.

26. Do I need to become an expert in treating transgender Veterans?

No, but all clinicians and staff who provide clinical services to transgender Veterans need to be knowledgeable about transgender health issues. Providers are encouraged to consult with specialists on any aspect of care for which they need advice or for ongoing management, as they would for any other Veteran. Everyone needs to be aware that transgender Veterans deserve to receive health care at VA and need to be treated with dignity and respect.

27. What education is available to VA staff?

Cultural awareness and sensitivity education, as well as clinical trainings, are available and can be found on the Transgender SharePoint:

http://go.va.gov/Transgender. NOTE: This is an internal VA website that is not available to the public. For local trainings, the LGBTQ+ Veteran Care Coordinator will have access to the most current information.

28. What do I do if I become aware of possible discrimination or harassment of a transgender Veteran?

VA is founded on respect of Veterans and does not tolerate discrimination or harassment. To report concerns, you may work with the LGBTQ+ Veteran Care Coordinator, your supervisor, and/or the patient advocates. The VA Medical Facility Director is responsible for implementing corrective actions and training.

29. As a VA staff member, where can I find good resources on transgender care?

There are VA and non-VA resources that can be helpful. A good repository for this information is https://dvagov.sharepoint.com/sites/vhava-lgbt-resources/HealthCareTopics/SitePages/Transgender-%26-Gender-Diverse-Resources.aspx. You may also wish to consult with your local LGBTQ+ Veteran Care Coordinator about training. *NOTE:* This is an internal VA website that is not available to the public.

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30. Who typically serves as LGBTQ+ VISN Leads and Veteran Care Coordinators?

a. VA employees who serve in LGBTQ+ VISN Lead positions are familiar with LGBTQ+ Veteran health issues, best clinical practices, VA medical facility clinical operations and VHA policies and are motivated to improve care for LGBTQ+ Veterans in the VISN. LGBTQ+ VISN Leads are most effective when they meet regularly with VISN Leadership and VA medical facility LGBTQ+ VCCs as detailed in this directive. A clinical background can be an advantage to advise VA medical facility LGBTQ+ VCCs and resolve issues involving gaps or conflicts in clinical processes.

b. VA employees who serve as VA medical facility LGBTQ+ VCCs are knowledgeable about their local community and the availability of LGBTQ+ services there. Effective VA medical facility LGBTQ+ VCCs are excellent advocates for Veterans and teachers who are able to tailor educational or training content for different clinical and non-clinical learners.

31. How have VA medical facilities staffed LGBTQ+ VCC positions to provide appropriate coverage?

This directive offers guidance for the minimum allocated time for VA medical facility LGBTQ+ VCCs based on the size of the VA medical facility. Other factors, such as the number of campuses, community-based outpatient clinics (CBOCs) and size of the LGBTQ+ Veteran population also influence the amount of time provided for this role. See paragraphs 5.g. in the body of the directive. Many VA medical facilities have provided larger amounts of allocated time to their LGBTQ+ VCC. Some VA medical facilities have established a full-time LGBTQ+ VCC position or multiple part-time LGBTQ+ VCCs. Having more than one LGBTQ+ VCC and having VCCs located in CBOCs may be especially advantageous for coverage of very large VA medical facilities or VA medical facilities with multiple campuses. Multiple VCCs can be helpful for engaging CBOCs, as well as providing coverage during leave.

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ADDITIONAL GUIDANCE FOR LGBTQ+ VETERAN CARE COORDINATORS

- 1. The Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ+) Veteran Care Coordinator (VCC) program was established in 2016 to ensure that culturally competent LGBTQ+ clinical services are provided at Department of Veterans Affairs (VA) medical facilities consistent with Veterans Health Administration (VHA) policies and priorities. Research shows that LGBTQ+ Veterans expect to experience discrimination in VA medical facilities which may impair their engagement in care. Research also shows that LGBTQ+ Veterans as a group experience higher rates of several health conditions compared to non-LGBTQ+ Veterans including suicidal ideation and attempts. The elevated risk for health inequities is attributed to the psychosocial stressors inherent in belonging to a minority group. Therefore, additional efforts to reduce minority stress and engage this vulnerable population are necessary to provide equitable health care for LGBTQ+ Veterans. See https://doi.apa.org/doiLanding?doi=10.1037%2Fa0034826 for additional information. *NOTE:* This website is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.
- 2. The LGBTQ+ Health Program in collaboration with LGBTQ+ Veterans Integrated Service Network (VISN) Leads, LGBTQ+ Veteran Care Coordinators (VCC), and Network leadership strongly recommend that LGBTQ+ VCCs follow guidance under four priority areas listed below. LGBTQ+ VCCs are encouraged to complete at least three activities listed for each priority area. Furthermore, LGBTQ+ VCCs are encouraged to participate in additional activities specific to the needs of the VA medical facility.

a. Create a safe and affirming environment throughout the VA medical facility.

- (1) Place LGBTQ+ VCC program materials throughout the facility (e.g., LGBTQ+ posters, handouts, fact sheets), including main campuses and community clinics.
- (2) Make outreach information available at VA medical facilities to inform LGBTQ+ Veterans of LGBTQ+ specific services, role, and contact information of the LGBTQ+ VCC.
- (3) Display or distribute LGBTQ+ safety signals (e.g., pins, lanyards) to raise awareness and denote spaces where staff are trained in affirming practices. Decisions to display safety signals, and which signals, are made by VA medical facility leadership.
 - (4) Connect Veterans to LGBTQ+-focused programing.
- (5) Collaborate with the Patient Experience Officer, Patient Advocate, Equal Employment Office (including Inclusion, Diversity, Equity, and Access (I-DEA) initiatives), and VA medical facility leadership in responding to compliments, complaints, inquiries, and recommendations from various stakeholders, including staff, patients, caregivers, congressional inquiries, White House Hotline, and others about LGBTQ+ care at the VA medical facility.

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- (6) Promote collection of preferred name, pronouns, sexual orientation and gender identity patient data in the electronic health record (EHR).
- (7) Support the VA medical facility's completion of the Healthcare Equality Index survey.

b. <u>Build a network of stakeholders, including building allies and partners within the VA medical facility, the community, and the Veterans Integrated Services Network.</u>

- (1) Maintain current contact information for LGBTQ+ VCCs on the VA medical facility website and LGBTQ+ Resource SharePoint, https://dvagov.sharepoint.com/sites/vhava-lgbt-resources. **NOTE:** This is an internal VA website that is not available to the public.
- (2) During the VA medical facility LGBTQ+ VCC's regular tour of duty, hold at least one joint event annually (e.g., training, outreach events, town halls) with the Equal Employment Office or other VHA programs (e.g., Mental Health, Women Veterans Health, Suicide Prevention, Intimate Partner Violence Assistance Program, Healthcare for Homeless Veterans, M2VA Post 9/11 Military to VA Care Management).
- (3) During the VA medical facility LGBTQ+ VCC's regular tour of duty, attend at least one external LGBTQ+ community event annually to foster collaborative relationships.
- (4) Meet at least annually with VA medical facility leadership to review the VA medical facility's LGBTQ+ VCC Program strategic plan and facilitate communication about achievements and ongoing needs for LGBTQ+ Veterans at the VA medical facility.
- (5) Participate in national LGBTQ+ Health Program and LGBTQ+ VISN calls to maintain awareness of program updates and resources.

c. Knowledge of LGBTQ+ services and identification of VA medical facility gaps in care.

- (1) Know what LGBTQ+ Veteran services are provided by VHA and what services are available at the VA medical facility. VA medical facility LGBTQ+ VCCs will participate in orientation to develop this foundational knowledge.
- (2) Identify gaps in local services and take steps to resolve as appropriate with VA medical facility leadership and relevant stakeholders.
- (3) Establish a process to address LGBTQ+ Veteran concerns about services, VHA policies, and processes.
- d. <u>Educate and train staff to reduce barriers to LGBTQ+ Veteran care to improve access to and quality of care at the VA medical facility.</u>

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(1) Provide LGBTQ+ trainings to staff and VA health care providers at least annually. Develop a plan with VA medical facility leadership regarding when and where trainings are needed (e.g., new employee orientation, clinic meetings, in response to complaints). Examples of training content include the need for and how to collect preferred name, pronouns, sexual orientation and gender identity data in the EHR and ways to provide affirming health care and service to LGBTQ+ Veterans. Trainings can be accessed through the LGBTQ+ Health Resource SharePoint: https://dvagov.sharepoint.com/sites/vhava-lgbt-resources. *NOTE:* This is an internal VA website that is not available to the public.

(2) Disseminate information (e.g., emails, VA medical facility newsletters, posters, brochures, announcements in meetings) to staff and VA health care providers about LGBTQ+ Veteran health trainings, resources, services, and events.

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PROVIDING HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. **PURPOSE:** This Veterans Health Administration (VHA) Directive establishes policy regarding the respectful delivery of health care to transgender and intersex Veterans who are enrolled in the Department of Veterans Affairs (VA) health care system or are otherwise eligible for VA care.

- **2. BACKGROUND:** In accordance with the medical benefits package (title 38 Code of Federal Regulations (CFR) section 17.38), VA provides care and treatment to Veterans that is compatible with generally accepted standards of medical practice and determined by appropriate health care professionals to promote, preserve, or restore the health of the individual.
- a. VA provides health care for transgender patients, including those who present at various points on their transition from one gender to the next. This applies to all Veterans who are enrolled in VA's health care system or are otherwise eligible for VA care, including those who have had sex reassignment surgery outside of VHA, those who might be considering such surgical intervention, and those who do not wish to undergo sex reassignment surgery but self-identify as transgender. Intersex individuals may or may not have interest in changing gender or in acting in ways that are discordant with their assigned gender.
- b. VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes.

c. Definitions

- (1) **Sex.** Sex refers to the classification of individuals as female or male on the basis of their reproductive organs and functions.
- (2) **Gender.** Gender refers to the behavioral, cultural, or psychological traits that a society associates with male and female sex.
- (3) **Transgender.** Transgender is a term used to describe people whose gender identity (sense of themselves as male or female) or gender expression differs from that usually associated with their sex assigned at birth.
- (a) <u>Transsexual (Male-to-Female)</u>. Male-to-female (MtF) transsexuals are a subset of transgender individuals who are male sex at birth but self-identify as female and often take steps to socially or medically transition to female, including feminizing hormone therapy, electrolysis, and surgeries (e.g., vaginoplasty, breast augmentation).

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(b) <u>Transsexual (Female-to-Male)</u>. Female-to-male (FtM) transsexuals are a subset of transgender individuals who are female sex at birth but self-identify as male and often take steps to socially or medically transition to male, including masculinizing hormone therapy and surgeries (e.g., phalloplasty, mastectomy).

- (4) **Sex reassignment surgery.** Sex reassignment surgery includes any of a variety of surgical procedures (including vaginoplasty and breast augmentation in MtF transsexuals and mastectomy and phalloplasty in FtM transsexuals) done simultaneously or sequentially with the explicit goal of transitioning from one sex to another. This term includes surgical revision of a previous sex reassignment surgery for cosmetic purposes. **NOTE:** This term does not apply to non-surgical therapy (e.g., hormone therapy, mental health care, etc.) or intersex Veterans in need of surgery to correct inborn conditions related to reproductive or sexual anatomy or to correct a functional defect.
- (5) **Gender Identity Disorder (GID).** GID is a conflict between a person's physical sex and the gender with which the person identifies.
- (6) **Intersex.** Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female. People with intersex conditions are often assigned male or female gender by others at birth (e.g., parents), although the individual may or may not later identify with the assigned gender.
- **3. POLICY:** It is VHA policy that medically necessary care is provided to enrolled or otherwise eligible intersex and transgender Veterans, including hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery. Sex reassignment surgery cannot be performed or funded by VA.

4. ACTION

- a. <u>Veterans Integrated Service Network (VISN) Director.</u> Each VISN Director must ensure that necessary and appropriate health care is provided to all enrolled or otherwise eligible Veterans based on the Veteran's self-identified gender, regardless of sex or sex reassignment status.
- b. Medical Facility Director, Chief of Staff, and Associate Director for Patient Care Services or Nurse Executive. The medical facility Director, Chief of Staff, and Associate Director for Patient Care Services or Nurse Executive are responsible for ensuring:
- (1) Transgender patients and intersex individuals are provided all care included in VA's medical benefits package including but not limited to: hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery to the extent that the appropriate health care professional determines that the care is needed to promote, preserve or restore the health of the individual and is in accord with generally-accepted standards of medical practice.

(a) Patients will be addressed and referred to based on their self-identified gender. Room assignments and access to any facilities for which gender is normally a consideration (e.g., restrooms) will give preference to the self-identified gender, irrespective of appearance and/or surgical history, in a manner that respects the privacy needs of transgender and non-transgender patients alike. Where there are questions or concerns related to room assignments, an ethics consultation may be requested.

- (b) The documented sex in the Computerized Patient Record System (CPRS) needs to be consistent with the patient's self-identified gender. In order to modify administrative data (e.g., name and sex) in CPRS, patients must provide official documentation as per VHA guidance and policy on <u>Identity Authentication for Health Care Services</u> and <u>Data Quality Requirements for Identity Management and Master Patient Index Functions</u>.
- (c) Sex reassignment surgery as defined in subparagraph 2c(4), will not be provided or funded
- (d) Non-surgical, supportive care for complications of sex-reassignment surgery must be provided. For example, a MtF patient over the age of 50 may be offered breast cancer screening and may wish to discuss the benefits and harms of prostate cancer screening with her provider. A FtM transsexual patient may be offered screening for breast and cervical cancer.
- (e) A diagnosis of GID, or other gender dysphoria diagnoses, is not a pre-condition for receiving care consistent with the Veteran's self-identified gender.
- (2) All other health services are provided to transgender Veterans without discrimination in a manner consistent with care and management of all Veteran patients.
- (3) All staff, including medical and administrative staff, are required to treat as confidential any information about a patient's transgender status or any treatment related to a patient's gender transition, unless the patient has given permission to share this information.
- (4) VA Mandates diversity awareness and maintains a zero-tolerance standard for harassment of any kind.

5. REFERENCES

Title 38 CFR § 17.38 (c).

- **6. FOLLOW-UP RESPONSIBILITY:** The Office of Patient Care Services (10P4) is responsible for the contents of this Directive. Questions related to medical care may be referred to the Lesbian, Gay, Bisexual and Transgender (LGBT) Program (10P4Y) by Email at VALGBTPROGRAM@VA.gov. Questions related to mental health care may be referred to the Office of Mental Health Services (10P4M) at (202) 461-7310.
- **7. RESCISSIONS:** VHA Directive 2011-024, Providing Health Care for Transgender and Intersex Veterans, is rescinded. This VHA Directive expires February 28, 2018.

Robert A. Petzel, M.D. Under Secretary for Health

Attachment

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 2/11/2013

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Attachment A

FREQUENTLY ASKED QUESTIONS (FAQ) REGARDING THE

PROVISION OF HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. What is the prevalence of transgender individuals? Is there a difference between transgender and transsexual individuals?

- a. The prevalence of transgender individuals is not known in general or in the Veteran population. This is because of challenges in defining gender identity, the reluctance of individuals to identify themselves to others as transgender, and measures that are narrowly focused on subsets of individuals who either have been diagnosed with gender identity disorder (GID) or have had sex reassignment surgery. It is for these reasons that the Institute of Medicine issued their report "The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding" (March 31, 2011) and called on Health and Human Services (HHS) and other Federal agencies to "implement a research agenda designed to advance knowledge and understanding of Lesbian, Gay, Bisexual, and Transgender (LGBT) health. This agenda includes appropriate data gathering on sexual orientation and gender identity in public health research tools and electronic health records.
- b. Current estimates of the prevalence of transsexual individuals with GID are approximately 1:11,000 natal males and 1:30,000 natal females. The prevalence of all transgender individuals is much higher since "transgender" is an umbrella term that includes individuals who do not have GID.
- c. Based on these data, the estimated prevalence of Male-to-Female (MtF) to Female-to-Male (FtM) transsexual individuals is approximately 3:1 in the general population. This prevalence ratio is likely to be higher in the predominantly male Veteran population. It is important to note that FtM transsexual individuals are also part of the Veteran population.
- d. Intersex Veterans, that is, individuals who are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female, may or may not identify as transgender.

2. Is transgender the same as being "gay" or "lesbian?"

No. The term "transgender" refers to gender identity or the sense of oneself as male, female, or other, (e.g., androgynous, eunuch, etc.). The terms "gay" (in the case of men) and "lesbian" (in the case of women) refer to sexual orientation. The sexual orientation of gay and lesbian persons is attraction to the same gender whereas heterosexual persons are attracted to the opposite gender. A transgender Veteran may identify as heterosexual ("straight"), gay, lesbian, bisexual (i.e., attracted to both genders), queer, pansexual, asexual, etc. Knowing someone's gender identity gives you no information about their sexual orientation.



3. What is intersex?

Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female. People with intersex conditions are often assigned male or female gender by others at birth (e.g., parents), although the individual may or may not later identify with the assigned gender.

4. Do all intersex individuals identify as transgender?

No. For example, an individual may be assigned the physical status of "female" at birth and identify as female throughout her lifetime, with or without knowledge of an intersex condition. Some intersex persons with male chromosomes who have been assigned female become gender dysphoric even without knowing that they were "reassigned" at, or near, birth. Knowing someone has an intersex condition gives you no information about their gender identity or sexual orientation

5. What is sex reassignment surgery?

Sex reassignment surgery includes any of a variety of surgical procedures done simultaneously or sequentially with the explicit goal of transitioning from one gender to another. This term includes surgical revision of a previous sex reassignment surgery for cosmetic purposes. This term does not apply to non-surgical therapy (e.g., hormone therapy, mental health care, etc.) or to intersex Veterans in need of surgery to correct inborn conditions related to reproductive or sexual anatomy or to correct a functional defect.

6. Will VA provide sex reassignment surgery and plastic reconstructive surgery if needed?

VA does not provide sex reassignment surgery in VA facilities or through non-VA care. In addition, VA does not provide plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. However, patients with GID or other gender dysphoria conditions may elect to have one or more medical or surgical procedures over their lifetime to bring their bodies into a closer alignment with their perceived gender. *NOTE:* Only a minority of transgender Veterans will undergo sex reassignment surgery, as their symptoms may often be adequately treated with other therapeutic interventions. Some Veterans receiving care at the VA may have had sex reassignment surgery somewhere else. The VA does provide health care to pre- and post-operative transsexual Veterans, including treatment of surgical complications.

7. Will the VA provide for electrolysis through non-VA care for male-to-female transsexual (MtF) Veterans?

No. VA will not provide electrolysis as this is considered by VHA to be cosmetic rather than medically necessary to promote, preserve, or restore health of the Veteran.



8. What are the guidelines for clinical care and the informed consent process?

a. Effective clinical care for transgender and intersex patients ideally involves an interdisciplinary, coordinated treatment approach with special attention to the needs of the individual patient and collaboration among multiple specialties, notably: gynecology, mental health, primary and specialty care, women's health, pharmacy, and urology. For all treatments and procedures, informed consent and shared decision-making needs to be the basis for individualized care that weighs the possible benefits and harms, with an emphasis on the lowest (safest) dose to achieve benefits. **NOTE:** Procedures regarding informed consent can be found in VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures at: http://www1.va.gov/vhapublications/ViewPublication.asp?pub ID=2055.

b. For treatment plans that include cross-sex hormone therapy, VA clinicians must, consistent with requirements of informed consent (VHA Handbook 1004.01), discuss the risks, benefits, and limitations of cross-sex hormone therapy with the patient. Signature consent is <u>not</u> required for cross-sex hormone therapy. Ongoing monitoring of treatment is required.

9. Will VA provide feminizing or masculinizing hormone therapy?

Yes, if it is consistent with the patient's wishes, the treatment team's clinical recommendations, and VA treatment guidance.

10. What guidance is available to clinicians regarding hormone therapy?

VA Pharmacy Benefits Management Services has developed guidance for the use of hormone therapy in transgender and intersex patients in VA. This guidance is located at: http://vaww.national.cmop.va.gov/PBM/default.aspx. *NOTE:* This is an internal Web site and is not available to the public.

11. What are the goals of cross-sex hormonal treatment? What effects and risks are associated with hormonal treatment?

- a. Cross-sex hormonal treatment is used to reduce or eliminate gender dysphoria and other symptoms related to the discordance between a transgender or intersex individual's gender identity and their biological sex at birth or the gender they were assigned at birth. The treatment produces changes in hormonally-sensitive sex characteristics (i.e., reducing characteristics of the original sex and inducing those of the opposite sex). VA clinicians need to provide transgender and intersex patients with a careful evaluation prior to providing a prescription for cross-sex hormonal therapy.
- b. The goal of cross-sex hormone therapy in treatment of MtF transgender patients is to suppress testosterone levels and introduce estrogen to achieve a pre-menopausal female hormonal range. The effects are decreased facial and body hair, redistribution of fat, breast development and prostate and testicular atrophy. Risks include venous thromboembolism, liver dysfunction, hypertension, and cardiovascular disease. As with any medical therapy, benefits



and harms of treatment need individualization using principles of shared decision-making, with an emphasis upon the lowest (safest) dose to achieve benefits.

c. The goal of cross-sex hormone therapy in treatment of FtM transgender patients is to maintain testosterone and estrogen levels in the normal male range, generally through testosterone supplementation and sometimes in combination with a Gonadotropin Releasing Hormone (GnRH) agonist or progestins to suppress menses. The effects are increased facial and body hair and muscle, acne, permanent deepening of the voice, cessation of menses, redistribution of fat mass, and clitoral enlargement. Risks include hypertension, erythrocytosis, liver dysfunction, lipid changes, weight gain, and sodium retention.

12. Are there specific diagnostic criteria to consider in prescribing cross-sex hormone therapy?

- a. A diagnosis of GID or other dysphoria condition should be the basis for prescription for cross-sex hormonal therapy for transgender patients. There may be clinical exceptions to the diagnosis for prescribing cross-sex hormone therapy (e.g., transgender individuals with "GID not otherwise specified").
- b. Intersex patients are excluded from the GID diagnosis by DSM IV criteria. Transgender patients with intersex conditions who are seeking hormonal treatment need to fulfill DSM IV criteria for "GID not otherwise specified." Intersex and transgender individuals may have different mental health considerations.
- 13. Transgender and intersex Veterans are presenting to VA providers with prescriptions for hormones from outside sources, such as from another provider, the internet, or illicit sources. Should we stop these medications while we do a full evaluation or should a VA provider rewrite the prescriptions so they can be filled in a VA pharmacy and continued?

Under current VHA National Dual Care Policy, VA providers are not permitted to simply rewrite prescriptions from an outside provider, unless the VA provider has first made a professional assessment that the prescribed medication is medically appropriate. However, cross sex hormones cannot generally be stopped abruptly without negative physical and psychiatric consequences. If the patient has records that support a thorough evaluation and psychotherapy prior to initiation of hormones, then it may be appropriate for a VA provider to rewrite the prescriptions so they can be filled in a VA pharmacy and continued while the evaluation is in progress and to monitor hormone levels. A mental health exam in this situation is not required and is based on the clinical situation. Very high doses of cross-sex hormones are associated with a greater likelihood of side effects, and a reduction in dose may be required. Additionally, the benefits and harms of hormonal therapy differ based upon the presence or absence of risk factors for, or occurrence of, serious complications (cardiovascular, thrombotic-embolic) and thus dosage needs to be individualized.



14. What if a transgender or intersex Veteran presents to VA and self-reports that they have been taking cross sex hormones that they would like to continue but can provide no supportive documentation from a physician?

Consistent with the VHA National Dual Care Policy, VA clinicians need to provide transgender patients with a careful medical and mental health evaluation <u>prior</u> to providing a prescription for cross-sex hormonal therapy.

15. Is a mental health evaluation necessary or required?

A thorough and careful mental health evaluation needs to be completed prior to provision of hormone therapy and needs to include evaluation and treatment for psychiatric comorbidities that may have overlapping presentations, such as depression, anxiety, Post Traumatic Stress Disorder (PTSD) or substance use disorders. The presence of other psychiatric and physical conditions is not necessarily a barrier to initiating treatment. For patients who enter VA with well-documented cross-sex hormone therapy from outside clinicians, mental health evaluations are optional based on the clinical presentation.

16. I understand that VA does not provide sex reassignment surgery, but are there any special considerations regarding a mental health evaluation prior to sex reassignment surgery?

Mental health evaluation prior to surgery includes specialized exams by knowledgeable doctoral level clinicians. Some professional associations with expertise on transgender issues (see resources in paragraph 28 of this Attachment) recommend that individuals contemplating genital surgery need to participate in a minimum of a 1-year "real life experience" i.e., living full time in the preferred gender role, prior to any genital surgical intervention.

17. In what ways would a pre-operative medical evaluation differ for these Veterans?

Medical evaluation prior to surgery includes pre-operative cardiac risk assessment and careful evaluation of current medications including hormone dosing.

18. What types of surgeries might transgender Veterans consider?

- a. As part of their transition, FtM patients might consider undergoing several types of surgery including mastectomy, hysterectomy or oopherectomy, and neophallus construction. The common complications of neophallus construction include flap or graft necrosis, fistulae, urinary tract infection, donor site scarring, and infections. Mastectomy and hysterectomy have far fewer complications. Clinicians need to be aware that VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care.
- b. As part of their transition, MtF patients might consider undergoing several types of surgery including orchiectomy, penectomy, vaginoplasty, breast implants, laryngeal shave, and facial feminization procedures. Common complications of genital surgeries include strictures,



infections, fistulae, urinary tract complications and loss of genital sensation. Clinicians need to be aware that VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. MtF patients may consider undergoing electrolysis for hair removal. Clinicians need to be aware that VA does not provide electrolysis as this is considered a cosmetic rather than a medically necessary procedure.

19. If a patient has had sex reassignment surgery, how do we handle preventive screening requirements?

In addition to treatments related to their new gender identity, transgender patients need appropriate medical screening and/or treatment specific to their birth sex. This includes prostate exams and mammograms for MtF patients and vaginal exams and mammograms for FtM patients, as indicated.

20. Can a transgender Veteran request a change of gender or sex in Computerized Patient Record System (CPRS) before having sex reassignment surgery?

Amending the gender or sex of the Veteran in CPRS is based on the Veteran making a request to the facility Privacy Officer and providing the official documentation as required by VHA policies. Sex reassignment surgery is not a prerequisite for amendment of gender or sex in the Veteran's record.

21. What constitutes "official documentation" in order for gender or sex to be changed in CPRS?

A Veteran's request for amendment to gender or sex in the record is considered a Privacy Act "amendment request."

- a. One of the following is required as supporting documentation: Legal documentation (i.e., amended birth certificate or court order), passport or a signed original statement on office letterhead, from a licensed physician. Sex reassignment surgery is not a prerequisite for amendment of gender/sex in the Veteran's record.
 - b. The licensed physician's statement must include <u>all</u> of the following information:
 - (1) Physician's full name;
 - (2) Medical license or certificate number;
 - (3) Issuing state of medical license or certificate;
- (4) Drug Enforcement Administration (DEA) registration number assigned to the physician or comparable foreign designation, if applicable;
 - (5) Address and telephone number of the physician;



(6) Language stating that the physician has treated the patient or reviewed and evaluated the medical history of the applicant. The physician also has a doctor patient relationship with the applicant, which is evident in having one or more clinical encounters between doctor and patient;

- (7) Language stating that the patient has had appropriate clinical treatment for gender transition to the new gender (specifying male or female); and
- (8) Language stating, "I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct."

22. Do I need to become an expert in treating transgender Veterans?

- a. All clinicians and staff who provide clinical services to transgender Veterans need to become more knowledgeable about transgender health issues. Everyone needs to be aware that transgender Veterans deserve to receive health care at VA and need to be treated with dignity and respect. Primary Care and Mental Health providers need to be encouraged to consult with specialty physicians on any aspect of management for which they need advice or for ongoing management, as they would for any other complex patient. The initial VA prescription for cross-sex hormone therapy need to be restricted to facility-designated providers experienced with the use of cross-sex hormone therapy (e.g., women's health specialist, endocrinologist, psychiatrist, or other local designee).
- b. The potential lack of clinical expertise in specialties such as endocrinology, mental health, and surgery regarding clinical care of transgender and intersex Veterans, may necessitate establishing a mechanism for timely expert consultation on complicated cases within Veterans Integrated Service Networks (VISN) or facilities.

23. What education will be provided to VA staff?

Cultural awareness and sensitivity education for field staff was developed and implemented in fiscal year 2012. The VA standard of zero tolerance for discrimination, harassment, or abuse of Veterans applies to VHA treatment of transgender and intersex Veterans.

24. What is the correct pronoun to use when speaking with a transgender Veteran and in documentation of the clinical encounter in a progress note?

Transgender Veterans should always be addressed and referred to based on their self-identified gender, in conversation and in documentation in the patient record, irrespective of the Veteran's appearance. Neither sex reassignment surgery nor official documentation of change in sex is required for Veterans to be identified by their preferred gender or for documentation of preferred gender in the patient record.

25. Are transgender Veterans allowed to use the bathroom of their choice?

Transgender Veterans who presently self-identify as female are allowed to use bathrooms for women. Likewise, those who presently self-identify as males are allowed to use bathrooms for



men. This is irrespective of the Veteran's appearance or whether the Veteran has had sex reassignment surgery. The privacy needs of other patients must also be considered; availability of "unisex" bathrooms (for men and women) throughout facilities is a practical approach to this issue and is common practice in some facilities.

26. What about room assignments?

Patient room assignments are made in accordance with the patient's self-identified gender irrespective of the Veteran's appearance or whether the Veteran has had sex reassignment surgery, and in consideration of the needs of other patients. *NOTE:* Ethics consultations are encouraged when concerns arise related to the provision of respectful care for transgender and intersex Veterans and other patients.

27. In situations where shared inpatient rooms are common, might assignments be made such that a MtF transsexual patient and a biologic female would be assigned to share a room or a FtM transsexual patient and a biologic male would be assigned to share a room?

Yes. According to current VHA policy, "room assignments will give preference to the self-identified gender, irrespective of appearance and/or surgical history, in a manner that respects the privacy needs of transgender and non-transgender patients alike." Privacy and confidentiality dictate that staff may not share any information about one patient with another without express permission. If a room assignment leads to distress for either patient, then efforts need to be made to assign one of them to a private room. When this cannot be accommodated or when there are questions or concerns related to room assignments, an ethics consultation needs to be requested.

28. Are there any recommended resources for further information?

VA does not currently have clinical practice guidelines for the care of transgender and intersex Veterans. While VA does not endorse the following private sector guidelines, they may serve to provide information and education about the complexities of caring for this patient population.

- a. World Professional Association for Transgender Health's Standards of Care for Gender Identity Disorders, Version 7, 2011. Available from www.WPATH.org
- b. Endocrine Society Guidelines http://www.endo-society.org/guidelines/final/upload/Endocrine-Treatment-of-Transsexual-Persons.pdf
- c. Clinical Protocol Guidelines for Transgender Care http://www.vch.ca/transhealth or http://transhealth.vch.ca/resources/careguidelines.html
- d. The Joint Commission: *Advancing Effective Communication, Cultural Competence and Patient-and-Family Centered Care for the Lesbian, Gay, Bisexual and Transgender (LGBT) Community: A Field Guide.* Oak Brook, IL, Oct. 2011. http://www.jointcommission.org/lgbt/



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- b. Institute of Medicine. (2011). *The health of lesbian, gay, bisexual, and transgender people: Building a foundation for better understanding*. Washington, DC: The National Academies Press: http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.
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Transgender Military Service in the United States

by Gary J. Gates and Jody L. Herman May 2014



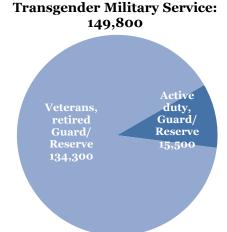
Introduction

This research brief offers analyses from several data sources to estimate the number of transgender individuals who have served in the US armed forces, including the number who are likely on active duty or serving in the Guard or Reserve forces, and the number who are veterans or retired from Guard or Reserve service.

On September 20, 2011, the military policy known as "Don't Ask, Don't Tell" (DADT) ended, allowing gay, lesbian, and bisexual service members to serve openly. Yet, military medical policies still exclude transgender people from serving openly in the US armed forces.1 These medical policies lay out exclusions for what are deemed to be "psychosexual disorders," including transsexualism, cross-dressing, or a history of gender transition.2 Therefore, transgender individuals who wish to join the US armed forces are prohibited from doing so if their transgender status is known. Furthermore, those already serving can be medically discharged if suspected of being transgender.

Our estimates suggest that approximately 15,500 transgender individuals are serving on active duty or in the Guard or Reserve forces. We also estimate that there are an estimated 134,300 transgender individuals who are veterans or are retired from Guard or Reserve service (see Figure 1).

Figure 1. Estimates of military service among transgender adults, by type of service.



Data and methodology

The primary data source for the estimates of transgender military service is the National Transgender Discrimination Survey (NTDS), which was conducted by the National Gay and Lesbian Task Force and the National Center for Transgender Equality.3 This 70-item survey was distributed in cooperation with over 900 organizations across the United States and also was announced through listservs and online communities. It was made available both online and on paper in English and Spanish. The survey was fielded over six months beginning in fall 2008 and resulted in 6,546 valid responses, which is the largest sample of transgender people in the US to date.4 Respondents answered questions about a broad array of topics, including whether they had served in the US armed forces in the following question:

¹ Kerrigan, M.F. 2012. Transgender discrimination in the military: The new Don't Ask Don't Tell. *Psychology, Public Policy, and Law* 18(3): 500–518.; Harrison-Quintana, J. and Herman, J.L. 2013. Still Serving in Silence: Transgender Service Members and Veterans in the National Transgender Discrimination Survey. *LGBTQ Policy Journal at the Harvard Kennedy School*, Volume 3, 2012-2013.

² Witten, T. M. 2007. Gender identity and the military—Transgender, transsexual, and intersex-identified individuals in the U.S. Armed Forces. Santa Barbara, CA: Palm Center.; Harrison-Quintana and Herman, see note #1.

³ The NTDS defined "transgender" broadly to include those whose gender identity or expression differs from those traditionally associated with their assigned sex at birth. This includes, but is not limited to, those who self-identify as transgender, transsexual, genderqueer, gender non-conforming, and cross-dressers.

⁴ Grant, J.M. et al. 2011. *Injustice at every turn: A report of the National Transgender Discrimination Survey*. Washington, DC: National Gay and Lesbian Task Force and National Center for Transgender Equality.

Have you ever been a member of the armed forces?

☐ Yes
☐ No

☐ I was denied entry because I am transgender/gender non-conforming

As a purposive sample of transgender adults in the US, estimates derived directly from the NTDS could be biased if the true demographic characteristics of the transgender population differ from the characteristics of transgender respondents to the survey. For example, relative to the US population, NTDS respondents are younger and report higher levels of education. Both factors would be associated with lower levels of lifetime military service. Given the lack of demographic data on the transgender population derived from population-based sources, it is not possible to determine if the age and educational attainment levels of NTDS respondents are different from the general US population because younger and more educated transgender individuals were more likely than others to have completed the survey (known as selection bias) or if transgender individuals are, in fact, younger and more likely to have higher levels of education compared to the general population.5

More than 93% of NTDS respondents provided information using an online web-based survey. Samples from online surveys are often biased toward more educated respondents. Reisner and colleagues (2014) found that NTDS respondents who used paper survey forms tended to report lower income and educational levels.⁶ It is possible that the web-based approach of the NTDS contributed to selection bias toward higher education, which would result in a bias toward lower military service.

To address these possible biases, the estimates of military service among the transgender population in these analyses adjust the characteristics of NTDS

⁵ Several studies have found higher levels of education among transgender individuals. These include: Xavier, J., Hannold, J.A., and Bradford, J. 2007. The Health, Health-related Needs, and Lifecourse Experiences of Transgender Virginians. Richmond, VA: Virginia HIV Community Planning Committee and Virginia Department of Health; Hartzell, E., Frazer, M. S., Wertz, K. and Davis, M. 2009. The State of Transgender California: Results from the 2008 California Transgender Economic Health Survey. San Francisco, CA: Transgender Law Center; Jenness, V., Sexton, L., Sumner, J. 2011. Transgender Inmates in California's Prisons: An Empirical Study of a Vulnerable Population. Report submitted to the California Department of Corrections and Rehabilitation, State of California. Sacramento, California. ⁶ Reisner, S.L., Conron, K., Scout, Mimiaga, M.J., Haneuse, S., Austin, S.B. 2014. Comparing In-Person and Online Survey Respondents in the U.S. National Transgender Discrimination Survey: Implications for Transgender Health Research . LGBT Health 1(2): 98-106.

respondents such that they have the age and educational attainment patterns of the US population. Military service rates also differ by race and ethnicity. Unfortunately, the race and ethnicity categories used in the NTDS are not consistent with those used in Census Bureau surveys. Educational attainment, like race and ethnicity, captures some of the variation in socio-economic status which may contribute to differences in military service rates.

This adjustment effectively assumes that being transgender is not associated with age or educational attainment. It also leads to estimates of military service rates for the transgender population that are slightly higher than the unadjusted calculations from the NTDS, which includes younger and more educated individuals who are less likely to report military service than older or less educated individuals. Alternatively, if the NTDS age and educational patterns are actually reflective of the transgender population in the US, then the adjustment procedure would produce estimates of transgender military service that may be higher than true military service rates among transgender individuals.

Population age and educational attainment data are derived from analyses of the US Census Bureau's 2011 American Community Survey.

The estimation procedure also assumes that NTDS respondents who report that they were assigned male at birth share the age and educational attainment patterns of the adult male population in the US while NTDS respondents that were assigned female at birth share the patterns of the adult female population. We make this assumption and report differences based on the sex assigned at birth because it is likely that most transgender veterans and service members would have entered and served in the military according to their sex assigned at birth. Estimates for the total number of transgender individuals who are currently or have ever served in the military are derived separately for those assigned male at birth (approximately 60% of the total NTDS sample) and those assigned female at birth (approximately 40% of the total NTDS sample).

Men are substantially more likely than women to serve in the US military. The estimates of transgender military service assume that, consistent with findings from the NTDS, approximately 60% of the transgender population was assigned male at birth while 40% was assigned female at birth. If, in fact, the transgender population is comprised of a larger portion of individuals assigned male at birth, then the estimation procedure likely understates

transgender military service. Conversely, if those assigned female at birth are actually a larger proportion of the transgender population, then the estimation procedure may overstate transgender military service.

The estimation begins by calculating the percent of NTDS respondents who report military service by their age and educational attainment status. Respondents are separated into five age categories and five educational attainment categories as follows:

- Age (a)
 - 0 18-24
 - 0 25-44
 - 0 45-54
 - 55-6465 and older
- Education (e)
 - Less than high school
 - o High school diploma
 - Some college
 - o College degree
 - Graduate degree

The percent of NTDS respondents who report service in the armed forces is calculated for those in each age/education category (mil_{ae}). Data from the 2011 American Community Survey Public Use Microdata Sample (ACS PUMS) are used to calculate the percent of adults age 18 and older who are within each age and education category (p_{ae}).

The adjusted estimate for transgender military service MIL_{adj} determines what the military service patterns of NTDS respondents (separated by sex assigned at birth) would be if they had the same age and educational attainment levels of the male and female population in the US by calculating a weighted average as follows:

$$\text{MIL}_{adj} = \sum_{e}^{a,e} (\text{mil}_{ae} \times \text{p}_{ae})$$

In the US, approximately 5.8% of all adults who have ever served in the armed forces are currently on active duty and 4.4% are now serving in the Guard or Reserve. An estimated 86.8% are veterans who served on active duty in the past and 3.0% are retired from Guard or Reserve service.⁷ The number

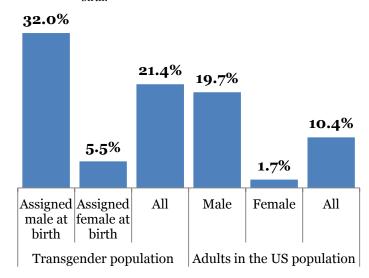
of transgender adults in each category is estimated by applying these same proportions to the estimated number of transgender individuals who report any service in the armed forces.

Transgender military service

Analyses of the unadjusted NTDS data show that 29.6% of respondents assigned male at birth reported that they have served in the armed forces along with 6.0% of those assigned female at birth. In total, 20% of NTDS respondents reported some type of military service.

Assuming NTDS reported rates of military service are true of the transgender population in the US, Figure 2 shows adjusted estimates of military service for the transgender population (separated by sex assigned at birth) and for adult men and women in the US. When figures are adjusted such that the age and educational patterns of the US adult male and female population are applied to the NTDS sample, an estimated 21.4% of transgender individuals have served in the military. The adjusted estimates suggest that 32.0% of those assigned male at birth and 5.5% of those assigned female at birth have served.

Figure 2. Adjusted estimates of service in the armed forces among transgender individuals and estimates of service by adults in the US, by sex or sex assigned at birth



By comparison, approximately 10.7% of adults in the US have served. This implies that transgender

Factfinder, Table B21002, show that an estimated 21.5 million Americans are civilian veterans. It should be noted that estimates of the number of veterans and reservists may not be mutually exclusive as some reservists may be veterans with prior service on active duty in the military.

⁷ The US Census Bureau's 2012 Statistical Abstract, Table 511 reports that 1,481,000 individuals are on active duty in the US military. Table 513 indicates that approximately 1.1 million individuals are serving in the Ready, Standby, and Retired Reserve forces. Findings from the 2011 American Community Survey, as reported on the US Census Bureau's American

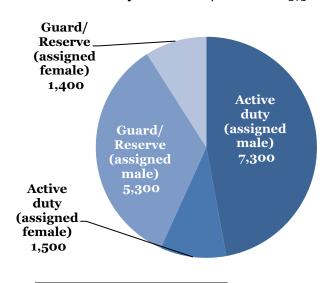
individuals are about twice as likely as adults in the US to have served their country in the armed forces. Transgender individuals assigned female at birth are nearly three times more likely than all adult women and those assigned male at birth are 1.6 times more likely than all adult men to serve.

Gates (2011) estimates that approximately 700,000 adults in the US are transgender.⁸ If, like in the NTDS, this group is 60% male assigned at birth and 40% female assigned at birth, then the estimates above imply that there are approximately 150,000 transgender adults in the US who are now serving or who have served in the armed forces.

In the US, 5.4% of men who report any military service are on active duty along with 9.8% of women. Applying these figures to the estimates of transgender military service would imply that approximately 8,800 transgender individuals are currently on active duty, of whom nearly 7,300 are assigned male at birth and about 1,500 are assigned female at birth. The estimates also suggest that 6,700 transgender individuals are serving in the Guard or Reserve forces, of whom 5,300 are assigned male at birth and 1,400 are assigned female at birth (see Figure 3).

Figure 3. Estimates of active duty and Guard/Reserve service among transgender adults, by type of service and sex assigned at birth.

Active Duty and Guard/Reserve: 15,500

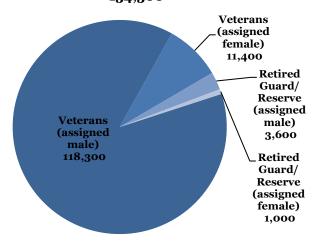


⁸ Estimates of the size of the transgender population from national population-based surveys do not exist. This estimate is based on two state-level population-based surveys in which questions regarding transgender status implied a gender transition or at least discordance between sex at birth and current gender presentation.

The estimates also suggest that there are more than 134,000 transgender individuals in the US who are veterans or have retired from Guard or Reserve service (see Figure 4).

Figure 4. Estimates of veterans and retired Guard/Reserve service among transgender adults, by type of service and sex assigned at birth.

Veterans and Retired Guard/Reserve: 134,300



These estimates imply that approximately 0.6% of adults who report service in the armed forces are transgender.

Discussion

Data that allow for a direct tabulation of the number of transgender individuals who serve in the US military simply do not exist. The estimates in this research brief rely on a variety of assumptions that could affect their accuracy.

Men are more likely to serve in the military than are women. If individuals assigned male at birth are, in fact, more than 60% of the transgender population, then transgender military service is likely understated in these estimates. Conversely, if those assigned female at birth represent more than 40% of the transgender population, then estimates of transgender military service are likely overstated.

The estimates also assume that the transgender population shares the age and educational attainment characteristics of the US population. If the true transgender population is younger and more educated than the US population (consistent with the NTDS sample), then the estimates could be overstating transgender military service.

Despite these possible biases, the estimates certainly suggest that transgender individuals are part of the

US armed forces, perhaps in portions that exceed that of the general population.

There is other evidence that transgender individuals represent a larger portion of those in the military than their proportion among adults in the US population. In a survey of transgender people assigned male at birth, Shipherd et al. found that 30 percent had served in the military, which is similar to military service among transgender people assigned male at birth in the NTDS.9 A recent study by Blosnich et al. reviewed all health records of veterans receiving health care through the Veterans Health Administration (VHA) from 2000 through 2011 and found a prevalence of Gender Identity Disorder (GID) five times that of the US general population.10 Though individuals with GID diagnoses may or may not identify as transgender, the substantially higher prevalence of GID among veterans in the VHA system provides further evidence that transgender people are overrepresented in the US military.

About the authors

Gary J. Gates, PhD is the Williams Distinguished Scholar and a national expert in the demographic, geographic, and economic characteristics of the LGBT population.

Jody L. Herman, PhD, is the Peter J. Cooper Public Policy Fellow and Manager of Transgender Research at the Williams Institute, UCLA School of Law.

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9 Shipherd, J.C., Mizock, L., Maguen, S., and Green, K.E. 2012.
 Male-to-female transgender veterans and VA health care utilization. *International Journal of Sexual Health* 24(1): 78–87.
 10 Blosnich, J.R., Brown, G.R., Shipherd, J.C., Kauth, M. PhD, Piegari, R.I., and Bossarte, R.M. 2013. Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care. *American Journal of Public Health* 103(10): e27-e32. "Gender Identity Disorder" was removed for the *DSM-V*, which now includes "gender dysphoria."

About the Institute

The Williams Institute on Sexual Orientation and Gender Identity Law and Public Policy at UCLA School of Law advances law and public policy through rigorous, independent research and scholarship, and disseminates its work through a variety of education programs and media to judges, legislators, lawyers, other policymakers and the public.

For more information

The Williams Institute, UCLA School of Law Box 951476 Los Angeles, CA 90095-1476 (310)267-4382 williamsinstitute@law.ucla.edu www.law.ucla.edu/williamsinstitute

Citation

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Demographics, Insurance Coverage, and Access to Care Among Transgender Adults

Wyatt Koma, Matthew Rae (https://www.kff.org/person/matthew-rae/), Amrutha

Ramaswamy, Tricia Neuman (https://www.kff.org/person/tricia-neuman/),

Jennifer Kates (https://www.kff.org/person/jennifer-kates/), and

Lindsey Dawson (https://www.kff.org/person/lindsey-dawson/)

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On June 12th, the Trump Administration released a final regulation implementing Section 1557 of the Affordable Care Act, and revising an Obama era rule (https://www.kff.org/racial-equity-and-health-policy/issue-brief/the-trump-administrations-final-rule-on-section-1557-non-discrimination-regulations-under-the-aca-and-current-status/). In it, the administration removed explicit nondiscrimination protections based on gender identity and sexual orientation in health care. In light of a recent Supreme Court decision (https://www.supremecourt.gov/opinions/19pdf/17-1618 hfci.pdf), and based on other legal grounds, five lawsuits are currently challenging the Trump Administration rule and blocking its implementation. If the explicit protections provided under the Obama era rule are lifted, it could be easier for health care providers to refuse to see individuals who are transgender or who do not conform to traditional sex norms. Explicit protections on the basis of sexual orientation and gender identity could have significant and lasting implications for LGBTQ people, including the estimated 1.4 million (https://williamsinstitute.law.ucla.edu/publications/transadults-united-states/) transgender adults living in the US.

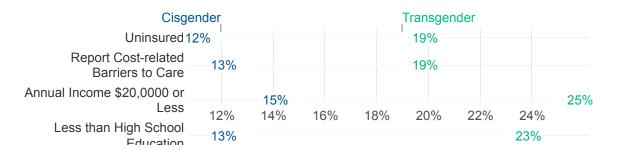
This analysis seeks to better understand the experiences of transgender people in the US health care system. We examine the demographic characteristics of transgender adults ages 18 and over and their access to health care. We analyzed pooled, cross-sectional data from a subset of the 2017 and 2018 Behavioral Risk Factor Surveillance System (BRFSS). We consider adults to be transgender based on their response to survey questions and define all other adults to be cisgender.

Key Takeaway

Our analysis finds that transgender adults are more likely to be uninsured (19% vs. 12%) and report cost-related barriers to care (19% vs. 13%) than cisgender adults. Transgender adults are also more likely to be non-Hispanic Black and low income than cisgender adults (**Figure 1** (https://www.datawrapper.de/ /kUtV4/)).

Figure 1. A Larger Share of Transgender Adults are Uninsured and Report Barriers to Care due to Cost than Cisgender Adults. *Transgender Adults are also More Likely to be non-Hispanic Black and Low Income*.



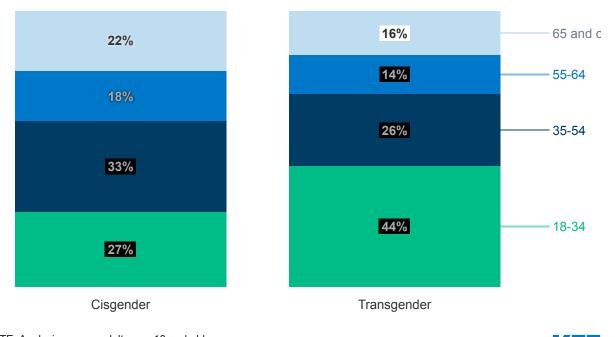


Findings

DEMOGRAPHICS

• **Age**. A much larger share of transgender adults are under age 35 (44%) than cisgender adults (27%) with one in four (25%) transgender adults under age 25 (data not shown). At the other end of the age spectrum, 16% of transgender adults are 65 years old or older, compared to 22% of cisgender adults (**Figure 2** (http://www.datawrapper.de/ /kWLxX/)).

Figure 2. A Much Larger Share of Transgender Adults are Under the Age of 35, Compared to Cisgender Adults



- NOTE: Analysis among adults and 18 and older
- **Education**. Transgender adults report fewer years of education compared to cisgender adults, holding age constant (analysis not shown). Nearly one quarter of all transgender adults (23%) have less than a high school education compared to 13% of their cisgender peers. A smaller share of transgender than cisgender adults graduated from college or technical school (15% vs. 27%, respectively).
- Race/Ethnicity. While a majority of transgender and cisgender adults are white, a larger share of transgender than cisgender adults are Black (16% vs. 12%, respectively).
- **Annual Household Income**. A larger share of transgender than cisgender adults live on lower incomes: 25% of transgender adults report an annual household income under \$20,000 compared to 15% of cisgender adults, based on income reported for 2017-2018 (**Figure 3** (http://www.datawrapper.de/ /Zgypg/)). Transgender adults are more likely to report an annual income under \$20,000 holding age constant (analysis not shown).

Figure 3. A Larger Share of Transgender Adults Report Lower Household Incomes compared to Cisgender Adults

Cisgender	Transgender
Under	15%
\$20,0000	25%
\$20,000-\$35,00	19%
\$35,000 to	11%
\$50,000	6%
\$50,000 to	13%
\$75,000	9%
\$75,000 or	29%
more	22%

• **Employment Status**. Among adults still in the labor force, a higher share of cisgender adults report being employed compared to transgender adults (56% vs. 48%, respectively). Nearly one in ten (9%) of transgender adults report they were unemployed from 2017-2018, a share much higher than that of cisgender adults (5%).

HEALTH STATUS, INSURANCE COVERAGE, AND ACCESS TO CARE

- Health Status. Transgender adults are more likely than cisgender adults to report being in poor health (10% vs. 5%, respectively).
- **Lifetime Depression**. Transgender adults report lifetime depression at twice the rate of cisgender adults (38% vs. 19%, respectively) (**Figure 4** (http://www.datawrapper.de//uaxn0/).

Figure 4. Nearly Four in Ten Transgender Adults Report Lifetime Depression

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NOTE: Analysis among adults age 18 and older.
SOURCE: KFF analysis of 2017 and 2018 Behavioral Risk Factor Surveillance System.



- Health Insurance Coverage. A larger share of transgender than cisgender adults (19% vs. 12%, respectively) report that they were uninsured over the 2017-2018 period.
- Cost-Related Barriers to Care. Nearly one in five (19%) transgender adults report experiencing barriers to care due to cost, more than the share reported by cisgender adults (13%).
- **Personal Doctor.** A similar share of transgender (22%) and cisgender (21%) adults report that they do not have a personal doctor or health care provider.
- **Time Since Last Checkup.** A similar share of transgender and cisgender adults report having gone more than one year since their last checkup (25% vs. 24%, respectively).

Discussion

Our analysis finds that transgender people differ from cisgender adults in a number of ways that could impact their health care, as a backdrop for understanding the potential implications of lifting anti-discrimination protections. Transgender adults are younger, less educated, have lower incomes, are in poorer health, with higher rates of lifetime depression, and are less likely to be white, employed and have health insurance. Transgender adults are also more likely than cisgender adults to experience barriers to care due to cost. In other ways, barriers to care faced by transgender people are similar to those faced by cisgender people.

Past <u>research (https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/)</u> shows that younger adults report lower incomes, and that people of color are also more likely to be uninsured, which may explain some of the differences in demographic characteristics and insurance coverage. However, <u>it has also been suggested (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5723709/)</u>that demographic differences alone do not completely explain why transgender adults experience more difficulty in accessing care in certain circumstances than their cisgender peers do.

Our analysis suggests that transgender adults experience barriers to care even with the Section 1557 health care protections based on gender identity in place. Removing these protections may exacerbate already-existing access problems, which may lead to increased barriers to care among these adults, at a time when access to health care is critical.

This work was supported in part by the Elton John AIDS Foundation. We value our funders. KFF maintains full editorial control over all of its policy analysis, polling, and journalism activities.

Methods

This brief analyzes pooled, cross-sectional data from the 2017 and 2018 Behavioral Risk Factor Surveillance System (BRFSS). BRFSS is an ongoing, state-based, random-digit-dialed telephone survey of non-institutionalized civilian adults living in the community. The BRFSS core questionnaire does not include questions about sexual orientation or gender identity; however, both the 2017 and 2018 BRFSS offer an optional, unified module on sexual orientation and gender identity. In each survey wave, select states opted to add the sexual orientation and gender identity module to the survey (2017: 27 states and Guam

(https://www.cdc.gov/brfss/questionnaires/modules/category2017.htm); 2018: 28 states and Guam (https://www.cdc.gov/brfss/questionnaires/modules/category2018.htm)).

In the subset of states which administered the optional module, adults were asked if they considered themselves to be transgender. We defined adults as transgender if they considered themselves to be: 1) transgender female; 2) transgender male; or 3) transgender, gender non-conforming. Of adults who identify as transgender adults in this analysis, 23% (n=433) identified as gender non-conforming. We considered adults who did not identify as transgender to be cisgender. Our study population includes 1,872 transgender adults and 430,817 cisgender adults in the subset of states which opted to administer the module in 2017 and 2018. Our analysis excluded adults who responded that they did not know or were not sure (n=1,684) or adults who refused to answer (n=3,184).

We examined differences in demographics and access to care through questions administered in the core BRFSS questionnaire. Our estimates of transgender and cisgender adults use the BRFSS survey weights to account for the complex sampling design, and our analysis excludes missing values. Missing is included as a valid category for education (.3%), race/ethnicity (1.6%), employment status (.9%) and income (15.4%). We did not provide estimates of sex assigned at birth as <u>several</u>

(https://pubmed.ncbi.nlm.nih.gov/32084102/) studies

(https://pubmed.ncbi.nlm.nih.gov/31162292/) have shown that measurement of sex assigned at birth using BRFSS significantly misclassifies transgender adults. All reported differences in demographics and access to care between transgender and cisgender adults are statistically significant. Results from all statistical tests were reported with p< .05 considered statistically significant.

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Community Provider Toolkit

Veterans with Transgender and Gender Diverse Identities

Transgender and gender diverse people can have a variety of identities including people who don't identify as male or female, sometimes called non-binary gender identification or gender diverse. In 2014, there were an estimated 134,000 U.S. transgender Veterans, with over 15,000 transgender people serving in the U.S. military (active duty and reserves). ¹

Werview

gender expression.¹
to enter an environment with clear rules about
military to escape family rejection or violence, or
Additionally, some transgender people join the
direction, and a family history of service.
as non-transgender people – patriotism, life
motivated to join the military for similar reasons
transgender people. Transgender people are
to have served in the U.S. military than non-
Transgender people are at least 2-3x more likely

Recent research suggests that Veteran status Top contribute to resilience and positive mental heature outcomes among some transgender individuals. A recent study of 183 transgender and gender

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diverse older adults (43 Veterans, and 140 non-Veterans) found that prior military service was associated with lower depression symptomatology, as well as greater psychological health related quality of life.²

Unfortunately, social stigma and discrimination are a reality for <u>transgender Veterans</u> ^{3,4}. Indeed, discrimination has been shown to be associated with high rates of <u>suicidal thoughts</u> ^{5,6}, with suicide attempts being elevated among <u>transgender Veterans</u> ⁷ and death by suicide at an earlier age than other Veterans. ⁸ Other concerns for transgender Veterans include <u>trauma exposure</u> , including <u>military sexual assault</u> ¹⁰ and homelessness ^{11, 12}.

Transgender people were not allowed to openly serve in the U.S. military until June 30, 2016, nearly 5 years after the repeal of Don't Ask, Don't Tell (DADT) policy. In April 2019, new policy tied enlistees to the performance standards associated with their birth sex. However, in January 2021, the policy changed again, allowing transgender individuals to enlist and to serve openly in the military. For more information, see the Department of Defense transgender policy webpage. ¹³

Transgender Veterans have always been eligible for being treated at the VHA, for more information about what care is currently covered see <u>policy report documents</u> by the Department of Veterans Affairs (2013) and Kauth and Shipherd (2016).^{14,15}

In June 2021 the Secretary of the VA
 announced that a rule-change process was
 being initiated to expand current health care
 benefits to include surgical procedures. The
 rule change process will take time and
 includes a period of public comment. Until

Case: 24-108

the final rule is published, VHA will continue to provide all other transition-related care including but not limited to hormones, gender affirming counseling, prosthetics, vocal coaching, and infertility treatment.

- Current data suggests that there are nearly 10,000 transgender Veterans receiving transition-related care in the VA healthcare system. This figure is an underestimate given that not all transgender Veterans meet criteria for a formal diagnosis of Gender Dysphoria and also many choose not to disclose their gender identity to providers.¹⁶
- For more information about transgender Veterans, please explore the VA LGBTQ+

Close

Video



Research

JAMA Surgery | Original Investigation

Association Between Gender-Affirming Surgeries and Mental Health Outcomes

Anthony N. Almazan, BA; Alex S. Keuroghlian, MD, MPH

IMPORTANCE Requests for gender-affirming surgeries are rapidly increasing among transgender and gender diverse (TGD) people. However, there is limited evidence regarding the mental health benefits of these surgeries.

OBJECTIVE To evaluate associations between gender-affirming surgeries and mental health outcomes, including psychological distress, substance use, and suicide risk.

DESIGN, SETTING, AND PARTICIPANTS In this study, we performed a secondary analysis of data from the 2015 US Transgender Survey, the largest existing data set containing comprehensive information on the surgical and mental health experiences of TGD people. The survey was conducted across 50 states, Washington, DC, US territories, and US military bases abroad. A total of 27 715 TGD adults took the US Transgender Survey, which was disseminated by community-based outreach from August 19, 2015, to September 21, 2015. Data were analyzed between November 1, 2020, and January 3, 2021.

EXPOSURES The exposure group included respondents who endorsed undergoing 1 or more types of gender-affirming surgery at least 2 years prior to submitting survey responses. The comparison group included respondents who endorsed a desire for 1 or more types of gender-affirming surgery but denied undergoing any gender-affirming surgeries.

MAIN OUTCOMES AND MEASURES Endorsement of past-month severe psychological distress (score of ≥13 on Kessler Psychological Distress Scale), past-month binge alcohol use, past-year tobacco smoking, and past-year suicidal ideation or suicide attempt.

RESULTS Of the 27 715 respondents, 3559 (12.8%) endorsed undergoing 1 or more types of gender-affirming surgery at least 2 years prior to submitting survey responses, while 16 401 (59.2%) endorsed a desire to undergo 1 or more types of gender-affirming surgery but denied undergoing any of these. Of the respondents in this study sample, 16 182 (81.1%) were between the ages of 18 and 44 years, 16 386 (82.1%) identified as White, 7751 (38.8%) identified as transgender women, 6489 (32.5%) identified as transgender men, and 5300 (26.6%) identified as nonbinary. After adjustment for sociodemographic factors and exposure to other types of gender-affirming care, undergoing 1 or more types of gender-affirming surgery was associated with lower past-month psychological distress (adjusted odds ratio [aOR], 0.58; 95% CI, 0.50-0.67; *P* < .001), past-year smoking (aOR, 0.65; 95% CI, 0.57-0.75; *P* < .001), and past-year suicidal ideation (aOR, 0.56; 95% CI, 0.50-0.64; *P* < .001).

CONCLUSIONS AND RELEVANCE This study demonstrates an association between gender-affirming surgery and improved mental health outcomes. These results contribute new evidence to support the provision of gender-affirming surgical care for TGD people.

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Author Affiliations: Harvard Medical School, Boston, Massachusetts (Almazan, Keuroghlian); Harvard T. H. Chan School of Public Health, Boston, Massachusetts (Almazan); The Fenway Institute, Fenway Health, Boston, Massachusetts (Keuroghlian); Department of Psychiatry, Massachusetts General Hospital, Boston (Keuroghlian).

Corresponding Author: Anthony N. Almazan, BA, Harvard Medical School, 25 Shattuck St, Boston, MA 02215 (anthony_almazan@hms.harvard.edu).

ransgender and gender diverse (TGD) people experience a disproportionate burden of mental health problems compared with the general population. ^{1,2} Prior studies of mental health among TGD people have demonstrated a 41% lifetime prevalence of suicide attempts, ² 7% to 61% lifetime prevalence of binge drinking, ³ and a 33% prevalence of tobacco use. ⁴ Increased adverse mental health outcomes among TGD people are likely attributable to stigma, discrimination, pathologization, economic marginalization, violence, and dysphoria associated with an incongruence between gender identity and societal expectations based on one's sex assigned at birth. ⁵

According to Standards of Care published by the World Professional Association for Transgender Health, genderaffirming surgery is a medically necessary treatment to alleviate psychological distress for many TGD people. The term gender-affirming surgery refers to any surgical procedures offered to affirm the gender identities of TGD people. The process of surgical gender affirmation is individually tailored because not all TGD people desire or access these procedures. In the largest survey of the TGD community to our knowledge to date, 25% of respondents reported undergoing some type of gender-affirming surgery.

As a result of professional recommendations, insurance nondiscrimination laws, and expansion of dedicated transgender health practices, demand for gender-affirming surgery is steadily rising. In the United States, incidence of gender-affirming surgeries has increased annually since 2000. Despite growing demand for and access to gender-affirming surgery, there is a paucity of high-quality evidence regarding its effects on mental health outcomes among TGD people.

Existing evidence on the association between genderaffirming surgeries and mental health outcomes is largely derived from small-sample, cross-sectional, and uncontrolled studies. 1,11,12 A seminal 1998 review of the experiences of more than 2000 TGD people from 79 predominantly uncontrolled follow-up studies demonstrated qualitative improvement in psychosocial outcomes following gender-affirming surgery. 11 Attempts since then to empirically demonstrate mental health benefits from gender-affirming surgery have generated mixed results. A meta-analysis of 1833 TGD people across 28 studies concluded that studies offered "low-quality evidence" for positive mental health benefits from surgical gender affirmation.¹² The largest existing study on this subject to our knowledge,¹³ a total population study including 2679 people diagnosed as having gender incongruence in Sweden, demonstrated a longitudinal association between gender-affirming surgery and reduced mental health treatment utilization. ¹³ However, a 2020 published correction of this study¹⁴ demonstrated no mental health benefit from gender-affirming surgery after comparison with a control group of TGD people who had not yet undergone surgery. Mental health effects of gender-affirming surgery thus remain controversial.

Given the increasing incidence of surgical gender affirmation among TGD people, there is a significant need for clarification of the mental health benefits of gender-affirming surgery. In this article, we present the largest study to our knowledge to date on the association between gender-

Key Points

Question Are gender-affirming surgeries associated with better mental health outcomes among transgender and gender diverse (TGD) people?

Findings In this secondary analysis of the 2015 US Transgender Survey (n = 27715), TGD people with a history of gender-affirming surgery had significantly lower odds of past-month psychological distress, past-year tobacco smoking, and past-year suicidal ideation compared with TGD people with no history of gender-affirming surgery.

Meaning These findings support the provision of gender-affirming surgeries for TGD people who seek them.

affirming surgeries and mental health outcomes. Using the 2015 US Transgender Survey, the largest existing data set on surgical and mental health experiences of TGD people, we investigate the hypothesis that gender-affirming surgeries are associated with improved mental health outcomes, including psychological distress, substance use, and suicidality.

Methods

Study Design

In this study, we performed a secondary analysis of the 2015 US Transgender Survey (USTS).⁸ This investigation is reported using Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

Study Population and Data Source

The 2015 USTS was a cross-sectional, nonprobability sample of responses from 27715 TGD adults from 50 US states, Washington, DC, US territories, and US military bases abroad. The survey was developed by researchers, advocates, people with lived experience, and subject experts over the course of a year. The final survey contained 324 possible questions with 32 domains addressing subjects including health and health care access. It was disseminated by community-based outreach and administered online from August 19, 2015, to September 21, 2015. The USTS protocol was approved by the University of California, Los Angeles institutional review board. The protocol for the present study was reviewed by the Fenway Institute institutional review board and did not meet criteria for human subjects research. For this reason, consent was not obtained.

Outcomes

Five binary mental health outcomes were examined, including endorsement or denial of the following: (1) past-month severe psychological distress (score on the Kessler Psychological Distress Scale meeting the previously validated threshold of \geq 13), ¹⁵ (2) past-month binge alcohol use (\geq 5 alcoholic drinks on one occasion), (3) past-year tobacco smoking, (4) past-year suicidal ideation, and (5) past-year suicide attempt.

Exposure Group

The exposure group included respondents who endorsed a history of gender-affirming surgery, defined as undergoing 1 or

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more types of gender-affirming surgery at least 2 years prior to submitting responses to the USTS. Respondents were asked about their experiences with gender-affirming surgeries through the question, "Have you had or do you want any of the health care listed below for gender transition?" Respondents were presented with 1 of 2 lists of gender-affirming surgeries based on their self-reported sex assigned at birth. For each surgery, respondents were able to indicate one of the following answers: "Have had it," "Want it some day," "Not sure if I want this," or "Do not want this." Respondents were included in the exposure group if they answered "Have had it" to 1 or more of the following types of gender-affirming procedures: breast augmentation, orchiectomy, vaginoplasty/ labiaplasty, trachea shave, facial feminization surgery, or voice surgery. Respondents were also included in the exposure group if they answered "Have had it" to one or more of the following types of gender-affirming procedures: chest surgery, hysterectomy, clitoral release/metoidioplasty/centurion procedure, or phalloplasty.

In this study, outcomes of interest included mental health symptoms in the year prior to taking the USTS. To ensure that exposure to gender-affirming surgeries temporally preceded all outcomes of interest, respondents were included in the exposure group if they had received their first gender-affirming surgery at least 2 years prior to submitting responses to the USTS. For each respondent with a history of gender-affirming surgery, the number of years since their first surgery was calculated by subtracting age at first surgery from current age.

Control Group

The control group included respondents who desired genderaffirming surgeries but had not yet received any. Respondents were included in this group if they answered "Want it some day" for at least 1 of the aforementioned genderaffirming procedures but did not answer "Have had it" for any of them. We excluded participants who did not report desire for any gender-affirming surgeries.

Covariates

The following sociodemographic covariates were examined: age (18-44 years, 45-64 years, and ≥65 years), education level (less than high school or high school graduate up to associate degree, bachelor degree, or higher), employment status (employed, unemployed, or out of labor force), gender identity (transgender woman, transgender man, nonbinary, or cross-dresser), health insurance status (uninsured or insured), household income (<\$25 000, \$25 000-\$99 999, or ≥\$100 000), race (Alaska Native/American Indian, Asian/Pacific Islander, Black/African American, Latinx/Hispanic, other/biracial/multiracial, or White), sex assigned at birth (female or male), and sexual orientation (asexual, lesbian/gay/bisexual, or heterosexual).

Family rejection was included as a covariate and was defined by the USTS as history of any of the following experiences with a family member owing to the respondent's gender identity: ending the relationship, physical violence, being forced out of their home, being prevented from wearing desired gender-concordant clothing, and exposure to gender identity conversion efforts. Lifetime exposures to other types of

gender-affirming care were also examined, including gender-affirming counseling, pubertal suppression, and hormone therapy. Given the possibility that any of these covariates could confound the relationship between gender-affirming surgeries and mental health outcomes, all covariates were included in the final multivariable models.

Statistical Analysis

All analyses were conducted using Stata, version 16.1 (StataCorp). Unweighted descriptive statistics for exposure and control groups were calculated and are presented as frequencies and percentages.

Multivariable logistic regression models adjusted for all covariates were generated to examine whether undergoing gender-affirming surgery is associated with each of the examined mental health outcomes. ^{16,17} To account for the survey's nonprobability sampling, all models incorporated survey weights to correct sampling biases related to age and race/ethnicity. Adjusted odds ratios (aORs), 95% CIs, and 2-sided *P* values are reported.

We performed a post hoc analysis to determine whether associations between gender-affirming surgeries and mental health outcomes differ based on the degree of surgical affirmation. The exposure variable was recoded as 3 categories: those who received all desired surgeries, some desired surgeries, and no desired surgeries. Because the USTS did not collect information on timing of each respondent's last surgery, respondents for this post hoc analysis could not be excluded to ensure that all exposures temporally preceded mental health outcomes. The recoded 3-category exposure variable was substituted into 5 additional multivariable logistic regression models, adjusted for all aforementioned covariates.

Owing to concerns that baseline mental health status may confound associations between gender-affirming surgery and mental health outcomes, we conducted an additional post hoc analysis to determine whether lifetime mental health measures were associated with exposure to gender-affirming surgeries. We did not incorporate these measures into the primary models due to collinearity. Four separate post hoc models, adjusted for all aforementioned covariates, regressed exposure to gender-affirming surgeries against lifetime suicidal ideation, lifetime suicide attempts, lifetime alcohol use, and lifetime smoking.

To account for multiple hypothesis testing, a Bonferroni correction was applied to adjust for 19 total tests. A *P* value of less than .002 was used as the corrected threshold for statistical significance.

Less than 2% of the study sample had missing data for exposure and outcome variables, and less than 9% of the study sample had missing data for any covariates. Given that these are acceptably low levels of missingness, ¹⁸ respondents with missing data were excluded without compensatory methods.

Results

Of the 27715 respondents, 3559 (12.8%) endorsed undergoing 1 or more types of gender-affirming surgery at least 2 years

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Table 1. Sample Sociodemographic					
	No. (%)	_			
Characteristic	No history of surgery (n = 16 401)	History of surgery (n = 3559)	Difference, % (95% CI)		
Age, y					
18-44	14 170 (86.4)	2012 (56.5)	29.9 (28.2 to 31.6)		
45-64	1922 (11.7)	1261 (35.4)	-23.7 (-25.4 to -22.1		
≥65	309 (1.9)	285 (8.0)	-6.1 (-7.0 to -5.2)		
Education					
Less than high school	682 (4.2)	37 (1.0)	3.1 (2.7 to 3.6)		
High school graduate up to associate degree	10 918 (66.6)	1243 (34.9)	31.6 (29.9 to 33.3)		
Bachelor degree or higher	4801 (29.3)	2279 (64.0)	-34.8 (-36.5 to -33.0		
Employment					
Employed	10 306 (62.8)	2585 (72.6)	-9.8 (-11.4 to -8.2)		
Unemployed	2474 (15.1)	202 (5.7)	9.4 (8.5 to 10.3)		
Out of labor force	3537 (21.6)	755 (21.2)	0.4 (-1.1 to 1.8)		
Family rejection					
Yes	7466 (45.5)	2328 (65.4)	-19.9 (-21.6 to -18.2		
No	7360 (44.9)	1173 (33.0)	11.9 (10.2 to 13.6)		
Gender identity					
Transgender woman	6277 (38.3)	1474 (41.4)	-3.1 (-4.9 to -1.4)		
Transgender man	4764 (29.1)	1725 (48.5)	-19.4 (-21.2 to -17.6		
Nonbinary	4958 (30.2)	342 (9.6)	20.6 (19.4 to 21.8)		
Cross-dresser	402 (2.5)	18 (0.5)	2.0 (1.6 to 2.3)		
Health insurance					
Uninsured	2397 (14.6)	304 (8.5)	6.1 (5.0 to 7.1)		
Insured	13 959 (85.1)	3253 (91.4)	-6.3 (-7.4 to -5.2)		
Household income					
<\$25 000	5960 (36.3)	768 (21.6)	14.7 (13.2 to 16.3)		
\$25 000-\$99 999	6829 (41.6)	1804 (50.7)	-9.1 (-10.9 to -7.2)		
≥\$100 000	2073 (12.6)	840 (23.6)	-11.0 (-12.4 to -9.5)		
Race/ethnicity					
Alaska Native/American Indian	206 (1.3)	39 (1.1)	0.2 (-0.2 to 0.5)		
Asian/Pacific Islander	436 (2.7)	64 (1.8)	0.9 (0.4 to 1.4)		
Black/African American	459 (2.8)	124 (3.5)	-0.7 (-1.3 to -0.03)		
Latinx/Hispanic	929 (5.7)	154 (4.3)	1.3 (0.6 to 2.1)		
Other/biracial/multiracial	963 (5.9)	200 (5.6)	0.3 (-0.6 to 1.1)		
White	13 408 (81.8)	2978 (83.7)	-1.9 (-3.3 to -0.6)		
Sex assigned at birth	· ·	• •	. ,		
Female	9032 (55.1)	2029 (57.0)	-1.9 (-3.7 to -0.1)		
Male	7369 (44.9)	1530 (43.0)	1.9 (0.1 to 3.7)		
Sexual orientation	,	/	,		
Asexual	2002 (12.2)	228 (6.4)	5.8 (4.9 to 6.7)		
Lesbian, gay, bisexual	11 433 (69.7)	2393 (67.2)	2.5 (0.8 to 4.2)		
Heterosexual	1729 (10.5)	782 (22.0)	-11.4 (-12.9 to -10.0		
Other gender-affirming care	1, 23 (10.3)	: 02 (22.0)	11 (12.5 to 10.0		
Counseling	9016 (55.0)	3099 (87.1)	-32.1 (-33.4 to -30.8		
Pubertal suppression	197 (1.2)	94 (2.6)	-1.4 (-2.0 to -0.9)		
Hormone therapy			-47.0 (-48.2 to -45.7		
полноне шегару	7104 (43.3)	3213 (90.3)	-47.0 (-40.2 t0 -45.7		

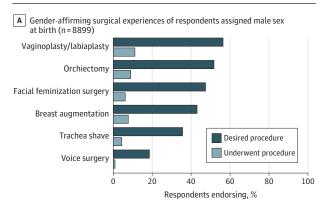
^a Column percentages may not add up to 100% because missing data are not displayed.

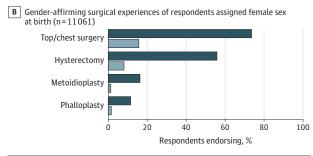
prior to submitting survey responses, while 16 401 respondents (59.2%) endorsed a desire to undergo 1 or more types of gender-affirming surgery but denied undergoing any of these.

Compared with the control group, the exposure group had higher percentages of respondents who were older, em-

ployed, more educated, endorsed family rejection, reported having health insurance, and reported higher household income. Respondents in the exposure group were more likely to endorse a history of gender-affirming counseling, pubertal suppression, and hormone therapy (Table 1).

Figure 1. Desire for and History of Gender-Affirming Surgical Procedures in Study Sample





Includes 2015 US Transgender Survey respondents who indicated they desired and either had or had not undergone at least 1 type of gender-affirming surgery. Respondents were presented with 1 of 2 lists of gender-affirming surgeries based on their self-reported sex assigned at birth.

For each surgical procedure, the percentage of people who desired it was higher than the percentage of people who endorsed undergoing it (Figure 1). For every adverse mental health outcome, the percentage of respondents who endorsed it was lower in the exposure group than in the control group (Figure 2).

After adjustment for sociodemographic factors and exposure to other types of gender-affirming care, undergoing 1 or more types of gender-affirming surgery was associated with lower past-month psychological distress (aOR, 0.58; 95% CI, 0.50-0.67; P < .001), past-year smoking (aOR, 0.65; 95% CI, 0.57-0.75; P < .001), and past-year suicidal ideation (aOR, 0.56; 95% CI, 0.50-0.64; P < .001). After Bonferroni correction, there was no statistically significant association between gender-affirming surgeries and past-month binge alcohol use or past-year suicide attempts (Table 2).

In the post hoc analysis stratifying by degree of surgical affirmation, $16\,401$ respondents were in the reference group who received no desired surgeries. Respondents who had undergone all desired surgeries (n = 2448) had significant reductions in the odds of each adverse mental health outcome, and these reductions were more profound than those among respondents who had received only some desired surgeries (n = 3311) (Table 3).

Measures of lifetime mental health were not associated with exposure to gender-affirming surgeries. After adjustment for all aforementioned covariates, undergoing gender-

Figure 2. Comparison of Mental Health Outcomes Among Respondents Who Did and Did Not Undergo Gender-Affirming Surgery

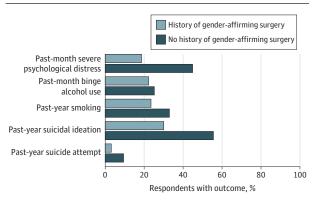


Table 2. Association Between History of Gender-Affirming Surgery and Mental Health Outcomes^a

Variable	aOR (95% CI) ^b	P value
Severe psychological distress (past month) ^c	0.58 (0.50-0.67)	<.001
Substance use		
Binge alcohol use (past month) ^d	0.83 (0.72-0.96)	.01
Smoking (past year)	0.65 (0.57-0.75)	<.001
Suicidality (past year)		
Ideation	0.56 (0.50-0.64)	<.001
Attempt	0.65 (0.47-0.90)	.009

Abbreviation: aOR, adjusted odds ratio.

- ^a Adjusted for age, education, employment status, family rejection, gender identity, health insurance, household income, race/ethnicity, sex assigned at birth, sexual orientation, history of gender-affirming counseling, pubertal suppression, and history of gender-affirming hormone therapy.
- ^b Reference/control group (n = 16 401) is composed of individuals who desired at least 1 type of gender-affirming surgery but had not received any surgeries. Exposure group (n = 3559) is limited to respondents who had their first surgery at least 2 years prior to submitting survey responses.
- ^c Defined as a score of at least 13 on the Kessler Psychological Distress Scale.
- ^d Defined as consuming at least 5 alcoholic drinks on the same occasion.

affirming surgery was not associated with lifetime suicidal ideation (aOR, 1.00; 95% CI, 0.85-1.20; P = .92), lifetime suicide attempts (aOR, 1.16; 95% CI, 1.01-1.34; P = .04), lifetime alcohol use (aOR, 1.00; 95% CI, 0.99-1.01; P = .96), or lifetime smoking (aOR, 1.00; 95% CI, 1.00-1.01; P = .34).

Discussion

To our knowledge, this is the first large-scale, controlled study to demonstrate an association between gender-affirming surgery and improved mental health outcomes. In this study, we demonstrate that undergoing gender-affirming surgery is associated with decreased odds of past-month severe psychological distress, past-year smoking, and past-year suicidal ideation. The post hoc analysis stratifying by degree of surgical affirmation demonstrates that TGD people who underwent all desired surgeries had significantly lower odds of all adverse mental health outcomes, and these benefits were stronger than

Table 3. Association Between Degree of Surgical Gender Affirmation and Mental Health Outcomes^a

	Received some desire (n = 3311) ^b	Received all desired s (n = 2448) ^b	Received all desired surgeries (n = 2448) ^b	
Variable	aOR (95% CI)	P value	aOR (95% CI)	P value
Severe psychological distress (past month) ^c	0.70 (0.60-0.81)	<.001	0.47 (0.39-0.56)	<.001
Substance use				
Binge alcohol use (past month) ^d	0.97 (0.84-1.11)	.63	0.75 (0.64-0.87)	<.001
Smoking (past year)	0.75 (0.66-0.86)	<.001	0.58 (0.49-0.68)	<.001
Suicidality (past year)				
Ideation	0.72 (0.63-0.81)	<.001	0.44 (0.38-0.51)	<.001
Attempt	0.70 (0.53-0.93)	.01	0.44 (0.28-0.70)	<.001

Abbreviation: aOR, adjusted odds ratio.

among TGD people who only received some desired surgeries.

The observed associations between gender-affirming surgery, psychological distress, and suicide risk reinforce previous small-sample studies suggesting that gender-affirming surgery improves mental health and quality of life among TGD people. 1,12 Our findings also reflect evidence from qualitative studies indicating perceived mental health benefits of genderaffirming surgeries among TGD people. 19-21 In our primary analysis, although gender-affirming surgery was associated with lower odds of past-year suicidal ideation, there was no statistically significant association between genderaffirming surgeries and past-year suicide attempts. However, in a post hoc analysis respondents who underwent all desired gender-affirming surgeries had significantly lower odds of past-year suicide attempts.

The association observed between gender-affirming surgeries and reduction in substance use behaviors is consistent with previous studies involving small community samples that demonstrated associations between gender-affirming medical care and lower odds of high-risk substance use. ^{22,23} In the primary analysis, undergoing gender-affirming surgery was not significantly associated with past-month binge alcohol use. This may be consistent with evidence that after adjustment for sociodemographic factors, gender minority identity itself does not predict high-risk alcohol use. ²⁴ However, in a post hoc analysis, respondents who underwent all desired gender-affirming surgeries had significantly lower odds of pastmonth binge alcohol use.

This investigation offers evidence to support the clinical practice of gender-affirming surgery. Guidelines for provision of gender-affirming medical and surgical care have historically been challenged based on a limited evidence base. The American Psychiatric Association has previously concluded that the quality of evidence for treatment of gender dysphoria is low, and consequently, recommendations regarding gender-affirming care have been driven by clinical consensus where empirical evidence is lacking. This study offers new data that substantiate the current clinical consensus by expanding the evidence base in support of gender-affirming surgical care.

The observed mental health benefits of gender-affirming surgeries in this study highlight the importance of policies that facilitate access to surgical gender affirmation. In the present study, the percentages of people who had undergone each gender-affirming surgical procedure were substantially lower than the percentages of people who desired them, suggesting significant barriers to accessing gender-affirming surgeries. Statelevel prohibitions against insurance exclusions for genderaffirming care have been associated with more extensive coverage of gender-affirming surgical procedures. 26 In light of this study's results, such policies may be of even greater public health interest. US federal policies related to genderaffirming care have included a recent reversal of Affordable Care Act insurance protections for gender affirmation and the continued prohibition of Veterans Affairs funding allocation for gender-affirming surgeries. 27,28 Formulation of evidencebased policies for the financing of gender-affirming surgery will be crucial for advancing the health and well-being of TGD communities.

Strengths and Limitations

This study's strengths include aspects of its design that address prior limitations in the existing literature on this subject. Multiple meta-analyses of studies examining the association between gender-affirming surgeries and mental health outcomes have demonstrated that much of the existing literature consists of evidence derived with small sample sizes, lack of control groups, and lack of adjustment for other kinds of gender-affirming care. ^{12,29} Our study is responsive to these methodologic concerns.

First, we used the largest existing data set containing information on the surgical and mental health experiences of TGD people. Second, this is, to our knowledge, the first large-scale study on this subject to use the ideal control group to examine associations between gender-affirming surgeries and mental health outcomes: individuals who desire gender-affirming surgery but have not yet received it. Experts have cautioned against using comparison groups that conflate TGD people who did not undergo gender-affirming surgery because they were waiting for it with TGD people not seeking it in the first place. Inability to differentiate these 2 groups likely

^a Adjusted for age, education, employment status, family rejection, gender identity, health insurance, household income, race/ethnicity, sex assigned at birth, sexual orientation, history of gender-affirming counseling, pubertal suppression, and history of gender-affirming hormone therapy.

^b Reference group is individuals who received none of their desired surgeries (n = 16 401).

^c Defined as a score of at least 13 on the Kessler Psychological Distress Scale.

^d Defined as consuming at least 5 alcoholic drinks on the same occasion.

Original Investigation Research

contributed to the lack of significant mental health benefit observed in the 2019 large-scale study on this subject. ^{13,30}

Third, although this survey-based investigation uses a cross-sectional study design, we constructed an exposure group that includes only individuals exposed to their first gender-affirming surgery prior to the window of assessment for any adverse mental health outcomes. Thus, we ensured that our exposure temporally preceded our outcomes, allowing us to better understand the direction of observed associations. These exclusions could not be performed in our post hoc analysis stratifying by degree of surgical affirmation, and that analysis should therefore be interpreted with caution.

Fourth, our data set allowed us to control for previous experiences of gender-affirming counseling, pubertal suppression, and hormone therapy. Consequently, this study is, to our knowledge, the first large-scale investigation to ascertain the mental health benefits of gender-affirming surgeries independent of other common forms of gender-affirming health care.

Our study has several limitations. The nonprobability sampling of the USTS may limit generalizability. All measures are self-reported and may be subject to response bias. Furthermore, the USTS only offers data on experiences with 10 specific types of gender-affirming surgeries and does not capture the full range of procedures that constitute gender-affirming surgery. Lastly, because this is an observational study, it may be subject to unmeasured confounding. Much of the literature on mental health benefits of gender-affirming surgery has been complicated by inability to adjust for a key con-

founder: baseline mental health status. Our post hoc analysis demonstrates that lifetime suicidality and substance use behaviors are not associated with the exposure variable in this sample. Therefore, prior mental health factors do not appear to confound associations between gender-affirming surgery and subsequent mental health outcomes in our study. There may nevertheless be other types of mental health problems not captured in the USTS that confound these associations. These limitations highlight the need for larger probability-based surveys with TGD communities, more consistent gender identity data collection across health care systems, and more comprehensive baseline health data collection with TGD populations.

Conclusions

In this article, we present the largest study to our knowledge to date on associations between gender-affirming surgeries and mental health outcomes. Our results demonstrate that undergoing gender-affirming surgery is associated with improved past-month severe psychological distress, past-year smoking, and past-year suicidal ideation. Our findings offer empirical evidence to support provision of gender-affirming surgical care for TGD people who seek it. Furthermore, this study provides evidence to support policies that expand and protect access to gender-affirming surgical care for TGD communities.

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Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: All authors.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Almazan.
Obtained funding: Keuroghlian.
Administrative, technical, or material support:
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Supervision: Keuroghlian.

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Invited Commentary -

Gender-Affirming Surgeries and Improved Psychosocial Health Outcomes

Andrew A. Marano, MD; Matthew R. Louis, MD; Devin Coon, MD, MSE

There is a growing body of literature supporting the positive outcomes of gender-affirming surgery (GAS) on transgender and gender diverse individuals. Mental health outcomes are



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among the most vital end points to study, given the fundamental intent of GAS to provide patients with

relief from gender dysphoria and improvement of psychosocial distress. Much of the data on this topic come from observational studies that lack either control groups or adequate sample size.^{1,2} In this issue of *JAMA Surgery*, Almazan and Keuroghlian³ contribute an analysis of the US Transgender Survey (USTS), examining the topic of mental health outcomes following GAS.

This study³ compared individuals who desired but had not undergone GAS with those who had, finding significantly lower rates of psychosocial distress, smoking, and suicidal ideation in the surgery group. When the analysis was broadened to include lifetime rather than recent symptoms (ie, the temporal association between surgery and symptoms was removed), the association became insignificant. The authors³ concluded the significant associations were not because of prior mental health status but rather a result of surgical intervention.

We commend the authors³ on their thorough exploration of the USTS, the largest collection of data on the experience of transgender and gender diverse individuals to our knowl-

edge to date. They provide a controlled, well-powered study, and their findings align with prior studies demonstrating the efficacy of GAS. However, the largest challenge in interpreting this association lies in the mental health screening typically necessary to be a candidate for GAS, which may convolute the specific connection between these 2 variables. The authors have fashioned a surrogate temporal association from cross-sectional data, but it is one that inevitably depends on certain key assumptions to hold true.

The second challenge is the use of USTS survey questions to quantify psychosocial distress, rather than a validated outcome instrument targeted toward psychosocial assessment in the transgender and gender diverse population. This is not as much a critique of the method as an acknowledgment of the scarcity of prospective longitudinal data sets measuring robust outcomes. Prospective cohort-level analyses (rather than population-level analyses) with well-validated outcome instruments are widely recognized as the area requiring greater progress. In the interim, though, this report³ contributes additional evidence to support the efficacy of GAS in alleviating dysphoria.

The availability of data on this community is a major impediment to addressing its needs and 1 reason the USTS was conducted in the first place, since nearly all governmental surveys continue to omit gender identity as a survey item. This issue has been recognized by numerous key public health

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NATIONAL VETERAN SUICIDE PREVENTION ANNUAL REPORT

VA Suicide Prevention Office of Mental Health and Suicide Prevention September 2022

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Introduction

This Department of Veterans Affairs (VA) 2022 National Veteran Suicide Prevention Annual Report documents decreases in Veteran suicide deaths and suicide rates during the two most recent years for which mortality data is available, 2019 and 2020.

The report provides *two decades* of Veteran suicide information, from 2001 through 2020. The report also evaluates Veteran suicide during 2020, in the initial period of the COVID-19 pandemic, comparing patterns of Veteran suicide and Veteran COVID-19 mortality over time and across Veteran subgroups.

Since the announcement of the worldwide COVID-19 pandemic, there have been prominent concerns that the pandemic could increase suicide rates. Mental health and suicide scholars described mechanisms by which pandemic effects could increase risks^{1,2} and "create a perfect storm of increased military Veteran suicide rates." Rapid and accurate information was urgently needed.⁴

In late March 2020, VA initiated near real-time surveillance of Veterans Health Administration (VHA) suicide-related indicators to monitor trends during the pandemic. This work did not identify increases in VHA site-documented suicides, on-campus suicides or VHA emergency department visits for suicide attempts. ^{5,6} However, comprehensive evaluation of potential effects on Veteran suicide required 2020 national death certificate data for all Veterans, which is now available. The present report examines Veteran suicide from 2001 through 2020 and evaluates potential pandemic effects on Veteran suicide by comparing patterns of Veteran suicide and COVID-19 mortality.

The report continues a *whole of VA* approach to Veteran suicide prevention that integrates strategic planning, program operations and program evaluation across VA, including VHA, Veterans Benefits Administration (VBA) and National Cemetery Administration (NCA). Further, work has been expanded in collaboration with other Federal agencies supporting a whole of Government approach, highlighted most recently in the White House report *Reducing Military and Veteran Suicide*. These efforts build upon the strong foundation of VA's 10-year *National Strategy for Preventing Veteran Suicide (2018)*. This strategy outlines a series of priority goals and executive actions to be pursued in collaboration not only with Federal agencies, but also with other Government programs, public-private partnerships and local communities to implement a full public-health approach unified in collective engagement for Veteran suicide prevention.

Reger, M. A., Stanley, I. H., & Joiner, T. E. (2020). Suicide Mortality and Coronavirus Disease 2019—A Perfect Storm? *JAMA Psychiatry*. 77(11), 1093-1094.

² Banerjee, D., Kosagisharaf, J. R., & Rao, T. S. S. (2021). 'The dual pandemic' of suicide and COVID-19: A biopsychosocial narrative of risks and prevention. *Psychiatry Research*. 295. https://doi.org/10.1016/j.psychres.2020.113577

³ Levine, J., & Sher, L. (2021). The prevention of suicide among military veterans during the COVID-19 pandemic. *European Archives of Psychiatry and Clinical Neuroscience*. 271:405-406.

⁴ Tandon, R. (2021). COVID-19 and suicide: Just the facts. Key learnings and guidance for action. *Asian Journal of Psychiatry*. 60. https://doi.org/10.1016/j. ajp.2021.102695. Tandon further notes that it was important to avoid sensational language regarding potential effects of the pandemic.

⁵ Department of Veterans Affairs. 2020 National Veteran Suicide Prevention Annual Report. https://www.mentalhealth.va.gov/docs/data-sheets/2020/2020-National-Veteran-Suicide-Prevention-Annual-Report-11-2020-508.pdf

⁶ Department of Veterans Affairs. 2021 National Veteran Suicide Prevention Annual Report. https://www.mentalhealth.va.gov/docs/data-sheets/2021/2021-National-Veteran-Suicide-Prevention-Annual-Report-FINAL-9-8-21.pdf

White House: Reducing Military and Veteran Suicide: Advancing a Comprehensive, Cross-Sector, Evidence-Informed Public Health Strategy. (2021). Available from: Military-and-Veteran-Suicide-Prevention-Strategy.pdf (whitehouse.gov). https://www.whitehouse.gov/wp-content/uploads/2021/11/Military-and-Veteran-Suicide-Prevention-Strategy.pdf

⁸ Department of Veterans Affairs. (2018). *National Strategy for Preventing Veteran Suicide*.

The report provides the most current information regarding:

- Suicide among Veterans overall and compared to non-Veteran U.S. adults
- Suicide among Veteran subpopulations, including:
 - Veterans who received VHA health care⁹ in the year or prior year, or in this report "Recent Veteran VHA Users," overall and for subgroups, including:
 - Demographic, diagnostic, rural/urban and priority eligibility groups
 - Veterans who were not Recent VHA Users, or in this report "Other Veterans"
- Veterans who died from suicide, including information on their receipt of VA services:
 - VHA health care encounters
 - VHA enrollment
 - · VBA services
- Veteran suicide during the COVID-19 pandemic:
 - · Suicide as a leading cause of death
 - Suicide relative to COVID mortality trends, overall and for Veteran subgroups

Key findings include:

- In 2020, there were 6,146 Veteran suicide deaths, which was 343 fewer than in 2019. The unadjusted rate of suicide in 2020 among U.S. Veterans was 31.7 per 100,000.
- Over the period from 2001 through 2020, age- and sex-adjusted suicide rates for Veterans peaked in 2018 and then fell in 2019 and 2020. From 2018 to 2020, age- and sex-adjusted suicide rates for Veterans fell by 9.7%.
- Among non-Veteran U.S. adults, age- and sex-adjusted suicide rates also peaked in 2018 and fell in 2019 and 2020. From 2018 to 2020, age- and sex-adjusted suicide rates for non-Veteran adults fell by 5.5%.
- In each year from 2001 through 2020, age- and sex-adjusted suicide rates of Veterans exceeded those of non-Veteran U.S. adults. The differential in adjusted rates was smallest in 2002, when the Veteran rate was 12.1% higher than for non-Veterans, and largest in 2017, when the Veteran rate was 66.2% higher. In 2020, the rate for Veterans was 57.3% higher than that of non-Veteran adults.
- From 2019 to 2020, the age- and sex-adjusted suicide rate for Veterans fell by 4.8%, while for non-Veteran U.S. adults, the adjusted rate fell by 3.6%.
- From 2019 to 2020, among Veteran men, the age-adjusted suicide rate fell by 0.7%, and among Veteran women, the age-adjusted suicide rate fell by 14.1%. By comparison, among non-Veteran U.S. men, the age-adjusted rate fell by 2.1%, and among non-Veteran women, the age-adjusted rate fell by 8.4%.
- In each year from 2001 through 2020, age- and sex-adjusted suicide rates of Recent Veteran VHA Users exceeded those of Other Veterans. The differential in adjusted rates was smallest in 2018, when the rate for Recent Veteran VHA Users was 9.4% higher, and largest in 2002, when the rate was 80.9% higher. In 2020, the age and sex-adjusted suicide rate of Recent Veteran VHA Users was 43.4% higher than for Other Veterans.
- In 2020, suicide was the 13th leading cause of death among Veterans overall, and it was the second leading cause of death among Veterans under age 45.

⁹ VHA health care receipt is here defined as having at least one VHA inpatient or outpatient utilization record.

- The COVID-19 pandemic was announced in early March 2020. By the year's end, COVID-19 was the 3rd leading cause of death in the United States, both overall¹⁰ and for Veterans. Despite the pandemic, the Veteran suicide rate in 2020 continued a decline that began in 2019.
- Comparisons of trends in Veteran suicide and COVID-19 mortality over the course of 2020, and across Veteran demographic and clinical subgroups, did not indicate an impact of the COVID-19 pandemic on Veteran suicide mortality.

Anchors of Hope

Hope serves as a key and necessary anchor to strengthen Veterans amidst numerous life circumstances. In a similar manner, hope must imbue the overall suicide prevention mission. The following hopeful data points from this year's report serve as anchors:

- There were 343 fewer Veterans who died from suicide in 2020 than in 2019, and 2020 had the lowest number of Veteran suicides since 2006.
- From 2001 through 2018, the number of Veteran suicides increased on average by 47 deaths per year. From 2019 to 2020, there were consecutive reductions, of 307 and 343 suicides, respectively, an unprecedented decrease since 2001.
- From 2018 to 2020, adjusted rates for Veterans fell by 9.7%. By comparison, the adjusted rate for non-Veteran U.S. adults fell by 5.5%.
- The age-adjusted suicide rate for women Veterans in 2020 was the lowest since 2013, and the age-adjusted suicide rate for Veteran men was the lowest since 2016.
- From 2019 to 2020, among Veteran men, the age-adjusted suicide rate fell by 0.7%, and among Veteran women, the age-adjusted suicide rate fell by 14.1%. Among non-Veteran U.S. men, the age-adjusted rate fell by 2.1%, and among non-Veteran women, the age-adjusted rate fell by 8.4%.
- Assessment of Veteran suicide rates by race showed decreases from 2019 to 2020 for all groups.
- Despite the 24.6% decrease in the Veteran population from 2001 to 2020, the number of Veterans with VHA health care encounters in the year or prior year rose 55.0%, from 3.8 million to 5.9 million.
- Despite onset of the COVID-19 pandemic in 2020, age and sex-adjusted suicide rates among Veterans fell 4.8% from 2019 to 2020, versus a 3.6% decline among non-Veteran U.S. adults.

The overall downward trends in Veteran suicide in 2019 and 2020 are encouraging. They followed VA's launch of the 2018 *National Strategy for Preventing Veteran Suicide* (National Strategy).¹¹ This was built upon the foundation of the U.S. Surgeon General's and National Action Alliance for Suicide Prevention's 2012 National Strategy for Suicide Prevention.¹² The 2018 strategy reflects a comprehensive public health approach to Veteran suicide prevention. This combines community-based suicide prevention strategies and clinically based interventions. The *National Strategy for Preventing Veteran Suicide* provided the vision to begin coordinated implementation of public health approaches across universal, selective and indicated approaches to reach all Veterans, including those without recent VA contact. These efforts were also fueled by the 2019 publication of the VA and Department of Defense (DoD) *Clinical Practice Guideline (CPG)* for the Assessment and Management of Patients at Risk for Suicide.¹³ This provided the latest analysis of research on suicide prevention in clinical settings. Together,

Murphy, S. L., Kochanek, K. D., Xu, J.Q., & Arias, E. Mortality in the United States, 2020. NCHS Data Brief, No. 427. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: https://dx.doi.org/10.15620/cdc:112079

Department of Veterans Affairs. (2018). National Strategy for Preventing Veteran Suicide. https://www.mentalhealth.va.gov/suicide_prevention/docs/ Office-of-Mental-Health-and-Suicide-Prevention-National-Strategy-for-Preventing-Veterans-Suicide.pdf

U.S. Department of Health and Human Services (HHS) Office of the Surgeon General and National Action Alliance for Suicide Prevention. 2012 National Strategy for Suicide Prevention: Goals and Objectives for Action. Washington, DC: HHS, September 2012. https://www.ncbi.nlm.nih.gov/books/ NBK109917/pdf/Bookshelf_NBK109917.pdf

Department of Veterans Affairs and Department of Defense. (2019). VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide. https://www.healthquality.va.qov/quidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf

the *National Strategy for Preventing Veteran Suicide* and the latest CPG provided a roadmap that would be operationalized in the deployments of the Suicide Prevention 2.0 (SP 2.0) and Suicide Prevention Now (SP Now) initiatives.

Approved for full launch in 2019, SP 2.0 is a 6-year strategic plan with national reach focused on the implementation of clinical and community-based prevention, intervention and postvention services that reflect the National Strategy's four pillars. The SP 2.0 Community-Based Interventions for Suicide Prevention (CBI-SP) domain focuses on enacting the four pillars through the Veterans Integrated Service Network-Based Community Coalition and Collaboration Building, Veteran-to-Veteran Coalition Building and State-Based Coalition and Collaboration Building models. Integrating diversity, equity and inclusion (DEI) is a critical aspect of community work. Community Engagement and Partnership Coordinators (CEPC) are trained in DEI considerations and prompt potential DEI questions through each phase of CEPC's work (Engage, Plan, Implement and Sustain) with local communities. This work is critical to design strategic plans for suicide prevention for each unique community. The SP 2.0 clinically based domain follows the vision associated with the National Strategy's treatment, recovery and support services pillar. SP 2.0 outlines a practical strategy for implementing CPG evidence-based treatments—for example through dissemination of telemental health suicide prevention services across all VHA local health care systems, bringing treatments into the homes of Veterans, a critical service particularly since the start of the COVID-19 pandemic.

While VA worked on the longer-term plan of SP 2.0 implementation, in collaboration with community partners, 2020 also saw the launch of the SP Now initiative, a bundled set of interventions, across five key domains, in alignment with the vision of the National Strategy. The SP Now plan aims to develop and deploy actions that available data suggests have the potential to be effectively implemented and to create meaningful results in a short amount of time. It is focused on these five critical areas:

- 1. Lethal means safety;
- 2. Suicide prevention in at-risk medical populations;
- 3. Outreach and understanding of prior and non-VHA users;
- Suicide prevention program enhancements; and
- 5. Media campaigns.

Part 1: Suicide Among Veterans and Non-Veteran U.S. Adults, 2001–2020

This section provides an overview of the most recent Veteran suicide data. ¹⁴ It is organized by Suicide Deaths, Average Number of Suicides Per Day and Suicide Rates.

Key Findings

- In 2020, there were 6,146 Veteran suicides. This was on average 16.8 per day. In 2020, there were 343 fewer Veteran suicides than in 2019, and the number of Veteran suicides was lower than each prior year since 2006.
- From 2018 to 2020, age- and sex-adjusted suicide rates for Veterans fell by 9.7%. This was a larger percentage decrease than was observed for non-Veteran U.S. adults (5.5%).
- In 2020, adjusting for population age and sex differences, the suicide rate for Veterans was 57.3% greater than for non-Veteran U.S. adults.

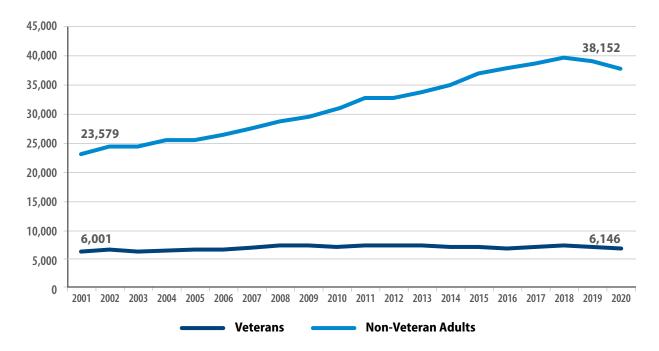
Among U.S. adults who died from suicide in 2020, firearms were more commonly involved among Veterans (71.0%) than non-Veterans (50.3%).

¹⁴ For this report, Veterans are defined as persons who had been activated for Federal military service and were not currently serving at the time of death. For more information, see the accompanying 2022 Veteran Suicide Surveillance Methods Summary.

Suicide Deaths

• Among Veterans, non-Veteran adults and U.S. adults overall, the number and rate of suicide deaths fell in 2019 and again in 2020, after increases from 2001 through 2018 (Figures 1 and 3).

Figure 1: Suicide Deaths Among Veterans and Non-Veteran U.S. Adults, by Year, 2001–2020



• Figure 2 on the next page details variation in the number of Veteran suicides, by year from 2001 through 2020. Veteran suicide deaths rose from 6,001 in 2001 to 6,796 in 2018 and then fell to 6,146 in 2020.

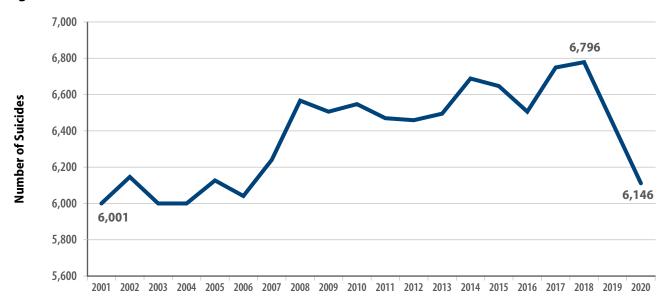


Figure 2: Veteran Suicide Deaths, 2001–2020

Average Number of Suicides Per Day¹⁵

- Among all U.S. adults—including Veterans—the average number of suicides per day rose from 81.0 per day in 2001 to 121.0 in 2020. The average number of suicides per day among U.S. adults was highest in 2018 (127.4 per day).
- The average number of Veteran suicides per day rose from 16.4 in 2001 to 16.8 in 2020. It was highest in 2018 (18.6 per day). Of the on average 16.8 Veteran suicides per day in 2020, approximately 39.7% (6.7 per day) were among Recent Veteran VHA Users¹⁶ and 60.3% (10.1 per day) were among Other Veterans.

Suicide Rates

Over the 2 decades from 2001 through 2020, the Veteran population decreased by 24.6%, from 25.7 million to 19.4 million. In the same years, the non-Veteran U.S. adult population increased by 27.2%, from 186.6 million to 237.3 million. In this context, it is important to assess suicide mortality rates, which convey the incidence of suicide relative to the size of the population.

Unadjusted suicide rates represent the number of suicide deaths in a population relative to the population's time at risk of being observed with a suicide death.¹⁷ Rates are reported as suicides per 100,000.¹⁸ Adjusted rates are used for comparisons while adjusting for population differences, such as age and sex distributions.¹⁹ To describe the burden of

¹⁵ It should be noted that decreases in the size of the Veteran population and simultaneous increases in the size of the U.S. population over this time period limit interpretation of these statistics. Rates of suicide, stratified by group, are more appropriate for understanding changes in Veterans and non-Veteran populations and are provided throughout this report.

¹⁶ With regard to suicide in 2020, Recent Veteran VHA Users were defined as Veterans with VHA health care encounters in 2019 or 2020.

¹⁷ Risk time was measured using mid-year population estimates when individuals' exact risk times were unavailable, and risk time was calculated exactly for analyses of subgroups of Veterans with recent VHA care.

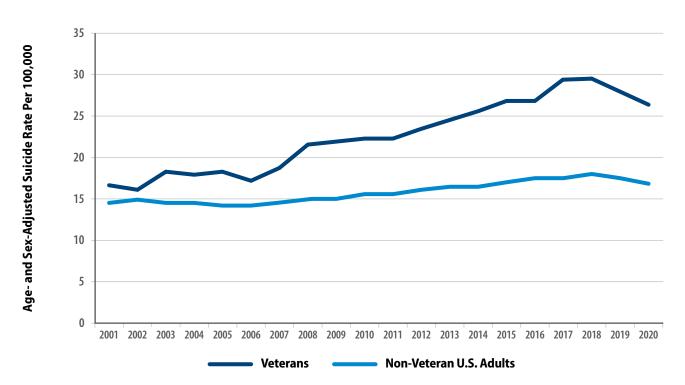
¹⁸ For the Veteran population, risk time was assessed using the mid-year population estimate. When risk time was assessed per individual level risk-time information, we included "per 100,000 person-years."

¹⁹ Unadjusted rates directly communicate the magnitude of suicide mortality in a given population over a period of time. For example, we know that Veteran and non-Veteran adult populations differ by age and sex. In 2020, 9.4% of Veterans were aged 18-34, compared to 31.3% of non-Veteran adults. Also, 89.7% of all Veterans were men, while men accounted for 45.4% of non-Veteran U.S. adults. Suicide risks differ across age and sex categories, and, consequently, if groups differ in terms of these characteristics, then that may account for some of the differences in unadjusted rates. Technically, adjusted rates translate the unadjusted rate for a population into a measure of what the rate would be if the compared populations had the same distributions of the demographic factors that are adjusted for. Per standard practice, adjusted rates are calibrated to the demographic distribution of the U.S. adult population in 2000. Calculating adjusted rates (e.g., age-adjusted or age- and sex-adjusted rates) enables rate comparisons while adjusting for population demographic differences.

suicide in a given population and time period, we use unadjusted rates. To compare rates across populations or periods, we use adjusted rates.²⁰

- The unadjusted suicide rate for Veterans was 23.3 per 100,000 in 2001 and 31.7 per 100,000 in 2020. For non-Veteran U.S. adults, the suicide rate was 12.6 per 100,000 in 2001 and 16.1 per 100,000 in 2020.
- In 2020, Veterans age 18-34 had an unadjusted suicide rate of 46.1 per 100,000, while the rate was 31.8 per 100,000 for those age 35-54, 27.4 per 100,000 for those age 55-74 and 32.0 per 100,000 for those age 75 and older.
- In 2020, the unadjusted suicide rate of Veteran men was 33.7 per 100,000 (2.3% lower than in 2019), and it was 13.8 per 100,000 for Veteran women (20.3% lower than in 2019).
- Age- and sex-adjusted suicide rates from 2001 through 2020 are presented in Figure 3 below for Veterans and non-Veteran U.S. adults, by year. From 2001 through 2020, adjusted rates rose faster for Veterans than for non-Veteran U.S. adults. The difference in rates was greatest in 2017, when Veteran adjusted rates were 66.2% greater than those of non-Veteran adults. In 2020, this differential fell to 57.3%.
- From 2019 to 2020, the age- and sex-adjusted suicide rate among Veterans fell by 4.8%. By comparison, the adjusted rate for non-Veteran U.S. adults fell by 3.6%.
- From 2018 to 2020, adjusted rates for Veterans fell by 9.7%. By comparison, the adjusted rate for non-Veteran U.S. adults fell by 5.5%.

Figure 3: Age- and Sex-Adjusted Suicide Rates, Veterans and Non-Veteran U.S. Adults, 2001–2020

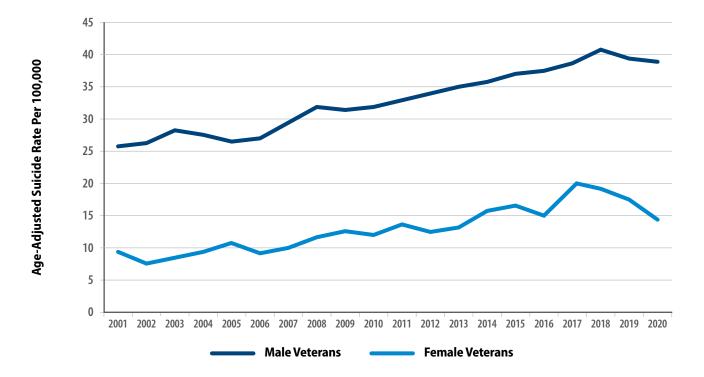


The interpretation of adjusted rates is somewhat technical. They represent the level of suicide mortality that we would see in the population and time period if the population had the same demographic distribution of a standard population, at least in terms of the adjustment variable(s). Consistent with current practice, in this report, adjusted rates use the U.S. adult population in 2000 as the standard population. When adjustment was not possible, due to small numbers within adjustment strata, unadjusted rates are presented.

Suicide Rates by Sex

• Figure 4 below presents age-adjusted suicide rates for Veteran men and for Veteran women, by year, 2001-2020. For Veteran men, rates were highest in 2018 and declined through 2020. For Veteran women, rates were highest in 2017 and declined through 2020.

Figure 4: Age-Adjusted Suicide Rate Per 100,000, Male and Female Veterans, 2001–2020



Suicide Rates by Age

Figure 5 below presents unadjusted suicide rates for Veterans, by age categories and year, 2001-2020. From 2001 to 2020, the unadjusted suicide rate among Veterans between the ages of 18 and 34 increased by 95.3%. For those age 35-54, the rate increased by 12.9%; for those age 55-74, the rate increased by 58.2%; and for those age 75 and older, the rate increased by 21.2%. From 2019 to 2020, suicide rates among Veterans between the ages of 18 and 34 increased, while rates for each other age group decreased.

60 50 40 Rate Per 100,000 30 20 10 2007 2001 2002 2003 2004 2005 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2006 2008 2009 18-34 35-54 55-74

Figure 5: Unadjusted Suicide Rate Per 100,000, Veterans, by Age Group, 2001–2020

Suicide Rates by Sex and Age

We examined unadjusted suicide rates for Veteran men and for Veteran women, by age categories and year, 2001-2020.

- In 2001, Veterans between the ages of 35 and 54 had the highest suicide rates, among both Veteran men and Veteran women. In 2020, suicide rates were highest among Veterans between the ages of 18 and 34 (52.3 per 100,000 among Veteran men age 18-34 and 19.5 per 100,000 among Veteran women age 18-34).
- Suicide rates among both male and female Veterans ages 18-34 increased from 2019 to 2020, while for all other groups, rates decreased.

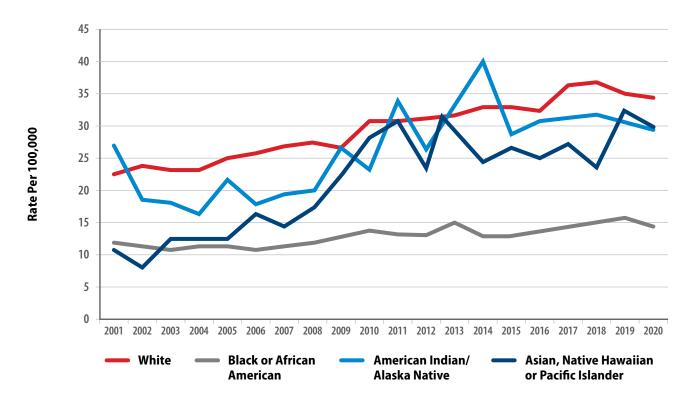
Suicide Rates by Race and Ethnicity

Figure 6 below presents unadjusted Veteran suicide rates, by race.²¹

In 2020, the suicide rate was 34.2 per 100,000 among White Veterans; 30.2 per 100,000 among Asian, Native Hawaiian or Pacific Islander Veterans; 29.8 per 100,000 among American Indians or Alaska Native Veterans; and 14.2 per 100,000 among Black or African American Veterans.

In 2020, the suicide rate among White Veterans was more than twice the rate among Black or African American Veterans. From 2019 to 2020, rates decreased for Veterans in each category.

Figure 6: Unadjusted Suicide Rates, Veterans, by Race, 22 2001–2020



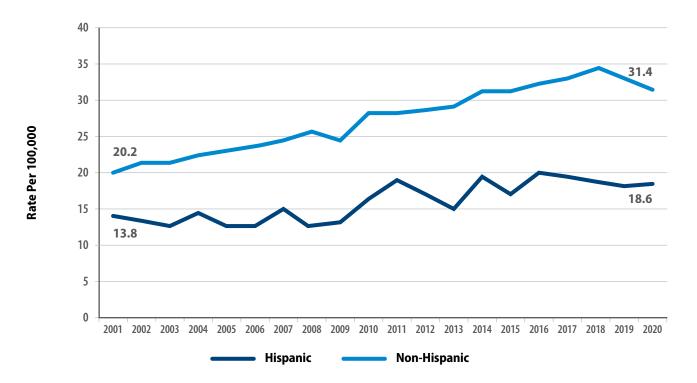
²¹ It was not possible to generate adjusted rates, due to data constraints. Consequently, differences in rates may in part be due to population differences in demographic factors that are independently associated with suicide risk.

²² Categories presented are mutually exclusive. Individuals identified as multiple races are categorized separately, and not presented due to inconsistent data availability over the reporting period. The availability of information regarding race demographics for the overall Veteran population is limited, sometimes combining the Asian, Native Hawaiian and Pacific Islander race categories. To provide the most complete information available, we present information using this combined category.

Figure 7 below presents unadjusted suicide rates for Veterans, by Hispanic ethnicity.²³

- In each year, unadjusted suicide rates were lower among Veterans with Hispanic ethnicity than among non-Hispanic Veterans.
- From 2019 to 2020, rates increased among Veterans with Hispanic ethnicity, while decreasing for other Veterans.

Figure 7: Unadjusted Suicide Rates, Veterans, by Hispanic Ethnicity, 2001–2020



- Among U.S. adults overall, similar patterns were observed. Suicide rates were higher for those who were not Hispanic or Latino (14.7 per 100,000 in 2001 and 18.7 per 100,000 in 2020) than for those who were Hispanic or Latino (7.1 per 100,000 in 2001 and 9.9 per 100,000 in 2020).
- From 2019 to 2020, rates increased among U.S. adults overall with Hispanic ethnicity, while decreasing for other U.S. adults.

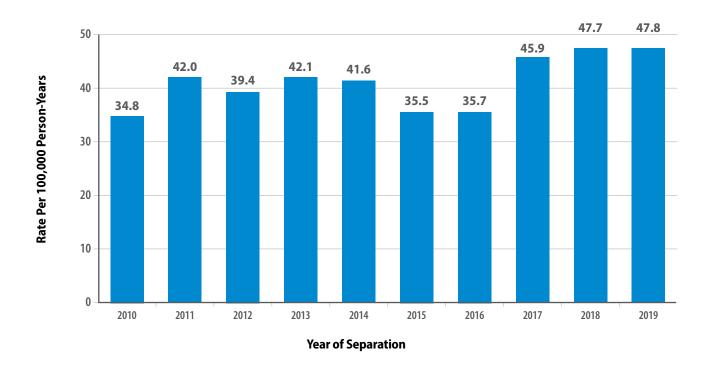
²³ It was not possible to generate adjusted rates, due to data constraints. Consequently, differences in rates may in part be due to population differences in demographic factors that are independently associated with suicide risk.

Suicide Rates in Year Following Military Separation

Figure 8 below presents the unadjusted suicide rate per 100,000 over 12 months following Veterans' separations from active military service, by year of separation, 2010-2019. 24,25

• Suicide rates following separation ranged from 34.8 per 100,000, for Veterans who separated in 2010, to 47.8 per 100,000 for Veterans who separated in 2019.

Figure 8: Unadjusted Suicide Mortality Rate, 12 Months Following Separation from Active Military Service, by Year of Separation, 2010–2019



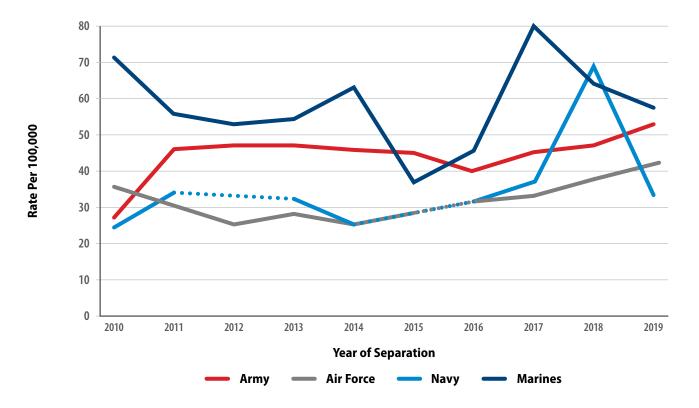
²⁴ Twelve-month suicide mortality rates are reported for cohorts of Veterans who separated from military service in the years 2010 through 2019. Separations were identified using VA/DoD Identity Repository (VADIR) data. Reporting is not included for years prior to 2010, due to data constraints. Given small cell sizes, it was not possible to calculate adjusted rates. Ninety-five percent confidence intervals were overlapping for each year. We note that a 2020 separation cohort is not included here, as 12-month following would require 2021 mortality data, which is not currently available.

²⁵ In 2010, there were 227,084 Veterans with separations from active military service, and there were 209,164 in 2019. For Veterans who separated in 2010, 16.8% were female and the median age at separation was 26. For those who separated in 2019, 17.2% were female and the median age at separation was 27. There were 79 and 100 Veteran suicides within 12 months of military separations in 2010 and 2019, respectively.

Figure 9 below presents unadjusted suicide rates in the 12 months following separations, by year of separation and service branch.

• For the most recent separation cohort, who separated from active military service in 2019, suicide rates over the following 12 months were highest among those who separated from the Marines (58.3 per 100,000), followed by the Army (52.7 per 100,000), Air Force (42.4 per 100,000) and Navy (34.4 per 100,000).

Figure 9: Unadjusted Suicide Mortality Rate, 12 Months Following Separation from Active Military Service, by Year of Separation and Branch of Service, 2010–2019²⁶



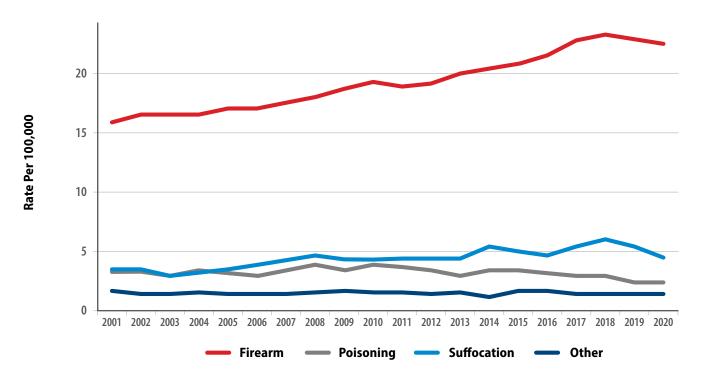
²⁶ Rates are suppressed if there were fewer than 10 suicide deaths, with dotted lines connecting non-suppressed data points. The dotted lines represent suppressed rates and should not be interpreted as estimated rates.

Method-Specific Suicide Rates

Figure 10 below shows method-specific suicide rates among Veterans, by year, 2001-2020.

- From 2001 to 2020, method-specific rates increased for firearm suicide mortality (+45.0%) and suffocation suicide mortality (+44.8%). Rates decreased 13.8% for poisoning suicide mortality and increased 22.9% for suicide involving other methods. These changes may underlie overall trends in Veteran suicide from 2001 through 2020.
- From 2018 to 2020, method-specific suicide rates decreased for firearm suicide mortality (-2.5%), poisoning suicide mortality (-17.6%) and suffocation suicide mortality (-16.8%), while increasing for suicide involving other methods (+3.4%).
- From 2019 to 2020, rates decreased for firearm suicide mortality (-1.2%), poisoning suicide mortality (-4.8%) and suffocation suicide mortality (-13.7%), while increasing for suicides involving other methods (+3.2%).

Figure 10: Unadjusted Method-Specific Suicide Rates, Veterans, 2001–2020



Further analyses indicate that firearm suicide mortality rates in 2020 were greater among Veteran men (24.3 per 100,000) than Veteran women (6.7 per 100,000).

Lethal Means Involved in Suicide Deaths

Table 1 below provides information on lethal means involved in suicide deaths of non-Veteran U.S. adults and Veterans in 2020, and a measure of change compared to suicides in 2001.

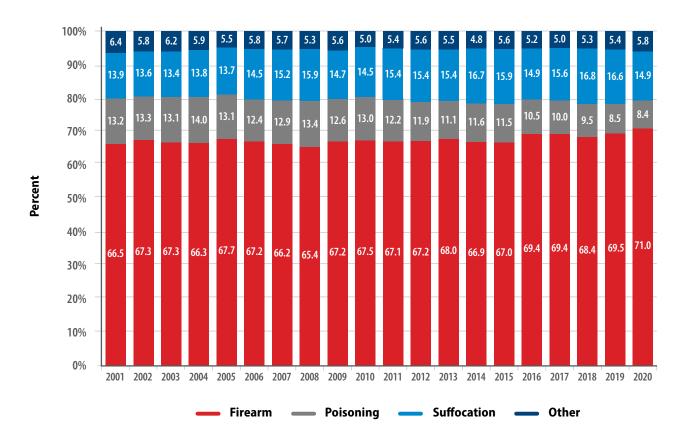
Table 1: Suicide Deaths, Methods Involved, 2020 and Difference From 2001*

	SUICIDE DECEDENTS, METHODS INVOLVED											
		/eteran Adults	Vete	erans		eteran en		eran len		/eteran omen		eran men
	2020	Change*	2020	Change*	2020	Change*	2020	Change*	2020	Change*	2020	Change*
Firearms	50.3%	-2.3%	71.0%	+4.5%	55.3%	-2.7%	72.1%	+4.8%	33.3%	-2.1%	48.2%	+11.2%
Poisoning	12.8%	-5.6%	8.4%	-4.8%	8.0%	-4.3%	7.5%	-4.9%	29.3%	-8.7%	26.8%	-16.0%
Suffocation	28.4%	+7.6%	14.9%	+0.9%	28.6%	+6.2%	14.7%	+0.6%	27.7%	+12.0%	19.2%	+8.8%
Other	8.4%	+0.3%	5.8%	-0.6%	8.1%	+0.8%	5.8%	-0.5%	9.6%	-1.1%	5.8%	-3.9%

^{*}Difference compared to suicide deaths in 2001

Figure 11 presents the distribution of methods involved in Veteran suicide deaths, 2001-2020.

Figure 11: Methods Involved, Percentage, Veteran Suicide Deaths, 2001–2020

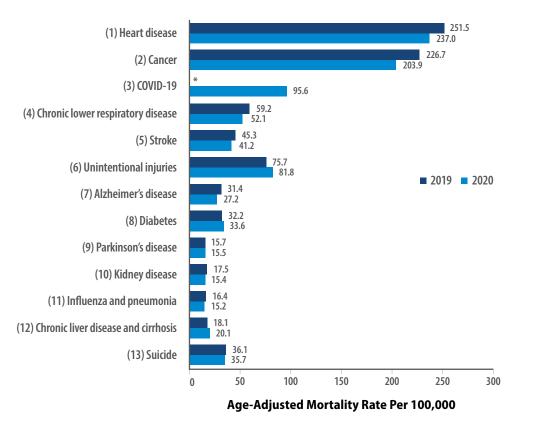


- Among Veteran suicide deaths in 2020, relative to those in 2001, there were increases in the percentage involving firearms (+4.5%) and suffocation (+0.9%) and decreases for those involving poisoning (-4.8%) and other means (-0.6%).
- For suicide deaths of non-Veteran U.S. adults, there were increases from 2001 to 2020 in the percentage involving suffocation (+7.6%) and other means (+0.3%) and decreases in the percentage involving firearms (-2.3%) and poisoning (-5.6%).
- From 2019 to 2020, among Veteran suicide deaths, the involvement of firearms increased from 69.5% to 71.0%, while poisoning and suffocation involvement decreased, from 8.5% to 8.4% and from 16.6% to 14.9%, respectively.
- In 2020, firearms were involved in 72.1% of suicides by male Veterans, up from 70.6% in 2019 and in 48.2% of suicides by female Veterans, down from 48.4% in 2019.
- The distribution of methods involved in suicides by non-Veteran U.S. adults changed from 2019 to 2020: Involvement of firearms increased from 47.7% to 50.3%, while poisoning and suffocation fell, from 13.9% to 12.8% and from 29.7% to 28.4%, respectively.

Leading Causes of Death, Veterans

Among all Veterans in 2020, suicide was the 13th leading cause of death.²⁷ Figure 12 shows age-adjusted, cause-specific mortality rates per 100,000, by leading cause in 2020.²⁸

Figure 12: Top 13 Leading Causes of Death in 2020, Veterans, Age-Adjusted Mortality Rates in 2019 and 2020



^{*}COVID-19 deaths were identified based on underlying cause of death ICD-10 code U07.1. This was added as a cause of death in 2020. There is no comparison rate for 2019.

²⁷ Thirteen leading causes were presented in order to be inclusive of suicide, the 13th leading cause among Veterans, overall. Causes of death are classified based on the underlying cause of death. Leading causes of death are ranked based on the number of deaths, by cause.

²⁸ In the top 7 leading causes of death, deaths from non-COVID-19 causes decreased from 2019 through 2020, with 1 exception: unintentional injuries. This category of death, which includes overdose mortality, increased among Veterans from 2019 through 2020.

The relative rank of suicide as a leading cause of death was higher among younger Veterans (Table 2).

Table 2: First and Second Leading Causes of Death in 2020, Veterans and Suicide Ranking, by Age and Sex

	FIRST LEADING CAUSE OF DEATH	SECOND LEADING CAUSE OF DEATH	RANK OF SUICIDE AS A LEADING CAUSE OF DEATH
All Veterans			
All Ages	Heart disease	Cancer	13th
18 to 34	Accidents (Unintentional Injuries)	Suicide	2nd
35 to 44	Accidents (Unintentional Injuries)	Suicide	2nd
45 to 54	Heart disease	Cancer	4th
55 to 64	Cancer	Heart disease	9th
65 to 74	Cancer	Heart disease	15th
75 to 84	Heart disease	Cancer	16th
85 and older	Heart disease	Cancer	17th
Male Veterans			<u>'</u>
All Ages	Heart disease	Cancer	13th
18 to 34	Accidents (Unintentional Injuries)	Suicide	2nd
35 to 44	Accidents (Unintentional Injuries)	Suicide	2nd
45 to 54	Heart disease	Accidents (Unintentional Injuries)	4th
55 to 64	Heart disease	Cancer	9th
65 to 74	Cancer	Heart disease	15th
75 to 84	Heart disease	Cancer	16th
85 and older	Heart disease	Cancer	17th
Female Veterans		·	<u>'</u>
All Ages	Cancer	Heart disease	10th
18 to 34	Accidents (Unintentional Injuries)	Suicide	2nd
35 to 44	Accidents (Unintentional Injuries)	Cancer	3rd
45 to 54	Cancer	Heart disease	5th
55 to 64	Cancer	Heart disease	9th
65 to 74	Cancer	Heart disease	16th
75 to 84	Cancer	Heart disease	*
85 and older	Heart disease	Alzheimer's disease	*

^{*}Not reported when based on fewer than 10 deaths

Part 2: Veterans, by Contact with VA Administrations

Here we present information specific to subgroups of Veterans defined by contact with two VA administrations, VHA and VBA. VHA delivers health services for Veterans. VBA supports Veterans in five areas of benefits and entitlements: Compensation and Pension; Education; Home Loan Guaranty; Insurance; and Veteran Readiness and Employment.

Findings include suicide rates for annual cohorts of Veterans who received VHA health care²⁹ in the year or prior year, who in this report are described as "Recent Veteran VHA Users" or as "VHA Veterans," including by demographic and clinical subgroups, rurality, VHA enrollment and VA eligibility priority groups. For Veterans who died from suicide in 2020, we report on points of VA contact, including receipt of VHA health care, VHA enrollment and VBA services.

Veterans Health Administration (VHA) Health Care

VHA Health Care Engagement, 2001–2020

From 2001 to 2020, the Veteran population decreased by 24.6%. Over these years, VA expanded health care eligibility³⁰ and there were substantial increases in Veterans' receipt of VHA health care. Despite the overall Veteran population decreases, the number of Veterans with VHA health care encounters in the year or prior year rose 55.0%, from 3.8 million to 5.9 million. By comparison, the number of Other Veterans, who were not recent VHA users, fell 38.6%, from 21.8 million to 13.4 million. In 2020, Recent Veteran VHA Users accounted for 30.6% of all Veterans, up from 14.9% in 2001.

Prior studies report differences between Veterans with versus without VHA health care services utilization. For example, Veterans receiving VHA care are more likely to be unmarried, smokers and from minority populations, with less education, lower annual incomes, poorer self-reported health status, more chronic medical conditions³¹ and self-reported disability due to physical or mental health factors³² and greater reporting of trauma, lifetime psychopathology and current suicidality.³³

To inform Veteran suicide prevention approaches—including clinically and community-focused initiatives—it is important to understand trends in suicide mortality among Recent Veteran VHA Users and among Other Veterans.

²⁹ VHA health care receipt is here defined as having at least one VHA inpatient or outpatient utilization record, per VHA Corporate Data Warehouse records.

³⁰ For example, the National Defense Authorization Act of 2008 extended the period of eligibility for health care for Veterans who had served in a theater of combat operations after 11/11/1998 to 5 years following discharge or release. Qualifying Veterans would be eligible for enrollment in Priority Group 6 unless eligible for enrollment in a higher priority group. https://www.va.gov/healthbenefits/assets/documents/publications/FS16-4.pdf

³¹ Dursa, E. K., Barth, S. K., Bossarte, R. M., & Schneiderman, A. I. (2016). Demographic, Military, and Health Characteristics of VA Health Care Users and Nonusers Who Served in or During Operation Enduring Freedom or Operation Iraqi Freedom, 2009-2011. *Public Health Reports*, 131(6), 839-843.

³² Nelson, K. M., Starkebaum, G. A., & Reiber, G. E. (2007). Veterans Using and Uninsured Veterans Not Using Veterans Affairs (VA) Health Care. 122:94-100.

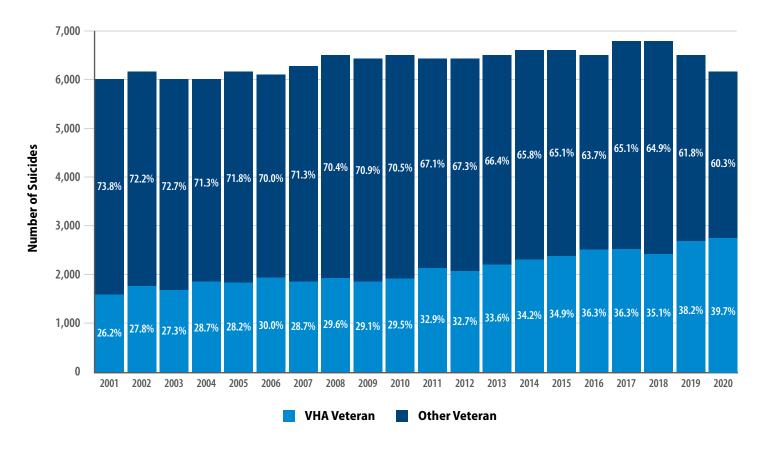
Meffert, B. N., Morabito, D. M., Sawicki, D. A., Hausman, C., Southwick, S. M., Pietrzak, R. H., & Heinz, A. J. (2019). U.S. Veterans Who Do and Do Not Utilize VA Healthcare Services: Demographic, Military, Medical, and Psychosocial Characteristics. *Primary Care Companion CNS Disorders*, 21(1). doi:10.4088/PCC.18m02350

Suicide Deaths

Figure 13 below presents the annual number of Veteran suicide deaths, 2001-2020 and the percentage among Recent Veteran VHA Users ("VHA Veteran") and Other Veterans.

• Among Veteran suicide decedents, the percentage with recent VHA encounters increased from 26.2% in 2001 to 39.7% in 2020.

Figure 13: Veteran Suicides, Percentages With and Without Recent³⁴ VHA Health Care Encounters, 2001–2020



³⁴ Dursa, E. K., Barth, S. K., Bossarte, R. M., & Schneiderman, A. I. (2016). Demographic, Military, and Health Characteristics of VA Health Care Users and Nonusers Who Served in or During Operation Enduring Freedom or Operation Iraqi Freedom, 2009-2011. Public Health Reports, 131(6), 839-843.

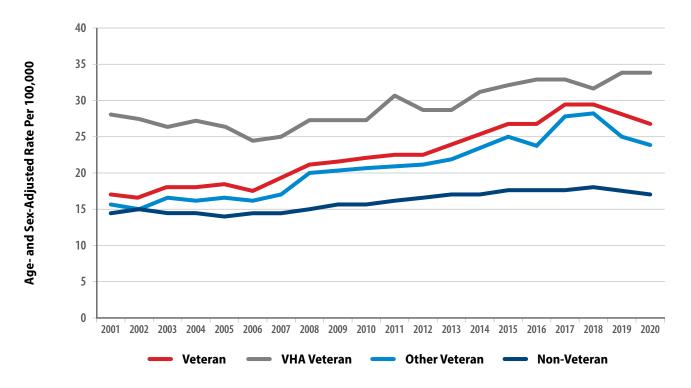
Average Number of Suicides Per Day

- Among annual cohorts of Recent Veteran VHA Users, the average number of suicides per day increased from 4.3 in 2001 to 6.7 in 2020.
- From 2001 through 2020, the average per day was highest in 2019 (6.8 per day).

Suicide Rates

Figure 14 below presents trends in age- and sex-adjusted suicide rates among Veterans overall, Recent Veteran VHA Users ("VHA Veteran"), Other Veterans and non-Veteran U.S. adults, 2001-2020.

Figure 14: Age- and Sex-Adjusted Suicide Rates, Veterans, Overall and by Recent VHA Care and Non-Veteran U.S. Adults, 2001–2020



- Age- and sex-adjusted suicide rates for 2001 and for 2020 were higher among Recent Veteran VHA Users than for Other Veterans.
- As shown in Table 3 on the next page, from 2001 to 2020, adjusted rates increased by 22.6% for Recent Veteran VHA Users and by 54.0% among Other Veterans. From 2001 through 2020, adjusted rates rose more steeply for Other Veterans than for Recent Veteran VHA Users. From 2019 to 2020, adjusted rates among Recent Veteran VHA users fell by 0.5% and rates among Other Veterans fell by 6.3%.
- For Veteran men with recent VHA care, the age-adjusted rate rose by 4.4% from 2019 to 2020, while for Veteran women with recent VHA care, the age-adjusted suicide rate fell by 11.9%.
- From 2001 to 2020, age-adjusted suicide rates rose 20.4% for male Veterans with recent VHA use and 46.4% for male Veterans without recent VHA use. Age-adjusted suicide rates rose 23.2% for female Veterans with recent VHA use and 68.2% for female Veterans without recent VHA use.

Table 3: Veteran Age- and Sex-Adjusted Suicide Rates Per 100,000, 2001, 2019 and 2020

	2001	2020	Change	2019	2020	Change
Recent Veteran VHA Users	27.8	34.1	+22.6%	34.3	34.1	-0.5%
Other Veterans	15.5	23.8	+54.0%	25.4	23.8	-6.3%

Figure 15: Age- and Sex-Adjusted Suicide Rates Per 100,000, with 95% Confidence Intervals, Veterans, by Recent VHA Care, 2001–2020

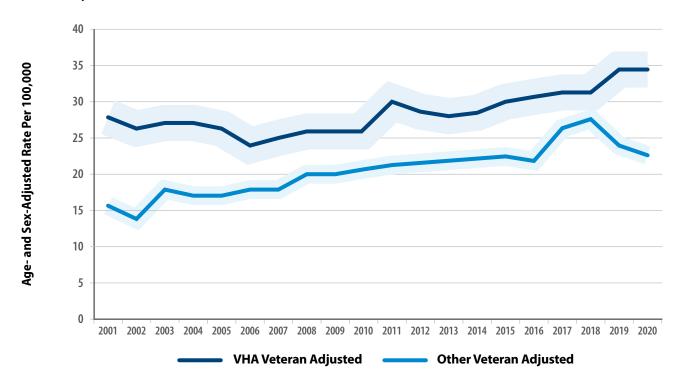


Table 4 on the next page presents focused comparisons, by sex, of age-adjusted suicide rates, for 2020 versus 2001 and for 2020 versus 2019.

• Adjusted rates rose substantially from 2001 through 2020 for Recent Veteran VHA Users and for Other Veterans. From 2019, age-adjusted rates rose only among Veteran men with recent VHA health care, while falling for Veteran women with recent VHA care and for both men and women Veterans who were not recent VHA users.

Table 4: Age-Adjusted Suicide Rates Per 100,000, Veteran VHA Users and Other Veterans, by Sex35

	2001	2020	Change	2019	2020	Change		
Recent Veteran VHA Users								
Men	43.4	52.2	+20.4%	50.1	52.2	+4.4%		
Women	13.6	16.8	+23.2%	19.1	16.8	-11.9%		
Other Veterans								
Men	23.3	34.1	+46.4%	35.1	34.1	-2.7%		
Women	8.3	13.9	+68.2%	16.2	13.9	-13.9%		

Mental Health and Substance Use Disorder Diagnoses

Ensuring access to mental health and substance use disorder services is a VHA priority and part of VA's *National Strategy* for Preventing Veteran Suicide.³⁶

- From 2001 to 2020, the prevalence of VHA mental health or substance use disorder (SUD) diagnoses among annual cohorts of Recent Veteran VHA Users rose from 27.9% to 41.9%.³⁷
- VHA mental health or SUD diagnoses were documented for 56.1% of Recent Veteran VHA Users who died from suicide in 2001 and for 58.0% of those who died in 2020.
- Among those who died from suicide in 2020, the prevalence of depression diagnoses was 35.2%, anxiety 25.6%, posttraumatic stress disorder (PTSD) 24.4%, alcohol use disorder 19.6%, cannabis use disorder 8.3%, bipolar disorder 7.5%, opioid use disorder 4.9%, personality disorder 4.6% and schizophrenia 4.5%.
- Conversely, 42.0% of Recent Veteran VHA Users who died from suicide in 2020 did not have a documented VHA
 mental health or substance use disorder diagnosis.
- The suicide rate among cohorts of Recent Veteran VHA Users with mental health or substance use disorder diagnoses fell from 77.7 per 100,000 in 2001 to 55.5 per 100,000 in 2020. By contrast, the rate among Recent Veteran VHA Users who did not have documented mental health or SUD diagnoses rose from 25.6 per 100,000 in 2001 to 29.8 per 100,000 in 2020.
- Trends in rates varied by condition. From 2001 to 2020, suicide rates fell 28.7% for patients with mental health/SUD diagnoses, while rising 16.6% for patients without documented diagnoses.
- From 2001 to 2020, suicide rates fell for Recent Veteran VHA Users with diagnoses of:
 - Mental health or SUD (-28.7%)
 - Depression (-38.6%)
 - Sedative use disorder (-38.5%)³⁸
 - PTSD (-29.2%)
 - Anxiety (-30.3%)

³⁵ Note: Rates in Tables 2 and 3 are not comparable. In Table 2, they are age- and sex-adjusted, while in Table 3, rates are age-adjusted, stratified by sex.

³⁶ https://www.mentalhealth.va.gov/suicide_prevention/docs/Office-of-Mental-Health-and-Suicide-Prevention-National-Strategy-for-Preventing-Veterans-Suicide.pdf

³⁷ Diagnoses were assessed in the year or prior calendar year. An individual's likelihood of having a documented diagnosis may vary by the number of VHA health care contacts in the relevant time period. VHA transitioned from International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), to ICD-10-CM diagnosis codes on Oct. 1, 2015. Diagnoses were not mutually exclusive, and analyses do not adjust for demographic differences or comorbidities.

³⁸ In 2001, there were 21 suicides among recent Veteran VHA Users with sedative use disorder. In 2020, there were 33.

- Alcohol use disorder (-15.2%)
- Substance use disorders (-10.5%)
- Bipolar disorder (-8.8%)
- Personality disorder (-3.5%)
- And rates rose for those with:
 - Opioid use disorder (+35.4%)
 - Cocaine use disorder (+34.3%)
 - Schizophrenia (+19.3%)
 - Cannabis use disorder (+16.0%)
 - Stimulant use disorder (+6.7%)

For 2019 and 2020 Recent Veteran VHA User cohorts, Table 5 below presents the number of suicide deaths and unadjusted suicide rates per 100,000.

• Overall, while suicide rates fell from 2019 through 2020 for those with any mental health or SUD diagnosis, suicide rates rose for those with any substance use disorders.

Table 5: Suicide Deaths and Rates Among Recent Veteran VHA Users, by Mental Health and SUD Diagnoses, 2019 and 2020

	SUICIDE	SUICIDE DEATHS		E RATES PER 1	00,000 ³⁹
Diagnoses ⁴⁰	2019	2020	2019	2020	Change ⁴¹
Without MH Condition/SUD	1,005	1,025	28.2	29.8	+1.7
With Any MH Condition/SUD	1,472	1,415	57.1	55.5	-1.7
Anxiety	650	625	68.8	64.8	-4.0
Bipolar disorder	185	184	109.5	111.4	+1.9
Depression	946	859	66.6	60.9	-5.7
Personality disorder	122	112	154.0	147.9	-6.1
Posttraumatic stress disorder	599	595	53.8	52.9	-0.9
Schizophrenia	81	109	87.4	123.5	+36.1
Substance Use Disorder	623	626	87.1	89.9	+2.8
Alcohol use disorder	491	478	89.9	90.1	+0.2
Cannabis use disorder	177	202	93.0	108.8	+10.2
Cocaine use disorder	63	67	64.6	74.8	+15.8
Opioid use disorder	108	119	114.4	133.1	+18.7
Sedative use disorder	38	33	195.1	185.8	-9.3
Stimulant use disorder	85	93	138.9	159.9	+21.0

³⁹ Suicide rates and change in rates are per 100,000 person-years.

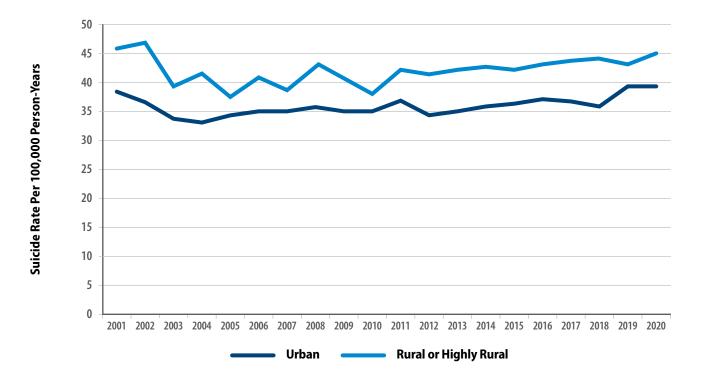
⁴⁰ Diagnosis categories are not mutually exclusive.

⁴¹ Calculated using non-rounded numbers.

Rurality

Among Veteran VHA Users, suicide rates were elevated for residents of rural areas, as compared to urban areas (Figure 16 below). For example, for individuals in rural or highly rural areas, the rate was 44.9 per 100,000 and it was 38.8 per 100,000 for those in urban areas. These differences may be partly attributed to demographic differences among Veteran VHA Users, by rurality status.⁴²

Figure 16: Unadjusted Suicide Rate Per 100,000 Person-Years, Recent Veteran VHA Users, by Urban, Rural or Highly Rural Status, 2001–2020



Previously documented differentials in suicide risk among VHA patients by rurality (McCarthy, J. F., Blow, F. C., Ignacio, R. V., Ilgen, M. A., Austin, K. L., & Valenstein, M. (2012). Suicide Among Patients in the Veterans Affairs Health System: Rural-Urban Differences in Rates, Risks and Methods. *American Journal of Public Health*, 102:S111-117.) may be substantially explained by demographic differences (Peltzman, T., Gottlieb, D. J., Levis, M., & Shiner, B. (2022). The Role of Race in Rural-Urban Suicide Disparities. *Journal of Rural Health*, 38(2), 346-354.). This interpretation was supported by supplemental analyses, not presented here, of trends in rates for combined annual VHA patient cohorts, 2016-2020, by race and Hispanic ethnicity status, stratified by rural/urban status. These document that between 2016 and 2020, the suicide rate in rural versus urban areas was 14.6% lower for American Indian or Alaska Native Veterans, 16.5% lower for Black Veterans, 2.7% higher for White Veterans, 3.8% higher for Native Hawaiian or Pacific Islander Veterans are not reported here, due to small numbers of suicide decedents.

Gender Identity

VA is working to enhance data resources to inform suicide prevention for Veteran subgroups by gender identity. Self-identified gender identity is the best approach for ascertaining gender identity, including transgender identity. However, current systems are not yet sufficiently developed for comprehensive reporting. Transgender Veterans—whose gender identity differs from the identity assumed by their assigned sex at birth—in VHA care are at increased risk for suicidal ideation⁴³ and non-fatal suicide attempts.⁴⁴ For this report, as a first step, we assessed a measure of transgender identity using diagnosis indicators⁴⁵ linked to transgender identity that are most often used in the context of gender-affirming therapy.⁴⁶

To enhance sensitivity of ascertainment, we generated annualized suicide rates, 2011-2019, for suicide in the year of interest through the end of the *subsequent* year, for recent Veteran VHA Users with a VHA diagnosis related to gender identity occurring in the year or the prior 3 years.

• The number of Veteran VHA patients with diagnoses related to gender identity increased from 2,515 in 2011 to 8,316 in 2019, and the unadjusted annualized suicide rate fell from 267.8 per 100,000 person-years in 2011 to 98.5 per 100,000 person-years in 2019 (Table 6 below).

Table 6: Suicide Rates Per 100,000 Person-Years, in the Year and Following Year, Veteran VHA Users with Diagnoses Related to Gender Identity in the Year or Prior 3 Years, 2011–2019*

Year	Veteran VHA Patients with Diagnoses Related to Gender Identity in Year or Prior 3 Years	Percentage of Veteran VHA Users	in γρατ	
2011	2,515	0.04%	13	267.8
2012	2,845	0.05%		
2013	3,313	0.05%		
2014	3,831	0.06%	10	134.6
2015	4,624	0.07%	12	133.1
2016	5,553	0.09%	11	101.7
2017	6,429	0.10%	17	136.2
2018	7,420	0.11%	17	118.0
2019	8,316	0.13%	16	98.5

^{*} Suppressed if number of suicides was less than 10

⁴³ https://www.va.gov/HEALTHEQUITY/docs/LGBT_Veterans_Disparities_Fact_Sheet.pdf

⁴⁴ Blosnich, J. R., Boyer, T. L., Brown, G. R., Kauth, M. R., & Shipherd, J. C. (2021). *Differences in Methods of Suicide Death Among Transgender and Nontransgender Patients in the Veterans Health Administration, 1999-2016*. 59:S31-S35.

⁴⁵ Diagnoses related to gender identity include ICD-9-CM codes 302.5, 302.6 and 302.85 and ICD-10-CM codes F64 and Z87.890.

⁴⁶ This approach likely undercounts the number of transgender Veterans in VHA care.

VHA Priority Eligibility Groups

Veterans who apply for VHA care are assigned to one of eight priority eligibility groups. Table 7 below presents unadjusted suicide rates per 100,000 person-years for annual cohorts of Veteran VHA Users, 2014-2020.⁴⁷ In 2020, the suicide rate was highest for Veterans in priority eligibility group 5, which includes income-based eligibility.

Table 7: Unadjusted Suicide Rates, Enrolled Recent Veteran VHA Users, by VHA Priority Eligibility Group, 2014–2020

	SUICIDE RATE PER 100,000 PERSON-YEARS			ON-YE	ARS	PRIORITY ELIGIBILITY GROUP CRITERIA		
	2014	2015	2016	2017	2018	2019	2020	
Group 1	39.4	41.8	38.8	38.8	39.7	40.2	39.9	Service-connected disability rated as 50% or more disabling, or have service-connected disability that makes one unable to work, or received the Medal of Honor.
Group 2	32.3	27.7	30.1	29.1	33.7	29.4	33.5	Service-connected disability rated as 30% or 40% disabling.
Group 3	29.7	31.8	31.8	32.9	32.9	34.6	28.8	Former prisoner of war, or received the Purple Heart medal, or were discharged for a disability that was caused by—or got worse because of—one's active-duty service, or service-connected disability rated as 10% or 20% disabling, or awarded special eligibility classification under Title 38, U.S.C. §1151, "benefits for individuals disabled by treatment or vocational rehabilitation."
Group 4	43.0	45.3	48.6	37.8	38.9	42.1	44.8	Are receiving VA aid and attendance or housebound benefits, or received a VA determination of being catastrophically disabled.
Group 5	51.2	49.4	51.1	52.4	48.9	51.5	52.0	Do not have a service-connected disability, or have a non-compensable service-connected disability rated as 0% disabling, and have an annual income level below our adjusted income limits (based on resident ZIP code), or receiving VA pension benefits, or eligible for Medicaid programs.
Group 6	22.9	25.1	21.1	25.7	32.3	28.8	33.6	Have a compensable service-connected disability rated as 0% disabling, or exposed to ionizing radiation during atmospheric testing or during the occupation of Hiroshima and Nagasaki, or participated in Project 112/SHAD, or served in the Republic of Vietnam between 1/9/1962 and 5/7/1975, or served in Persian Gulf War between 9/2/1990 and 11/11/1998, or served on active duty at Camp Lejeune 30+ days between 8/1/1953 and 12/31/1987. VA may also assign a Veteran to priority group 6 if they meet all of the requirements listed below. Veterans are: Currently or newly enrolled in VA health care, and served in a theater of combat operations after 11/11/1998, or were discharged from active duty on or after 1/28/2003, and were discharged less than five years ago. ⁴⁸
Group 7	35.7	39.9	44.8	35.7	36.0	44.7	33.5	Gross household income is below the geographically adjusted income limits (GMT) for where one lives and agrees to pay copays.
Group 8	37.8	37.8	39.3	38.9	36.4	41.1	46.1	Gross household income is above VA income limits and geographically adjusted income limits for where one lives, and agree to pay copays. Eligibility for VA health care benefits will depend on subpriority group.

⁴⁷ https://www.va.gov/health-care/eligibility/priority-groups/ Group 8 refers to subgroups A-D. Group 8EG (non-enrolled) is not reported, due to small numbers for most years. In 2020, Veteran VHA Users in group 8EG had 23 suicides and a suicide rate of 60.8 per 100,000 person-years. Reporting does not include Veterans whose eligibility was categorized as No Priority, per the VA Enrollment System Administrative Data Repository.

⁴⁸ Returning combat Veterans are eligible for these enhanced benefits for five years after discharge. At the end of this enhanced enrollment period, VA assigns Veterans to the highest priority group they qualify for at that time.

Lethal Means Involved, by Recent VHA Use

Table 8 below presents information on method of suicide among men and women Veterans, by recent VHA utilization status.

Table 8: Method of Suicide, Percentage, Veteran Suicide Decedents, by VHA Use and Sex⁴9

	2001	2020	Change	2019	2020	Change		
Recent Veteran VHA Users⁵0								
Men								
Firearm	66.6	73.6	+7.0	72.1	73.6	+1.5		
Suffocation	10.9	12.0	+1.1	14.3	12.0	-2.3		
Poisoning	14.2	7.9	-6.3	7.7	7.9	+0.2		
Other	8.3	6.4	-1.9	5.9	6.4	+0.5		
Women								
Firearm	27.0	50.0	+23.0	46.6	50.0	+3.4		
Suffocation		14.6		22.0	14.6	-7.4		
Poisoning	40.5	28.1	-12.4	27.1	28.1	+1.0		
Other								
Other Veterans								
Men								
Firearm	67.5	71.1	+3.6	69.7	71.1	+1.4		
Suffocation	15.1	16.4	+1.3	17.8	16.4	-1.4		
Poisoning	11.8	7.2	-4.6	7.2	7.2	0.0		
Other	5.6	5.3	-0.3	5.2	5.3	+0.1		
Women								
Firearm	40.2	47.2	+7.0	49.3	47.2	-2.1		
Suffocation	8.5	21.7	+13.2	19.4	21.7	+2.3		
Poisoning	43.6	26.1	-17.5	27.8	26.1	-1.7		
Other								

⁴⁹ Information is not presented when based on fewer than 10 deaths, indicated by "---."

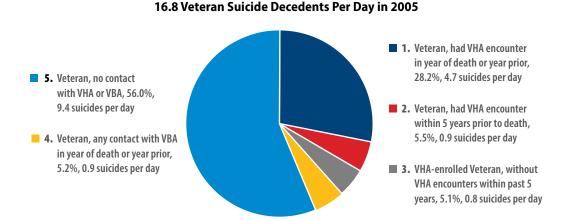
⁵⁰ With VHA health care encounters in the year or prior year.

Suicide Decedents in 2005 and 2020: Contacts with VHA and VBA

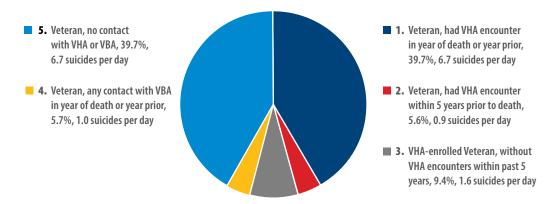
This section presents new analyses regarding points of VA contact by Veteran decedents, including VHA health care encounters, VHA enrollment and VBA contacts. We present findings for the 6,123 Veterans who died from suicide in 2005 and the 6,146 Veterans who died from suicide in 2020.⁵¹

As indicated in Figure 17 below, while most Veteran suicide decedents in 2005 (56.0%) did not have VHA health encounters in the prior 5 years, VHA enrollment or VBA contacts in the year of death or prior year, for Veterans who died by suicide in 2020, only 39.7% did not have any of these indications of VA contact. Veteran suicide decedents in 2020 were more likely than those in 2005 to have received VHA health care encounters and to have VHA enrollment.

Figure 17: Veteran Suicide Decedents in 2005 and 2020, Sequential Mutually Exclusive Categories of VA Points of Contact, Percentage and Average Suicides Per Day⁵²







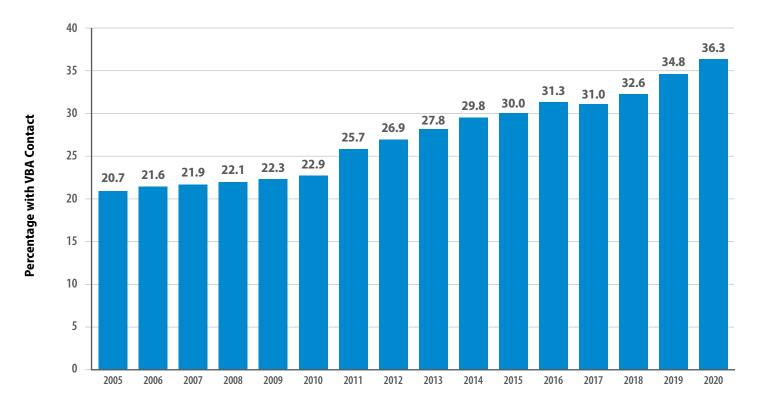
As background, this report shows that for Veterans who died from suicide in 2005, 28.2% had received VHA health care encounters in the year or prior year and 71.8% had not. For Veterans who died from suicide in 2020, 39.7% had recent VHA health care encounters and 60.3% had not. However, recent health care encounters represent only one measure of contact with the Department of Veterans Affairs. To consider VA points of contact more broadly, this section describes the distribution of Veteran suicide decedents across sequential, mutually exclusive categories of VA contact. These categories were, in order, recent VHA health care encounters, then contacts in the prior five years, then VHA enrollment, and, finally, contacts with VBA in the year of death or prior year. In each year, there were on average approximately 17 Veteran suicides per day. The figures below describe the distribution of Veteran suicide decedents across categories in terms of a percentage and in terms of average suicide deaths per day.

⁵² Sequential mutually exclusive categories of VA points of contact are ordered from 1 to 5.

Suicide Decedents, VBA Contact

Figure 18 below shows the prevalence of VBA contact among annual cohorts of Veteran suicide decedents, 2005-2020. This rose from 20.7% in 2005 to 36.3% in 2020.

Figure 18: VBA Contact in the Year or Year Prior Among Veteran Suicide Decedents, 2005–2020

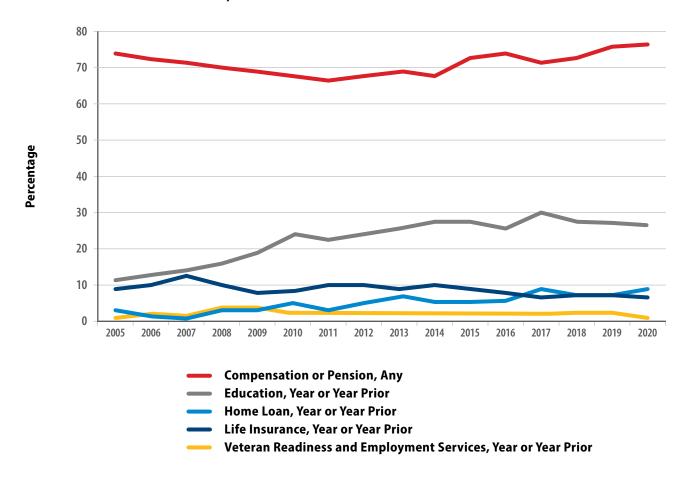


Suicide Decedents with Recent VBA Contact, VBA Services Received

Figure 19 below shows the prevalence of receipt of five non-mutually exclusive categories of VBA services by Veteran suicide decedents who had some VBA contact in the year of death or prior year. Of note, among Veteran suicide decedents with VBA contact, the percentage who received:

- Education-related benefits increased from 12.4% in 2005 to 28.2% in 2020
- Home loans increased from 2.6% in 2005 to 7.8% in 2020
- Life insurance decreased from 9.1% in 2005 to 6.3% in 2020

Figure 19: VBA Services Receipt Prior to Death Among Veteran Suicide Decedents with VBA Contact in the Year or Year Prior to Death, 2005–2020



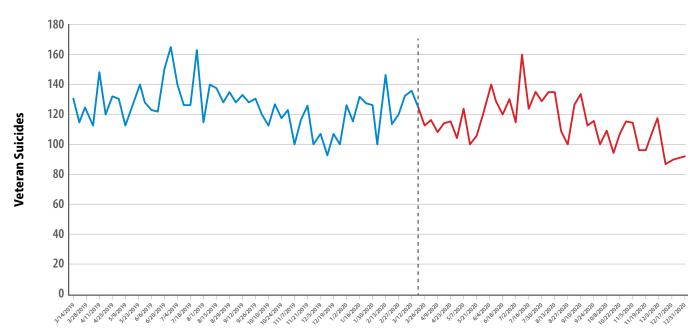
Part 3: COVID-19 Pandemic: Suicide Surveillance

VA has tracked VHA indicators of suicide-related behaviors prior to and following the start of the COVID-19 pandemic.⁵³ In the present report, using 2020 national death certificate data, we report on suicide mortality for the entire Veteran population.

Suicide Deaths, Pre- and Post-Pandemic Declaration

Figure 20 below shows the number of Veteran suicide deaths, by week, from 12 months prior to the declaration of the COVID-19 pandemic through 2020.

Figure 20: Veteran Suicide Deaths, by Week, 12 Months Prior to Onset of the COVID-19 Pandemic, Through 2020



- Trend analyses did not identify associations between onset of the pandemic and Veteran suicide mortality.⁵⁴
- Decreased Veteran suicide in 2020 continued a trend that began in 2019. This pattern was not associated with the COVID-19 pandemic in 2020.

Among Recent Veteran VHA Users, suicide rates were elevated among those with mental health or substance use disorder diagnoses. By contrast, COVID-19 mortality rates were more elevated among patients with chronic medical conditions.

In summary, our assessment of trends in Veteran suicide mortality and comparisons to patterns of Veteran COVID-19 mortality, both over the course of 2020 and across demographic and clinical subgroups, did not identify signals of an impact of the COVID-19 pandemic on Veteran suicide mortality.

U.S. Department of Veterans Affairs, Office of Mental Health and Suicide Prevention. (September 2021). 2021 National Veteran Suicide Prevention
 Annual Report. https://www.mentalhealth.va.gov/docs/data-sheets/2021/2021-National-Veteran-Suicide-Prevention-Annual-Report-FINAL-9-8-21.pdf.
 U.S. Department of Veterans Affairs, Office of Mental Health and Suicide Prevention. (November 2020). 2020 National Veteran Suicide Prevention Annual Report. https://www.mentalhealth.va.gov/docs/data-sheets/2020/2020-National-Veteran-Suicide-Prevention-Annual-Report-11-2020-508.pdf

⁵⁴ Trend analyses using Joinpoint did not identify changes in suicide mortality for Veterans or for non-Veteran U.S. adults, or, among Veterans, for Recent Veteran VHA Users or for Other Veterans.

Part 4: Next Steps in VA's Implementation of a Full Public Health Approach

Core Tenets and Guiding Vision

VA's three core tenets for suicide prevention continue to remain the foundation of our efforts to implement the National Strategy (2018), VA/DoD CPG for the Assessment and Management of Patients at Risk for Suicide (2019), and the White House strategy for Reducing Military and Veteran Suicide (2021):

- Suicide is preventable.
- Suicide prevention requires a public health approach combining clinical and community-based approaches.
- Everyone has a role to play in suicide prevention.

Our work involves a whole of Government and whole of Nation approach as Veteran suicide is a complex problem that cannot be addressed through a singular solution, nor can it only be addressed by VA or clinical intervention alone. Our data this year again confirms the need for including community prevention, alongside clinical interventions, in our public health approach. The vast majority of Veterans who died by suicide in 2020 were not recent VHA users (60.3%) and community approaches must be utilized to reach all Veterans, not just those within the VA system. Further, mental health solutions alone will not address Veteran suicide, particularly with 42.0% of Recent Veteran VHA Users who died from suicide in 2020 not having a documented VHA mental health or substance use disorder diagnosis. Unemployment, chronic pain, insomnia, relationship strain, homelessness and grief are examples of factors outside of mental health that may play a role in suicide. We must also move beyond the individual factors in suicide and look to address broader international, national, community and relational factors that play a role (e.g., inadequate access to care, global health concerns, war, economic crises, homelessness).⁵⁵

The White House strategy for *Reducing Military and Veteran Suicide* (2021) builds upon prior foundational efforts at the national level, including prior executive orders and the 2012 *National Strategy for Suicide Prevention*, along with its adaptation to military populations in 2015 and Veteran populations in 2018. This strategy's five major priority goals include:

- 1. Improve lethal means safety;
- 2. Enhance crisis care and facilitate care transitions;
- 3. Increase access to and delivery of effective care;
- 4. Address upstream risk and protective factors; and
- 5. Increase interagency research management, data sharing and evaluation efforts.

The priority goals here have been cross walked with VA's National Strategy to ensure alignment and operationalization of these goals along with the four directions of the National Strategy, including:

- 1. Healthy and Empowered Veterans, Families and Communities
- 2. Clinical and Community Prevention Services
- 3. Treatment, Recovery and Support Services
- 4. Surveillance, Research and Evaluation

⁵⁵ Turecki, G., & Brent, D. A. (2016). Suicide and suicidal behavior. *Lancet*, 387(10024), 1227-39.

VA has worked with its Federal partners to reinvigorate the Interagency Task Force on Military and Veterans Mental Health with the purpose of operationalizing the new strategy on military and Veteran suicide prevention. The 2012 Executive Order 13625, Improving Access to Mental Health Services for Veterans, Service Members and Military Families, established the Interagency Task Force on Military and Veterans Mental Health. The interagency task force (ITF) is focused on facilitating interagency collaboration, expanding staffing capacity at the Veteran Crisis Line and joint development of a national suicide prevention campaign focused on connecting Veterans and Service members to resources and support. In 2022, this ITF updated its charter to incorporate both targeted partnerships and overarching priority goals from the *Reducing Military and Veteran Suicide* strategy (White House, 2021). In conjunction with this ITF, VA continues to operationalize the National Strategy, White House Strategy and the 2019 CPG through the combined work of community and clinical strategies through SP 2.0 and SP Now initiatives along with demonstration projects, new innovations and implementation of recently enacted laws.

Community Prevention Highlighted Efforts

SP 2.0 Community Efforts

The SP 2.0 Community-Based Interventions for Suicide Prevention (CBI-SP) model reaches Veterans through facilitating community coalitions focused on ending Veteran suicide, thereby extending VA's reach to Veterans not being touched by VHA or VBA services. The program incorporates:

- State Governor's Challenge initiatives;
- · Together With Veterans rural peer-to-peer model; and
- VHA Community Engagement and Partnerships Coordinators.

This evidence-informed model focuses on three key priority areas, which reflect both the National Strategy (2018) and recent White House Strategy (2021):

- 1. Identify Service Members, Veterans and Their Families and Screen for Suicide Risk;
- 2. Promote Connectedness and Improved Care Transitions; and
- 3. Increase Lethal Means Safety and Safety Planning.

As of July 2022, 48 states and 5 territories are participating in the Governor's Challenge. By the end of fiscal year (FY) 2022, all 18 VHA Veterans Integrated Service Networks (VISN) will have CEPCs working with communities, and all states will be engaged in a comprehensive effort working to end Veteran suicide. Together with Veterans⁵⁶ is now established in 27 rural communities and has reached over 200,000 Veterans. As of August 2022, there are now more than 600 community coalitions actively working under the unifying community-based suicide prevention model with over 100 CEPCs already working in the field, expanding the critical efforts of our suicide prevention coordinators within the VHA system.

Through April 2022, the Don't wait. Reach out. campaign had a donated media value of \$5.1 million, showing a 132% return on investment, and over 475 million impressions. Likewise, the Keep It Secure campaign has generated over one billion impressions this fiscal year, and ongoing lethal means safety messaging focused on firearm safety will launch in FY 2023. The VCL campaign from February 2020-March 2022 reached over 1.8 billion impressions and launched 988 external messaging after the launch of Dial 988 then Press 1 on July 16, 2022.

Communication Campaigns

VA has emphasized three paid media campaigns as part of its efforts to reach all Veterans: 1) Don't wait. Reach out.;
2) Keep It Secure; and 3) the Veterans Crisis Line (VCL). To develop the Don't wait. Reach out. campaign, VA entered into an

⁵⁶ Together With Veterans (TWV) - MIRECC / CoE (va.gov)

agreement with the Ad Council, a national non-profit organization that uses donated communication industry resources to elevate messaging. The campaign strategy was informed by extensive research with Veterans and portrays real Veterans in all videos. The Keep It Secure campaign is a national public health campaign addressing the need for secure storage of firearms as part of suicide prevention. Finally, the VCL campaign works to reach Veterans and those who love them with 24/7 support during times of crisis. All three campaigns have exceeded performance expectations in FY 2022.

Staff Sergeant Parker Gordon Fox Suicide Prevention Grant Program

The 2020 Commander John Scott Hannon Veterans Mental Health Care Improvement Act (Hannon Act) also expands access to critical mental health care resources. Section 201 of the Hannon Act established the Staff Sergeant Parker Gordon Fox Suicide Prevention Grant Program, allowing VA to provide grants to eligible entities to expand suicide prevention services to eligible individuals and their families to reduce the risk of suicide. Community organizations can apply for grants worth up to \$750,000 and may apply to renew awards from year-to-year throughout the length of the program. The first applications were due in June 2022 and the first awards will be issued in September 2022. A robust evaluation program has simultaneously been developed to assess lessons learned for future applications.

Community Collaborations

VA collaborates closely with Veterans Service Organizations (VSO) and other entities that support suicide prevention efforts by facilitating opportunities, such as sharing and promoting content and materials or coordinating guest speakers at stakeholder events. VA works with organizations to promote social connectedness and provide resources through online platforms and mobile apps. These resources are ready for use now and are no cost to Service members, Veterans, their caregivers or families. VA also collaborates with state and local governments through the programs within CBI-SP, including the Governor's Challenge initiative. The coalitions and teams that are supported by CBI-SP include various nongovernmental organizations, such as VSOs, nonprofit organizations, faith-based community groups, academic affiliates, public safety agencies, businesses and state and local hospital systems.

One example of collaboration is VA's work with the PsychArmor Institute to launch a free, online suicide prevention training designed to help equip anyone who interacts with Veterans to demonstrate care, support and compassion when talking with a Veteran who could be at risk for suicide. VA is also working with the National Shooting Sports Foundation (NSSF) to produce videos focused on firearm safety, increase gunlock distribution and expand lethal means safety (LMS) training to community providers. Further, VA released a toolkit, *Suicide Prevention is Everyone's Business: A Toolkit for Safe Firearm Storage in Your Community*, developed in collaboration with the American Foundation for Suicide Prevention and NSSF to raise awareness about safe storage practices for local communities.

Clinical Intervention Highlighted Efforts

SP 2.0 Clinical Telehealth

In addition to community-based efforts, advancing the dissemination of evidence-based clinical practices for suicide prevention across the VHA system is critical. SP 2.0 Clinical Telehealth offers evidence-based psychotherapies, as outlined in the VA/DoD 2019 CPG, to Veterans with recent suicidal self-directed harm. This program ensures access to the following therapy interventions with the greatest evidence for impacting suicide: Cognitive Behavioral Therapy for Suicide Prevention (CBT-SP); Problem-Solving Therapy for Suicide Prevention (PST-SP); Dialectical Behavior Therapy; and the Safety Planning Intervention. Because the program uses a virtual care platform (video telehealth), it allows Veterans the opportunity to access treatment without leaving their homes, which is particularly helpful in a pandemic. As of April 2022, VA has hired 97 therapists and received over 3,000 consults for services.

SP NOW Initiative-Clinical Interventions

As noted above, SP Now is working to strengthen clinical suicide prevention initiatives in VHA. Suicide Prevention in the Emergency Department (SPED) has significantly improved implementation of this program, with 92% of Veterans who present to the emergency department (May 2022) engaged to develop a post-discharge safety plan compared with 60% in January 2020. This practice, through the new White House Strategy (2021), is being adapted to community hospital settings as part of a new integrated project team (IPT). Recovery Engagement and Coordination for Health – Veterans Enhanced Treatment (REACH VET) is exceeding benchmarks for all five performance metrics, with ongoing work to further strengthen the algorithm and expand the reach of impact. Enhanced implementation of universal suicide risk screening for Veterans, as outlined in the VA/DoD CPG,⁵⁷ is another critical effort in the SP Now initiative. SP Now clinical enhancements have also been made to further strengthen interventions for Veterans with a High Risk for Suicide Patient Record Flag (HRS-PRF), including: enhancing standard operating processes for flag management for consistency across the VHA enterprise; developing an e-consult to further standardize processes to refer Veterans at high risk for suicide for consideration of HRS-PRF placement; creating a standard progress note template to enhance completion of HRS-PRF referrals; and documenting all flag actions, including improved utilization of flag inactivation criteria.

SP Now implemented a systemic effort at the start of the pandemic to provide outreach and support to Veterans at high risk for suicide who have screened or tested positive for COVID-19. The Suicide Prevention Population Risk Identification and Tracking for Exigencies dashboard was utilized to identify and assist providers to identify and track this vulnerable group of Veterans. In May 2022, outreach was attempted to 93% of identified Veterans, with 83% of those Veterans receiving successful outreach.

Innovation Efforts, Research and Ongoing Statutory Implementation

Innovation Efforts

In FY 2022, VA's Suicide Prevention Program launched several demonstration projects to expand its public health approach through innovations. These projects were strategically aligned with priorities of both the VA *National Strategy for Preventing Veteran Suicide* (2018) and White House strategy on *Reducing Military and Veteran Suicide* (2021). Projects focus upon addressing individuals at risk for suicide across universal, selective and indicated categories and emphasize: 1) activation and engagement; 2) collaborations with key stakeholders—both within and outside the Federal Government; 3) amplifying dissemination of evidence-based strategies; 4) targeted and tailored approaches for reaching subpopulations (e.g., Native Veterans, Asian American/Pacific Islander Veterans, geriatric populations, homeless Veterans); and 5) continuous quality improvement with an emphasis on the efficacy of intervention, prevention and education efforts.

FY 2022 Suicide Prevention Demonstration Projects

- Acceptance and Commitment Training for Health Care Providers
- Assessing Social and Community Environments with National Data for Veteran Suicide Prevention
- CAT 2.0: Implementing Computerized Adaptive Testing (CAT) for Mental Health in Primary Care Mental Health Integration
- Clinical Practice Guidelines for Suicide Prevention
- Community-Based Early Intervention for Veterans at Risk of Unemployment and Suicide: A Demonstration Project for Supported Employment: Engage and Keep
- Conducting a national program evaluation of new suicide prevention methods within Coaching into Care

⁵⁷ Department of Veterans Affairs and Department of Defense. (2019). *VA/DoD clinical practice guideline for the assessment and management of patients at risk for suicide*. https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf

- Developing Artificial Intelligence Methods to Identify Firearm and Substance Use Risk Factors
- Enhancing Risk ID and SPED Among Homeless Veterans Accessing VHA Emergency Services ("Homeless SPED")
- Improving Safe Firearm Storage in Veterans Through Involving a Concerned Significant Other: A Feasibility and Acceptability Pilot
- Suicide Among Older Veterans: Addressing Firearm Safety
- Examination of the Implementation of High-Risk Flags for Suicide Prevention
- Internet-Delivered Cognitive Behavioral Therapy to Prevent Suicide in Veterans
- Optimizing the Use and Dissemination of Brief Cognitive Behavioral Therapy for Insomnia for the Purpose of Suicide Prevention
- Prevention, Recovery and Emergency Preparedness: Empowering Veterans to Promote Community Resilience (Empowering Veterans)
- Examining the Effectiveness of an Adaptive Implementation Intervention to Improve Uptake of the VA Suicide Risk Identification Strategy
- Centralizing Caring Communications Pilot-REACH VET
- Veterans Caring Buddies: Empowering Veterans to have conversations with Veteran buddies about lethal means safety as a community approach to suicide prevention
- Measuring Feasibility and Effectiveness of a Lethal Means Safety Suicide Prevention Module in Concealed Carry & Firearm Safety Classes in Louisiana
- Understanding Suicide Risk and Enhancing Suicide Prevention Among Asian American and Pacific Islander Veterans
- Veteran Outreach into the Community to Expand Social Support
- Understanding the impact of mental health clinic capacity and efficiency fluctuations on suicide-related events
- Optimizing a Low-Cost, Low-Burden Self-Help Crisis Intervention to Improve Mental Health and Reduce Suicidality Among At-Risk Primary Care Patients During Crisis
- Native Veteran Suicide Prevention: Tribal VHA partnerships for suicide prevention
- The Use of Peers to Extend Treatment Beyond the VA Walls, Promote Treatment Engagement and Reduce the Risk for Suicide
- The Community Context of Suicidal Behavior—Geospatial Mapping and Community-Based Interventions

Special Projects

- National Center for Veteran Financial Empowerment
- Implementation of Primary Care—Mental Health Integrated Collaborative Care Management and Behavioral Health Interdisciplinary Program Mental Health Care Coordination
- Integration of Mental Health into Pain Clinics: A prevention, early intervention and education pilot
- Integration of Mental Health in Oncology Clinics: A prevention, early intervention and education pilot
- Short-term evidence-based PTSD treatments in residential care settings

Mission Daybreak

In addition to these demonstration projects, VA launched "Mission Daybreak," a Suicide Prevention Grand Challenge that provides an opportunity to support outside entities, such as academia, industry experts, nonprofits, health innovators, technologists and community partners, to engage innovative solutions for Veteran suicide prevention. Through this \$20 million prize competition, submissions were encouraged in potential areas of focus, such as:

- Utilizing digital life data and early warning systems for suicide prevention;
- · Creating improved access to and efficiency of VCL services through technological innovations; and
- Preventing firearm suicide and enhancing lethal means safety for suicide prevention.

Initial submissions were due July 8, 2022, as part of Phase I, with finalists being announced to move into Phase II in the early fall and final winners announced in late 2022.

Research and Program Evaluation

Research and program evaluation are critical for VA's advancement of new innovations in suicide prevention, as well as continuing implementation of current initiatives through ongoing assessment for needed improvements and new directions. VA's Suicide Prevention Program works closely with VA's Rocky Mountain Mental Illness Research Education and Clinical Center, VISN 2 Center of Excellence for Suicide Prevention and VA's Office of Research and Development. This includes a regular assessment of VA's suicide prevention research portfolio to review alignment with the National Strategy and assessing the need for new research priorities; for example, expansion in a focus on lethal means safety and community-based suicide prevention efforts. VA's Suicide Prevention Program also regularly coordinates with its research center partners to translate new research findings into practice. Recent examples of these collaborations include the work with REACH VET and SPED, with ongoing shared efforts to support the field through technical assistance, consultation, and ongoing monitoring and feedback during national rollouts.

Ongoing development and implementation of robust program evaluation is critical for successful rollout of VA's suicide prevention initiatives. For example, VA has created a robust program evaluation for SP 2.0 involving an interrupted time series and a modified stepped wedge design, which VA can use to assess short-term and intermediate outcomes of programs and surveillance data to evaluate population impact. These outcomes will not only inform implementation of a public health approach for suicide prevention in VA, but also the broader national work in suicide prevention. Likewise, VA's Suicide Prevention Program has worked with national experts in program evaluation to develop and now implement an in-depth evaluation of the Staff Sergeant Parker Gordon Fox Suicide Prevention Grant Program efforts to further inform our work in community-based initiatives. VA also incorporates program evaluation into our demonstration projects to inform opportunities for potential rollout nationally. Recently, VA's Suicide Prevention Program early demonstration pilot work showed the success of telehealth delivery of CBT-SP, supporting the decision to later implement this nationally through SP 2.0.

Ongoing Statutory Implementation

VA's suicide prevention efforts are also further advanced through ongoing implementation of new statutory authority. The National Suicide Hotline Designation Act of 2020 (P. L. 116-172) established a national 3-digit emergency number to simplify access to crisis services, replacing the full 1-800-273-8255 National Suicide Prevention Hotline number (press 1 to reach the VCL) with 988 (press 1 to reach the VCL). Full implementation of 988 by all telephone carriers was required by July 16, 2022, and provided a way to increase access to crisis services with an easy number to remember, similar to 911. The VCL increased responder staff by 56% to prepare for 988 implementation and ongoing hiring is underway. Additionally, to prepare fully for 988 increased demand, several VCL initiatives were implemented to improve access across IT modernization, complex caller interventions and air traffic control efficiency. These improvements have resulted in decreased outage time for technology issues, a reduction in abandoned calls (-22.58%), rollover rate reduction (-29.45%)

and reduction in answer time (-7.30%), translating into improved access for Veterans working to reach the VCL during times of crisis. Further, the VCL expanded beyond call support over the past 2 years, including implementation of Caring Letters and establishment of a new Peer Support Outreach Center (PSOC), providing extended reach of VCL interventions. Through Caring Letters, Veterans receive nine letters over the course of a year after their call to the VCL. This is an evidence-based practice recommended as part of the VA/DoD CPG. Since its launch in June 2020, the VCL has mailed over 900,000 Caring Letters to over 140,000 Veterans; approximately 95,600 of those letters were mailed to Veterans for Veterans Day (data through February 2022). The VCL also launched PSOC in May 2021, with the mission to provide support, hope and recovery-oriented services to Veterans who are identified at increased risk for suicide. PSOC provides compassionate outreach via phone services with several calls to identified Veterans over several months after their call to the VCL. PSOC is staffed by VHA peer specialists who are Veterans in recovery from a substance use or mental health disorder and who provide support, hope and recovery-oriented support to Veteran populations.

The Veterans Comprehensive Prevention, Access to Care and Treatment Act of 2020 (COMPACT Act of 2020, P. L. 116-214) includes provisions related to transitioning Service members, suicide prevention and crisis services, mental health education and treatment and improvement of services for women Veterans. Section 201 of the COMPACT Act requires VA to furnish emergent suicide care at either VA or community facilities, including through reimbursement, to eligible individuals. VA estimates that an additional nine million Veterans could qualify for benefits under this authority, roughly doubling the amount of existing and available services.

Next Steps Together

Enterprise-Wide Efforts: VHA, VBA, NCA

Critical to suicide prevention efforts is reaching across all VA administrations to expand our ability to engage Veterans across the system. VA suicide prevention efforts are coordinated across the enterprise, including required VA S.A.V.E.⁵⁸ training for every VA employee. Additionally, VA is addressing the risk factors of unemployment or underemployment, financial insecurity, disabilities (including physical and mental health), lack of access to care and recent transition from military service to civilian life with work within VBA and in coordination with VHA. VBA's provision of benefits and services can address or reduce some of these risk factors by enhancing vocational and financial well-being as well as providing support during higher risk times of transition from the military through programs like Transition Assistance Program and Solid Start. Likewise, VA's disability compensation and pension benefits, which provide financial support for Veterans, and Loan Guaranty Service, which assists Veterans and Service members in obtaining, retaining and adapting homes, are components of suicide prevention. Further, efforts through the Education/GI Bill, Veteran Readiness and Employment, and Personalized Career Planning and Guidance programs assist Veterans in establishing and achieving education and employment goals that serve as further protective factors. VBA has strongly partnered with the expansion of data surveillance allowing increasing reporting on data, as shown in this annual report, which assists with providing further direction to suicide prevention efforts nationwide.

Additional initiatives have also been launched to further address the economic concerns that factor into suicide risk. In 2018, VHA launched Financial Hardship Assistance Program for High-Risk Veterans, a suicide prevention pilot project targeting VA-debt issues among high-risk Veterans. Facilities were encouraged to design intake/screening assessments to incorporate a standardized question about VA indebtedness for Veterans who were identified as high-risk. Suicide Prevention Coordinators (SPCs) then connected Veterans with facility revenue staff who work personally with Veterans to apply for a VA financial hardship program. The program remains active in encouraging site SPCs and revenue staff to collaborate on Veteran identification and support.

As part of VA's response to the COVID-19 pandemic, debt collection for Veterans was temporarily put on hold. To ensure Veterans would have appropriate access to necessary risk mitigation strategies, VA created a toolkit for the field to use to support Veterans who would be receiving these letters and provide them with a variety of debt resolution resources.

⁵⁸ VA S.A.V.E. training consists of: 1) Signs of suicidal thinking; 2) Ask the question; 3) Validate the Veteran's experience; and 4) Encourage treatment and Expedite getting help.

Additionally, education was provided regarding the debt collection process, debt resolution resources and the toolkit to all facility SPCs and the VCL. Further, in 2020 and 2021, VA's Office of Mental Health and Suicide Prevention funded a pilot project, to support Veterans at risk for financial distress, by developing a resource guide and financial literacy programming. This work has informed and led to the development of the National Center for Veteran Financial Empowerment. This center will provide Veterans with support and resources for their unique financial needs. VA is currently hiring a director to lead this center and a full launch for the program is underway. In addition to these advances, the last 2 years have seen closer collaboration with suicide prevention efforts in NCA. Gun lock distribution will launch later this year across all NCA cemeteries. NCA is also expanding suicide prevention training materials for all their sites accessible to individuals who visit NCA cemeteries. Enterprise-wide efforts are critical to ongoing implementation of the full National Strategy.

A Fully Engaged Nation in Veteran Suicide Prevention

Perhaps what is most encouraging at present is the large outpouring of support and desire to act in Veteran suicide prevention across Federal agencies and broadly into communities. This is palpably seen in the work of the U.S. Domestic Policy Council and its interagency efforts in suicide prevention and leadership in launching the White House *Reducing Military and Veteran Suicide* strategy this past fall (2021). Federal agencies are working in a unified manner to share best practices and move forward focused priorities across the Nation. We also see this specifically in the work of the renewed IPT charged with implementing the full strategy.

Additionally, great progress has been made with engaging 48 states and over 500 local suicide prevention coalitions in the work of Veteran suicide prevention. Collaborations continue to expand with new support from broader communities like the firearm industry and technology innovators. Suicide cannot be addressed solely by mental health clinicians, and VA is encouraged to see the wider community embracing this awareness that suicide is not simply a mental health problem. A recent analysis of 365 research studies across 50 years found that mental health indicators were only weakly correlated with suicide or suicide attempts.⁵⁹ While mental health concerns contribute to the risk for suicide, broader societal issues must be addressed.⁶⁰ Identifying those solutions focused on the individual alone will not solve the broader problem of suicide. Societal interventions can address broader risk beyond the individual level (e.g., LMS efforts, communication campaigns). VA, along with other health care systems, must engage new models of care, involve those outside the walls of a clinic and address broader systemic issues through community-based efforts, public health campaigns, education, focused strategic community coalition development and other collaborations.

Further, we must continue to expeditiously and strategically advance implementation of evidence-based clinical interventions focused specifically on suicide prevention^{61,62} while continuing to innovate and study new interventions in clinical settings. Access to evidence-based interventions inside and outside the VA system for Veterans at risk for suicide requires significant expansion, and part of our work together with the White House strategy for *Reducing Military and Veteran Suicide* is considering new models of access to care. In collaboration with the National Academies of Sciences, Engineering and Medicine and experts in access across the Nation, we will need to work to study new models of access that we can test across our system to ensure Veterans can take advantage of these evidence-based treatments. Finally, we need everyone at the table, leveraging work within and outside of clinical health care delivery systems to decrease both individual and societal risk factors for suicide. The public health approach reminds us that what we do can and does make a difference.

To refer to this report, please use the following citation:

U.S. Department of Veterans Affairs, Office of Mental Health and Suicide Prevention. 2022 National Veteran Suicide Prevention Annual Report. 2022. Retrieved {insert date} from https://www.mentalhealth.va.gov/suicide_prevention/data.asp.

⁵⁹ Franklin, J. C., Ribeiro, J. D., Fox, K. R., Bentley, K. H., Kleiman, E. M., & Huang, X., et al. (2017). Risk Factors for Suicidal Thoughts and Behaviors: A Meta-Analysis of 50 Years of Research. *Psychol. Bull*, 143(2), 187-232.

⁶⁰ Turecki, G., & Brent, D. A. (2016). Suicide and suicidal behavior. *Lancet*, 387(10024), 1227-39.

⁶¹ Bryan, C. J. (2021). Rethinking Suicide: Why Prevention Fails, and How We Can Do Better. Oxford University Press.

⁶² Department of Veterans Affairs and Department of Defense. (2019). VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide. https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf

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VA research on

Depression

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Introduction

Depression causes sadness, loss of interest in activities people once enjoyed, withdrawal from others, and have little energy. Depression can also cause people to feel hopeless about the future and even think about suicide.

According to the National Institute of Mental Health (NIMH), major depression is one of the most common mental disorders in the United States, and it carries the heaviest burden of disability among mental and behavioral disorders. In 2014, NIMH <u>estimated</u> that some 15.7 million adults aged 18 or older in the United States had at least one major depressive episode in the past year. This number represented 6.7 percent of all U.S. adults.

Most experts believe a combination of genes and stressful life events can cause depression. Health problems such as anemia or an underactive thyroid gland can also lead to depression, as can certain medicines, such as steroids or narcotics.

Most people who experience depression need treatment to get better. The good news is that depression, even in its most severe forms, is a highly treatable disorder.

In 2008, VA <u>estimated</u> that about 1 in 3 Veterans visiting primary care clinics has some symptoms of depression; 1 in 5 has serious symptoms that suggest the need for further evaluation for major depression; and 1 in 8 to 10 has major depression, requiring

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Selected Major Accomplishments

treatment with psychotherapy or antidepressants.

- **2006:** Developed, through VA's TIDES project, an evidence-based collaborative approach to depression management
- 2006: Began the <u>Heart and Soul Study</u>, on how psychological factors influence the outcomes of patients with coronary heart disease
- 2008: <u>Demonstrated</u> that the link between depression and heart disease may hinge largely on behavioral factors associated with depression, such as lack of exercise and increased smoking
- 2012: <u>Found</u> that serotonin and norepinephrine reuptake inhibitors (SNRIs) may be more effective in treating depression symptoms than drugs that affect only serotonin (SSRIs)
- 2015: <u>Learned</u> that talk therapy delivered by two-way video calls is at least as effective as in-person treatment delivery for older Veterans with depression

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New, Ongoing, and Published Research

VA researchers are making important headway in treating, screening, and diagnosing depression and other mood disorders such as bipolar disorder, persistent despondency, and seasonal affective disorder.

Researchers are developing models of family interventions and social support to help Veterans recover from mood disorders, learning which risk factors make a person more likely to suffer from depression or to respond positively to a specific medication, and identifying and testing potential new drugs for depression and other disorders.

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➤ Depression among Veterans and non-Veterans

A team from the VA Palo Alto Health Care System and Stanford University School of Medicine <u>examined</u> data on 7,000 men age 50 or older in a study published in 2014, and found that Veterans were no more likely than non-Veterans to have depression or anxiety.

Because Veterans, especially those who served in combat, have generally experienced more stress and trauma in their lives than non-Veterans, the team had expected to see higher rates of depression among Veterans. Instead, they found just the opposite. Older Veterans actually scored better than non-Veterans in the same age group.

The team found 11 percent of Veterans reported elevated rates of depression, compared with 12.8 percent of non-Veterans. For anxiety, 9.9 percent of Veterans reported elevated levels, versus 12.3 percent



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New VA study to determine best drug for Veterans with treatment resistant depression



Genetic testing may benefit patients with depression

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for non-Veterans. These differences were not considered statistically significant.

Vietnam Veterans, however, were twice as likely to have elevated depression and anxiety than World War II or Korean War Veterans in the study. The team suggested further studies are needed to determine why this was true.

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➤ The TIDES project

VA researchers have learned that a team approach to providing care can improve the management of mental health conditions, as it has also been shown to do for other illnesses. VA's <u>TIDES</u> project demonstrated the value of an evidence-based collaborative approach to depression management that has now been successfully incorporated into the VA system. (TIDES is an acronym for "Translating Initiatives for Depression into Effective Solutions.")

The TIDES project provided guidelines for collaboration between mental health and primary care specialists with support for assessment and triage, patient education, and proactive follow-up of patients with symptoms of depression. The guidelines have helped VA systematically integrate collaborative care for depression into primary care settings throughout the VA health care system.

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➤ The VAST-D study

Several types of depression medications, or antidepressants, are used to treat depression and conditions in which depression is a component of the disease (such as bipolar disorder). These drugs improve symptoms of depression by increasing the availability of brain chemicals called neurotransmitters. It is believed that these chemicals help regulate brain circuits that affect emotions.

Often, the first antipsychotic medication physicians choose for their patients does not work well. The VA <u>Augmentation and Switching Treatments for Improving Depression Outcomes</u> (VAST-D) study, a VA cooperative study (CSP No. 576), is now underway at 34 VA facilities throughout the nation. Study researchers are working to determine research-based next steps for outpatients with major depressive disorder who have not had satisfactory outcomes to standard first-step treatments.

The team will attempt to determine for which patients, and under what circumstances, it is better to switch to other antidepressants, versus augmenting the first medication that was prescribed.

Researchers will also look at the results of augmenting the first medication with atypical antipsychotics, a newer generation of drugs used to help treat depression. These results will be compared with those achieved by switching to or augmenting the first medication with

Women Veterans with chest pain heavier, more depressed than men, University of Michigan press release, Feb. 2015

Different mental disorders lined to same brain-matter loss, study finds, Stanford University News Center press release, Feb. 4, 2015

Charleston VA researchers say magnetic treatment can put depression in remission, ABC4 News, Sept. 15, 2015

You need face-to-face contact for your mental health, Health, Oct. 6, 2015

UCLA researchers develop therapy to treat PTSD, depression, UCLA Daily Bruin, Jan. 28, 2016

Portable seizure device yields unexpected mood benefits to PTSD patients, Dotmed.com, Feb. 4, 2016

US panel reaffirms depression screening for adolescents, Fox News, Feb. 9, 2016

Cogito and MGH test voice app to monitor moods, The Boston Globe, Feb. 24, 2016

VA AND OTHER U.S. GOVERNMENT ONLINE RESOURCES

Mental Health: <u>Depression</u>, U.S. Department of Veterans Affairs

Mental Health: <u>Bipolar</u>, U.S. Department of Veterans Affairs

Mental Health: <u>Suicide</u>
<u>Prevention</u>, U.S. Department of Veterans Affairs

Homeless Veterans Mental Health Services, U.S. Department of Veterans Affairs

<u>Vet Center Program</u>, U.S. Department of Veterans

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more "typical" medications first developed in the 1950s. These "first generation" antipsychotics include Haldol and Thorazine.

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➤ Non-drug treatments for depression

Telemedicine talk therapy—In 2015, a <u>study</u> led by researchers from VA's Heath Equity and Rural Outreach Innovation Center (HEROIC) in Charleston, S.C., found that talk therapy delivered by two-way video calls is at least as effective as in-person treatment delivery for older Veterans with depression.

In the study, the research team recruited 241 Veterans aged 58 or older with major depression. The Veterans were randomly assigned to receive either telemedicine or same-room psychotherapy. both groups received the same kind of treatment: behavioral activation, a talk therapy that emphasizes reinforcing positive behaviors.

The team found that telemedicine-delivered psychotherapy produced similar outcomes to in-person treatment. After a year of treatment, 39 percent of telemedicine patients and 46 percent of in-person therapy patients were no longer depressed, according to structured clinical interviews.

The team concluded that telemedicine is a good option for depressed older adults who have barriers to mobility, have some kind of stigma, or are geographically isolated.

Transcranial magnetic stimulation—Researchers at eight VA medical centers throughout the nation are conducting a cooperative study (CSP No. 556) to determine if repetitive transcranial magnetic stimulation (TMS) helps Veterans with depression and possible PTSD or substance abuse who have not responded adequately to medication. The therapy is already approved by the Food and Drug Administration to treat refractory (treatment-resistant) depression, but past studies have typically not included patients who also have other mental conditions—such as PTSD or substance abuse—along with their depression. Such combinations are more common in VA patients than in the general population.

In TMS, clinicians take an electromagnetic coil, charge it with electricity, and apply it to specific points on the skull. The result is a targeted magnetic field that can affect brain cells in a specific area.

Participants in the study receive a 30-minute session of this kind, five days per week, for six weeks. Researchers use the electronic coil to stimulate the participants' prefrontal cortex, the part of the brain responsible for emotions and mood regulation.

The study is expected to be completed in spring 2016.

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➤ Depression and heart disease: the Heart and Soul Study

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Moving Forward: overcoming life's challenges, U.S. Department of Defense

<u>Depression</u>, healthfinder.gov

Depression, Medline Plus

<u>Depression</u>, National Institute of Mental Health, National Institutes of Health

<u>Depression</u>, NIH Senior Health, National Institutes of Health

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The Heart and Soul <u>Study</u> is an ongoing project led by VA and University of California, San Francisco, researchers. It is helping to determine how psychological factors influence the outcomes of patients with coronary heart disease.

A total of 1,024 patients in the San Francisco area, including 440 Veterans, were enrolled in the study between 2000 and 2002. Researchers have followed them ever since to understand the association between psychological factors and cardiovascular events.

A 2008 paper by study researchers, published in the *Journal of the American Medical Association*, provided evidence that the link between depression and heart disease may hinge largely on behavioral factors associated with depression, such as lack of exercise and increased rates of smoking.

The most recent <u>study</u> by the Heart and Soul team, published in 2016, further explored whether depression is mainly a *cause* or a *consequence* of poor health behaviors.

The team found that among 667 patients with coronary heart disease, depressive symptoms were linked to a range of lifestyle risk factors. These risk factors included smoking, low levels of physical activity, poor sleep quality, and poor medical adherence. The research showed that each of these lifestyle factors significantly worsened over a five-year period in depressed individuals, more so than in individuals who were not depressed. This lends credence to the idea that depression is primarily a *cause* of poor health behaviors, rather than a *consequence*. Researchers continue to study this question, with the goal of generating additional insights to help guide prevention and treatment.

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➤ Depression and heart disease: other VA studies

Mental disorders and heart attack risk—By examining the health histories of more than 350,000 Veterans over a seven-year period, researchers from the St. Louis VA Medical Center <u>reported</u>, in 2010, that those with depression are at about 40 percent higher risk than others for having a heart attack.

General anxiety and panic disorder seem to raise the risk to a similar extent, and posttraumatic stress disorder (PTSD) also raises the risk—but to a lesser degree. Researchers are continuing to study whether treating these mental disorders reduces heart risk.

Vascular depression—In a follow-up study, whose results were published in 2012, researchers <u>found</u> that those who had depression in middle age were at an increased risk of developing vascular depression (depression caused by reduced or blocked blood flow to the brain) in old age, and that their mid-life depression could be a causal risk factor.

Ischemic heart disease—In 2014, researchers at the VA Puget Sound Health Care System <u>reported</u> that Veterans with depression

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are more likely to complain of increased chest pain related to ischemic heart disease.

Ischemia is a condition in which blood flow, and therefore oxygen, is restricted or reduced in a part of the body. Ischemic heart disease, also known as coronary artery disease, is the term given to heart problems caused by narrowed heart arteries.

The research team's findings indicated that changes in depression symptoms could affect the perception of a patient's chest pain, or angina. The greater the perception of chest pain, regardless of the actual extent of the disease, the greater the likelihood of cardiac intervention. Multiple procedures and tests are both costly and can adversely affect quality of life.

In their study of 569 Veterans, the team found that Veterans whose depression had begun recently were the ones most dramatically affected, reporting more chest pain and physical limitations, along with poorer quality of life. Veterans who were persistently depressed also reported more problems in these areas than those with ischemic heart disease who were not depressed.

CART-CL—Through the <u>CART-CL</u> (Clinical Assessment Reporting and Tracking System for Cath Labs) program, VA researchers are focusing in on how cardiac catheterization is done at VA laboratories throughout the nation. The CART-CL program collects data from all 77 VA cath labs. Researchers use that data to improve VA's clinical performance.

Cardiac catheterization is used to diagnose and treat cardiovascular conditions. During the procedure, a long thin tube called a catheter is inserted in an artery or vein in the groin, neck, or arm, and is threaded through the blood vessels to the heart. The procedure allows cardiologists to investigate what's going on in the heart, or to open blocked arteries impeding blood flow.

A 2015 <u>study</u> by researchers with the VA Ann Arbor Healthcare system and the University of Michigan used CART-CL data to look at nearly 86,000 Veterans who underwent the procedure at a VA facility between October 2007 and September 2012. Nearly 3,200 of those Veterans were women.

The researchers found that women Veterans who underwent the procedure tended to be younger and more obese than men, and that they were more likely to have PTSD or depression. They were also significantly less likely to have obstructive coronary disease, and consequently were less likely to have been prescribed heart medications.

However, their long-term health outcomes were about the same as those of their male counterparts. According to the research team, the findings suggest that a significant percentage of women Veterans may have chest pain that is not attributable to obstructive coronary artery disease, and that further research is needed into the reasons for that chest pain.

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➤ Iraq and Afghanistan Veterans and depression

Many Iraq and Afghanistan Veterans have developed mental and behavioral conditions as a result of their combat experiences or other war-zone stressors. A 2015 <u>study</u> by researchers at VA's <u>Translational Research Center for TBI and Stress Disorders</u> at the VA Boston Healthcare System identified three such conditions that cause the greatest level of difficulty in Veterans when they occur together.

The three conditions are depression, PTSD, and traumatic brain injury (TBI). Patients with those conditions, which the researchers call the "deployment trauma factor," have higher disability scores than those with any other three-diagnosis combination.

The disabilities measured include difficulty in getting around, communicating and getting along with others, self-care, and other daily tasks. Other common problems that appeared to predict disability included anxiety conditions other than PTSD, pain along with sleep difficulty, and substance abuse or dependence.

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➤ Seasonal affective disorder

In a 2015 <u>study</u>, researchers from VA's Baltimore and Denver Mental Illness Research Education and Clinical Centers (MIRECCs), along with researchers from several universities, found that cognitive behavioral therapy (CBT) can help Veterans and others with seasonal affective disorder (SAD). CBT is a form of psychotherapy that focuses on the integral relationship between people's thoughts and their behaviors

SAD is a form of clinical depression that occurs in fall and winter and is more highly prevalent in those who live in northern climates. The current prevalent treatment for SAD is light therapy, in which a patient sits in front of a bright light unit every day for a designated period of time to help regulate his or her body clock. Patients also receive antidepressants, mood stabilizing medications, or psychotherapy if needed.

In this study, some patients received CBT twice per week over six weeks in group sessions with a community therapist. They focused on behaviors that would help them cope with winter, such as changing negative thoughts associated with winter, and were encouraged to engage in fun activities during the winter to counteract their avoidance mechanisms. Others received light therapy instead.

The research team concluded that, while results from the two groups were similar, CBT may be better overall for patients with SAD. This is because CBT develops skills patients can use once the treatment ends, whereas light therapy requires daily therapy—every winter.

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➤ Genomics

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The Office of Research and Development will soon be funding a <u>project</u> led by the Genomic Medicine Implementation, HSR&D, and QUERI programs to study the genomics of major depressive disorder in Veterans. The project will examine strategies to use patients' genetic information to prescribe the best antidepressants and discover the most effective dosage.

Until now, there have not been many studies of genomic testing implementation in the clinical care setting. This program will actually return genomic test results to providers and patients, which may subsequently influence treatment. The study will look at at the most effective way return results to clinicians and patients to directly guide treatment. This type of study could serve as a primer for similar studies going forward.

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More on Our Website

- Study confirms that depression can shorten life, VA Research news feature
- Study: Depression, anxiety rates roughly equal among older Vets, non-Vets, VA Research Currents, Oct. 8, 2014
- <u>Depression can affect feelings of chest pain in heart patients</u>, study finds, VA Research Currents, Feb. 4, 2015
- Troubling trio—depression, PTSD, mild traumatic brain issue—linked to extra-high disability risk, VA Research Currents, Feb. 25, 2015
- Cognitive behavioral therapy as effective as light therapy for seasonal affective disorder, VA Research Currents, May 13, 2015
- <u>Depression study points to value of in-person social contact</u>, VA Research Currents, June 25, 2015
- Mood disorders after deployment: could a parasite be partly to blame?
 VA Research Currents, Aug. 26, 2015
- <u>Telemedicine works for older Veterans with depression</u>, VA Research
 Quarterly Update, Fall 2015
- <u>Determining key features of effective depression interventions</u>, VA Health Services Research & Development
- · Mental Illness Research, Education and Clinical Centers

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Selected Scientific Articles by Our Researchers

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UPDATED/REVIEWED: 2021-1-15

Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care

John R. Blosnich, PhD, George R. Brown, MD, Jillian C. Shipherd, PhD, Michael Kauth, PhD, Rebecca I. Piegari, MS, and Robert M. Bossarte, PhD

The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) defines gender identity disorder (GID) as having deeply rooted feelings of persistent discomfort with one's current biological gender and having the desire to be of the opposite gender to the extent that "the disturbance causes clinically significant distress or impairment in . . . important areas of functioning." ^{1(p260)}

Although the diagnosis is relatively rare, persons diagnosed with GID constitute a subpopulation of people who experience numerous disparities in physical and mental health as well as health care access.2 Although a precise estimate of GID occurrence among the general population is unknown, one theoretical framework (i.e., flight into hypermasculinity) posits that GID may be overrepresented in the military and among veterans,3 and there is support for this hypothesis in communitybased samples of transgender persons in which high prevalence of military service is observed.4 Furthermore, there is evidence of elevated risk for suicidal behavior among transgender populations. 5-10 However, prevalence of GID and suicide-related events (e.g., suicide planning, suicide attempt) have yet to be examined among veterans who have received Veterans Health Administration (VHA) services. We have addressed this unmet need.

GENDER IDENTITY DISORDER TERMINOLOGY

Although there are multiple ways that a person diagnosed with GID may self-identify, the 2 common terms used in the literature for this self-identification are transgender and transsexual. Transgender is a term with broader scope; it typically encompasses individuals who self-identify as being or living outside socially constructed gender roles of masculinity and

Objectives. We estimated the prevalence and incidence of gender identity disorder (GID) diagnoses among veterans in the Veterans Health Administration (VHA) health care system and examined suicide risk among veterans with a GID diagnosis.

Methods. We examined VHA electronic medical records from 2000 through 2011 for 2 official ICD-9 diagnosis codes that indicate transgender status. We generated annual period prevalence estimates and calculated incidence using the prevalence of GID at 2000 as the baseline year. We cross-referenced GID cases with available data (2009–2011) of suicide-related events among all VHA users to examine suicide risk.

Results. GID prevalence in the VHA is higher (22.9/100 000 persons) than are previous estimates of GID in the general US population (4.3/100 000 persons). The rate of suicide-related events among GID-diagnosed VHA veterans was more than 20 times higher than were rates for the general VHA population.

Conclusions. The prevalence of GID diagnosis nearly doubled over 10 years among VHA veterans. Research is needed to examine suicide risk among transgender veterans and how their VHA utilization may be enhanced by new VA initiatives on transgender care. (Am J Public Health. 2013;103:e27–e32. doi: 10.2105/AJPH.2013.301507)

femininity. Transsexual is often used to conceptualize a subset of transgender persons who usually desire to undergo physical changes to their bodies, potentially including cross-gender hormone treatments and gender reassignment surgery.¹¹

Because the data for our analysis did not permit an assessment of self-identified transgender or transsexual status, we have used the terms GID, transgender, and transsexual interchangeably, and our review of the literature includes findings of studies with GID, transgender, and transsexual samples. Although these populations share many qualities, we duly note that persons with GID constitute only a portion of transgender and transsexual communities. Thus, our focus on persons diagnosed with GID (i.e., a clinical subpopulation) should not be misinterpreted to represent either transgender or transsexual populations at large.

Currently, the most common treatments for GID are combinations of psychotherapy, cross-gender hormone therapy, living full time

in the cross-gender role, electrolysis, voice therapy, and surgical procedures. 12–14

PREVALENCE OF GENDER IDENTITY DISORDER

Precise estimates of the number of persons with GID are difficult to make, as not every person with GID is able to access care from a health care provider who is knowledgeable in this diagnosis. ^{5,15,16} Moreover, many studies of GID use records of gender reassignment surgeries as a proxy census (i.e., counting only transsexuals with severe forms of GID), ¹⁷ which likely produces underestimates of GID prevalence, as only a small fraction of GID-diagnosed individuals undergoes gender reassignment surgeries. ¹⁸

The *DSM-IV* estimates that 1 in 30 000 natal males and 1 in 100 000 natal females have GID among the US population; however, these figures are based on older, limited data.¹ More recent research, from other countries,

reports that GID may be more common,¹⁹ ranging from approximately 1 in 13 000 natal males and 1 in 34 000 females in Belgium²⁰ to 1 in 11 000 natal males and 1 in 20 000 natal females in the Netherlands.²¹ Although more precise estimates of population prevalence are unavailable, trends across studies suggest that GID is more common among natal males than among natal females,¹⁹ with a prevalence ratio of 3 natal males with GID to every 1 natal female with GID.¹⁷

SUICIDE RISK DISPARITIES

Research on GID-diagnosed, transgender, and transsexual populations is sparse, and no national-level health surveillance survey currently collects information that can be used to reliably identify these populations. The literature suggests that people diagnosed with GID may experience a significantly elevated risk for suicide. For example, a study of more than 300 transgender persons in Virginia documented that 65% had lifetime suicidal ideation. 6 Similarly, a study of 70 US military veterans, most self-referred for a gender evaluation, found that 61% reported lifetime suicidal ideation.⁷ These estimates are much higher than the estimated 8.4% prevalence of lifetime suicidal ideation among the general adult US population.²² Elevated suicidal ideation has similarly been found among other samples of transgender persons in the United States.^{5,8-10}

Research also suggests that attempted suicide is disproportionately higher among transgender populations. In a needs assessment of nearly 200 transgender persons in Philadelphia, Pennsylvania, nearly one third (30.1%) reported at least 1 lifetime suicide attempt. Clements-Nolle et al. also noted that roughly a third (32.2%) in their sample of more than 500 transgender respondents reported a lifetime suicide attempt. The studies report a lifetime suicide attempt prevalence ranging from 18% to 41% 6.24-27 By comparison, less than 3% of the general US population report a lifetime suicide attempt.

Relative to data about suicide ideation and attempt, information about suicide among persons with GID is perhaps the most limited, with the only known estimates derived from surveillance in the Netherlands. In a retrospective study of more than 1400 transsexual

outpatients from that country's largest clinic providing transsexual health care, van Kesteren et al. noted substantially higher death by suicide among transsexual patients than among the age- and gender-corresponding general Dutch population rates (standardized mortality ratio [SMR] = 9.29; 95% CI = 4.94, 15.88).28 In a recent follow-up study of outpatients from the same clinic in July 1997, the authors still found elevated rates of death from suicide, although they were not as pronounced as in their earlier findings (SMR = 5.70; 95% CI = 4.93, 6.54). More recent studies among transsexual persons in Sweden report a similar elevated risk of suicide.30 To our knowledge, no empirical investigation has examined similar rates of suicide mortality among US populations of persons with GID or who identify as either transgender or transsexual.

GENDER IDENTITY DISORDER AND VETERANS

There is a theoretical basis, informed by clinical case analysis, for the suggestion that the prevalence of GID may be disproportionately higher among persons with military service histories than among the general population. Based on a case series, Brown developed a flight into hypermasculinity theory, asserting that young men with GID may enlist in the military at critical periods in their psychosocial development to "become real men" or to purge their inner gender conflict through the strict rigor and focus on overtly masculine activities (e.g., weaponry training, physical training, combat).³

Supplementing Brown's theoretical framework is the fact that more than 95% of the VHA system's patients are male³¹; GID is suspected to occur with more frequency among natal males.¹ In a community-based sample of 141 transgender individuals, Shipherd et al. found that veteran status was endorsed at 3 times what is observed in the general population, and VHA use was elevated among transgender veterans (16.3% in the past 6 months) relative to general rates of VHA use (annual 6.2%–15.8%).⁴ Furthermore, in June 2011, the VHA issued a new directive outlining health care for transgender and intersex veterans, which may have

increased the willingness of transgender veterans to seek VHA care.

Thus, we first sought to document the prevalence of official diagnoses of GID within the VHA health care system. Second, because of evidence of greater risk for suicide attempt among transgender populations, we also examined suicide-related events among VHA-utilizing veterans with a diagnosis of GID.

METHODS

The VHA is the single largest integrated system for health care in the United States, annually serving more than 8 million veterans.32 Because the VHA has a national system of standardized electronic medical records,33 we employed a review of both inpatient and outpatient electronic patient treatment files from fiscal year (FY)2000 through FY2011. We specified inclusion criteria for a GID case as being a patient with an ICD-9 diagnosis code of either 302.85 (gender identity disorder in adolescents or adults; i.e., GID) or 302.6 (gender identity disorder not otherwise specified; i.e., GID-NOS) recorded during any inpatient stay or outpatient encounter or visit. We counted a patient with a GID diagnosis only once, and the first notation of the GID diagnosis in the patient treatment files indicated the FY in which said patient would be counted. We generated period prevalence estimates for each FY by dividing the number of unique GID diagnoses in that FY by the total number of patients seen in that calendar year. FYs start October 1 and end September 30. For example, FY2011 started October 1, 2010, and ended September 30, 2011.

Although there is prevalence of GID diagnoses beginning in FY2000, the VHA patient data were not obtainable for FY2000 or FY2001; thus, we could not calculate any period prevalence or incidence proportions of GID diagnoses for those years. Beginning in FY2002, we calculated incidence estimates using the prevalence of GID at FY2000 as the baseline for assessing new, unique cases of GID. An additional conservative assumption in annual incidence calculations was omitting the cumulative extant cases of GID from the population at risk (i.e., the denominator) for

each year, which assumes that a patient diagnosed with GID stayed in VHA care throughout the observed period and thus needed to be removed from the denominator of people at risk. For example, we subtracted the total new GID cases documented in both FY2000 and FY2001 from the FY2002 denominator for calculation of the most conservative FY2002 incidence.

It is important to note that although the vast majority of VHA users are veterans, the cohort of VHA users also includes some non-veterans (i.e., veterans' family members). We reviewed inpatient and outpatient files for the unique cases of GID for variables specifically identifying that person as a nonveteran. Overall, the numbers of nonveteran VHA users with GID was extremely small in each year, ranging from a low of zero in FY2005 through FY2007 to a high of 5 in FY2000. Because of the small number of nonveteran cases, we kept all identified cases.

We examined past year suicide-related event prevalence by cross-referencing all GID cases with the VHA's Suicide Prevention Application Network (SPAN) database. SPAN is a database of information about suicide-related behaviors reported by the national network of suicide prevention coordinators situated in every VHA medical center and large outpatient facility. We did not include suicide deaths among the outcomes. Suicide-related events include suicide-related behaviors recorded by the suicide prevention coordinators (e.g., interrupted suicide attempts, gestures with a firearm, suicide plans). Because the suicide prevention coordinators focus on behaviors, suicidal ideation is not a recorded outcome in SPAN. Furthermore, although SPAN does contain data on suicide deaths, the local reporting of deaths (i.e., from coroners or medical examiners) is not mandatory and is not considered complete. Thus all outcomes from SPAN used only nonfatal events.

We cross-referenced GID cases from available years of data from SPAN (i.e., FY2009–2011) for at least 1 suicide-related event noted in each year; we counted persons with multiple events in 1 year only once. To generate prevalence of suicide events, we divided the number of GID cases with at least 1 report of a suicide-related event for each year by the

cumulative data of GID diagnoses in that particular year.

RESULTS

Across the analytic period of FY2000–FY2011, 3177 unique persons had at least 1 diagnosis of GID in their files. Prevalence calculations suggest an increasing trend of GID in the VHA (Figure 1). Although we could not calculate estimates for FY2000–FY2001 because of a lack of data on the VHA cohort of patients, beginning with FY2002 data, we noted a baseline prevalence of 12.52 per 100 000.

The prevalence of GID among VHA users has nearly doubled over the 10-year period we examined, whereas the incidence has been relatively stable (Table 1). Beginning in FY2000, new cases have been identified in the VHA at an average rate of 246 cases per year, whereas some previously identified veterans with GID continue to use VHA care, resulting in a near doubling of the prevalence of GID diagnoses in the VHA. All 3 past year prevalence estimates of suicide-related events, ranging from 4000 per 100 000 to 5000 per 100 000, were much higher than are any currently

available general population metric of past year suicidal behavior (Table 2).

DISCUSSION

To our knowledge this is the largest study of a transgender population to date in the United States, and our findings indicate a much higher prevalence of GID among VHA veterans than what has been reported previously in the literature, 19 lending support to Brown's flight into hypermasculinity theory within military populations. Specifically, in FY2011, 22.9 per 100 000 VHA users had a diagnosis of GID, which is more than 5 times the DSM-IV prevalence estimate of GID in the general US population (4.3/100 000 persons). The results showed a relatively stable annual incident rate of 246 new diagnoses of GID, contributing to an increasing prevalence of VHA veterans with GID.

Why the prevalence of GID among this veteran population is higher than is that in the general population is beyond the scope of our study; several areas of future research are needed to better qualify these results. For instance, the estimate of GID from the *DSM* is based on older studies and may not accurately reflect the current prevalence of GID.

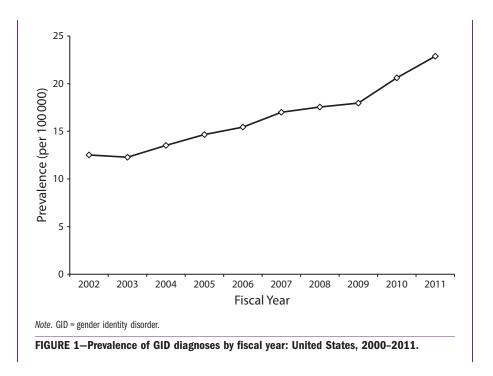


TABLE 1—Prevalence and Incidence of GID Diagnoses by Fiscal Year: United States, 2000-2011

	Total New GID	Total GID	Total VHA	Period	
Fiscal Year	Diagnoses, No.	Diagnoses, No.	Patients, No.	Prevalence ^a	Incidence
2000	472 ^b	472			
2001	261	475			
2002	283	569	4 544 353	12.52	6.23
2003	228	590	4 805 421	12.28	4.74
2004	235	673	4 977 772	13.52	4.72
2005	214	747	5 094 425	14.66	4.20
2006	196	801	5 188 825	15.44	3.78
2007	209	889	5 230 122	17.00	4.00
2008	203	930	5 299 645	17.55	3.83
2009	230	979	5 448 058	17.96	4.22
2010	285	1162	5 638 263	20.61	5.06
2011	361	1326	5 795 165	22.88	6.23

Note. GID = gender identity disorder; VHA = Veterans Health Administration. Prevalence = total GID diagnoses/total VHA patients; incidence = total new GID diagnoses/total VHA patients in previous years' diagnoses.

aPer 100 000 natients

Furthermore, because GID is more prevalent among natal males than among natal females, the VHA may see a disproportionately high prevalence because the majority of its patients are males. Reports of GID diagnoses from other large health systems in the United States would aid in examining how results from patients enrolled in different health systems (e.g., 1 not solely composed of those eligible for VHA benefits) compare with our findings and thus help to better understand the current prevalence of GID.

On the basis of simple de-identified counts, it is unclear whether these veterans continued to seek care over time in the VHA once diagnosed. The existence of transgender veterans poses many additional questions, such as what types of care are most utilized among this population. Preliminary studies suggest that

transgender veterans are likely to seek both medical and mental health care at VHA facilities. Utilization and quality of care are particularly salient questions since the VHA announced its first ever directive outlining health care provision to transgender and intersex veterans in June 2011, and there have been documented problems in accessing care for transgender persons. Onsequently, there may be historical effects in the trends of GID diagnoses in the time before and after the issuance of the directive. In addition to utilization, future research is needed to examine other facets of health, including comorbidities and sources of mortality.

Suicide is a particular concern for this population. Results show that suicide-related events occur at significantly elevated rates among this population, which corroborates

among this population, which corroborates

TABLE 2—Suicide-Related Event Prevalence Among GID-Diagnosed Veterans by Fiscal Year: United States. 2000–2011

	GID Patients With ≥1 Suicide-		Period Prevalence of Suicide-
Fiscal Year	Related Events	Total GID Patients	Related Events ^a
2009	40	979	4085.80
2010	49	1162	4216.87
2011	68	1326	5128.21

Note. GID = gender identity disorder.

results from other transgender samples.^{8-10,26,27} Estimates for each year-ranging from 4000 per 100 000 to 5000 per 100 000-were well above any general population metric related to suicidal behavior. For example, general population data available from the Centers for Disease Control and Prevention Web-based Injury Statistics Query and Reporting System indicate a past year crude rate of self-harm injuries of 150.61 per 100 000 in the year 2010.35 Among VHA veterans in general, the rate of suicide-related events in FY2010 was approximately 202 per 100 000 patients,³⁶ which makes the FY2010 rate among veterans with GID more than 20 times higher.

A recent World Health Organization multinational report of past-year suicidal behavior noted that approximately 2.0% of adults reported suicidal ideation, 0.6% reported suicide planning, and 0.3% reported a suicide attempt.³⁷ By contrast, estimates of unique suicide-related events among veterans with GID using VHA care ranged from 4.1% to 5.1%. Although comparisons are illustrative and studies strive to measure similar overarching constructs of suicide risk, exact definitions and measures of suicidal behavior differ, making direct comparison impossible. Moreover, it is unclear whether transgender veterans may have higher or lower burden of suicide risk compared with their transgender nonveteran peers, as veterans may carry unique experiences that are associated with suicide risk, such as combat exposure and traumatic brain injury. 38-40 Nor is it clear how this population of veterans with GID diagnoses compares with the larger population of transgender veterans who do not meet criteria for GID or GID-NOS.

The burden of suicide risk among this population clearly warrants more attention regarding etiology, prevention, and intervention. For example, high rates of early life trauma among transgender persons (e.g., childhood maltreatment, peer victimization)^{24,34,41,42} may contribute to the risk of suicide, but it is unclear how and whether trauma from military service interacts with previous trauma. In terms of prevention and because of the extremely high prevalence of suicide-related behavior among this sample of transgender veterans, more research is needed to examine whether suicide

^bUsed as baseline although formal diagnosis may have occurred before fiscal year 2000.

^aPer 100 000 patients.

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prevention campaigns and services are reaching or being utilized by this population. $^{43-45}$

Limitations

Several limitations of this study must be noted. First, although we have reported a census sample of all GID diagnoses in VHA medical records from FY2000 through FY2011, the specialized nature of this subpopulation (i.e., clinically diagnosed veterans) limits generalizability.

Second, the study period was before the VHA's June 2011 directive outlining health care for transgender veterans. Thus, the census of GID diagnoses may be an underestimate because transgender veterans may have felt uncomfortable seeking care from the VHA before the issuance of the directive. For instance, before the national directive a few localized VHA policies prevented access to specific types of care (i.e., cross-gender hormones) for veterans with GID, which may have resulted in veterans seeking care elsewhere.

Third, we were unable to assess for misclassification bias through potential mistaken diagnosis codes in the patient treatment files.

Fourth, we employed a definition of transgender status limited to clinical diagnoses, which may have missed persons without clinical diagnoses of GID who self-identify as transgender but may have included persons with GID who do not self-identify as transgender. Finally, although SPAN is currently the largest registry of suicide-related events in the United States, it may not capture all events and has operated only since 2008; thus, it is likely an underestimate of suicide risk for this population.

Conclusions

As research continues to develop, the VHA has taken steps to improve health care outcomes for transgender veterans since issuing the transgender health care directive. 46 Activities included system-wide communications and development of resources about transgender health care and a series of national virtual meetings for VHA clinical staff on conducting evaluations for hormone therapy, prescribing cross-gender hormones, and providing an integrated care approach for transgender veterans. Plans are underway to produce a web-based continuing education program on

transgender health care for new clinical staff and to establish formal clinical consultation services on culturally appropriate transgender care. These efforts are supported by recent joint commission guidelines that require accredited facilities to eliminate discriminatory policies and procedures and provide staff training on culturally and clinically appropriate care for lesbian, gay, bisexual, and transgender individuals.⁴⁷

This report contributes to a small but growing body of literature about transgender health and is a first step in exploring the unique health needs of GID-diagnosed veterans within the VHA. Transgender persons experience many barriers in seeking and access to health care, $^{4.5,34}$ but these issues have not been explored fully among transgender persons within the VHA, which is the nation's largest integrated health care system.

Several questions remain about the transgender veteran population, the most pressing of which includes addressing the unusually high burden of suicidal behavior and finding ways of identifying transgender populations beyond the sole use of diagnosis codes. More nuanced future examinations could also contribute to a better understanding about subgroups within the transgender veteran population. The VHA has made recent progress by issuing a directive outlining clinical care guidelines for transgender veterans and providing training to staff, but there is still much to learn about this veteran population's health care utilization and epidemiology of health issues.

About the Authors

John R. Blosnich is with the Department of Psychiatry, University of Rochester, Rochester, NY. George R. Brown is with the VA Office of Health Equity (10A6), Washington, DC. Jillian C. Shipherd is with VA Boston Healthcare System, Boston, MA. Michael Kauth is with VA South Central Mental Illness Research, Education, & Clinical Center, Michael E. DeBakey VA Medical Center, Houston, TX. At the time of this study, Rebecca I. Piegari was with Department of Veteran Affairs VISN-2 Center of Excellence for Suicide Prevention, Canandaigua, NY. Robert M. Bossarte is with the Department of Veteran Affairs VISN-2 Center of Excellence for Suicide Prevention.

Correspondence should be sent to John R. Blosnich,
Department of Veterans Affairs VISN-2 Center of Excellence
for Suicide Prevention, 400 Fort Hill Ave, Canandaigua, NY
14424 (e-mail: john_blosnich@urmcrochester.edu). Reprints
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J. R Blosnich analyzed the data. R. I. Piegari directed data analysis and management. R. M. Bossarte conceptualized the study. All authors contributed to the writing of the article.

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Human Participant Protection

This project was approved by the institutional review board of the Veterans Affairs Medical Center-Syracuse, NY.

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LOCAL NEWS

California Veteran Shares Story of Gender Transition

by: Nicole Comstock Posted: May 11, 2015 / 06:00 PM PDT Updated: May 11, 2015 / 06:00 PM PDT

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SACRAMENTO-

A local transgender veteran is sharing her story of transitioning with FOX40.

"I knew I was a soldier in the military but I felt like I was a female," Trudi Annelise Mathison said.

Mathison says she served in the army from 1978 to 1985, but has since changed her full name. Now, thirty years after fighting for our country, she is fighting for her identity.

"Now, it just feels like I flow just like water," Mathison said.

Although Mathison says she has felt like a woman her entire life, her physical transition into a woman has taken place rather quickly. Just months after starting hormone therapy and health counseling, Mathison decided to have sex reassignment surgery. It's a procedure some transgender men and women never chose to have.

"I'm going backwards. I'm starting from the bottom and going up. And I think it might be better that way," Mathison said.

Trudi told FOX40 a doctor in the United States quoted her \$26,000 for the procedure. She chose to have surgery in Tijuana, Mexico for \$8,500 as a way to save on medical expenses. She said the surgery was botched.

"I came home and some of my bottom parts kind of you know, came out. I had to call an ambulance and the EMTs didn't know what to do," Mathison said.

She's spent the past two years revising that operation. And becoming more confident in the woman she feels she was meant to be.

"I've been doing so much in the past 2 years and 5 months, it's just amazing," Mathison said.

Part of that time, Trudi lived in a transitional housing program provided by the Veteran's Resource Center in Sacramento.

Although the VA does not cover sex reassignment surgery, the VA Healthcare Directive for Transgender and Intersex Veterans say it is their policy to provide medically necessary post-operative care. Additionally, the VA's Homeless Provider's Grant funds housing at the Veteran's Resource Center, which placed Trudi in their women's housing unit.

"The VA has shown leadership in this area in the past, and I believe this is really an opportunity for them to show that leadership," Ben Hudson said.

Hudson is the Executive Director at Sacramento's Gender Health Center. It is another local support group Trudi relies on.

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"What we find is my survival is your su to be alive. Trudy has felt that and seen

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The Gender Health Center works with community. But the national data on t



Receive the latest news, updates and offers as they happen.

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have a strong transgender idy from UCLA, conducted in 2011,

Some argue when such information is under reported, it tends to be overlooked.

Ninety percent of people who responded to a recent national transgender discrimination survey reported employment discrimination, or said they hid who they were to avoid it. Fifty-three percent of people reported being verbally harassed or disrespected in public places.

"It's gonna take some time before society changes and understands how we feel," Mathison said.

Trudi's story is not the transgender story, but simply one of countless unique and very personal stories.

"I've got negative reactions or people who keep looking back and forth at me. Trying to decide who I was or who I am. I just figure they're trying to figure it out, and I already figured out who I am," Mathison said.

Mathison said her future plan was to become a peer counselor in the transgender community, so she can pay back all those people who have helped her along the way.

"I think that's my calling. I would tell them about my struggling and tell them it's not that bad. It will get better as you get older," Mathison said.

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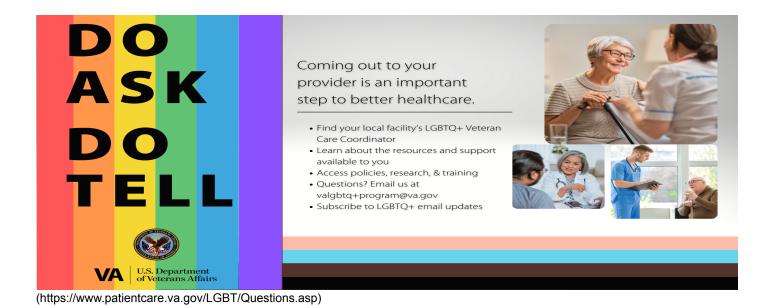
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Patient Care Services

VHA LGBTQ+ Health Program



LGBTQ+ Veterans

The Department of Veterans Affairs (VA) welcomes all Veterans, families, caregivers, and survivor beneficiaries, including diverse gender identities and sexual orientations. "LGBTQ+" refers to lesbian, gay, bisexual, transgender, and queer identities. The "+" sign captures identities beyond LGBTQ, including but not limited to questioning, pansexual, asexual, agender, gender diverse, nonbinary, gender-neutral, and other identities. LGBTQ+ Veterans have faced stigma and discrimination, which can affect health. As a healthcare institution, we need to make sure that LGBTQ+ Veterans know that they are welcome at Veterans Health Administration (VHA).

Vision Statement

LGBTQ+ Veterans will choose VA and receive affirming care and services to achieve optimal health and well-being.

Available Health Care Services

There is an <u>LGBTQ+ Veteran Care Coordinator (/LGBT/VAFacilities.asp)</u>(LGBTQ+ VCC) at every facility to help you get the care you need. VHA policies require that your health care is delivered in an affirming and inclusive environment and that VHA employees respect your identity. <u>Contact the LGBTQ+ VCC (/LGBT/VAFacilities.asp)</u> at your nearest facility.

VA health care (https://www.va.gov/health-care/) includes, among other services:

3 (https://www.patientcare.va.gov/LGBT/Questions.asp)

- Gender Affirming Hormone Therapy
- Substance use (https://www.mentalhealth.va.gov/substance-use/index.asp)/alcohol treatment
- Tobacco use treatment (https://www.mentalhealth.va.gov/quit-tobacco/)

- 12/4/23, 2:08 PM
 - Treatment and prevention of sexually transmitted infections PEP (post-exposure prophylaxis) and PrEP (preexposure prophylaxis) for Veterans at risk for HIV (https://www.hiv.va.gov/patient/index.asp).
 - Intimate partner violence (https://www.socialwork.va.gov/IPV/Index.asp) reduction and treatment of after effects
 - Military Sexual Trauma (https://www.mentalhealth.va.gov/msthome/index.asp) screening and treatment of after effects
 - Suicide prevention services (https://www.va.gov/health-care/health-needs-conditions/mentalhealth/suicide-prevention/). If you or someone you know is having thoughts of suicide, contact the Veterans Crisis Line to receive free, confidential support and crisis intervention available 24 hours a day, 7 days a week, 365 days a year. Dial 988 then Press 1, text 838255 or chat online at VeteransCrisisLine.net/Chat (https://gcc02.safelinks.protection.outlook.com/?

url=http%3A%2F%2Fveteranscrisisline.net%2FChat&data=05%7C01%7C%7C6e3f262be40246eb53ba08da95a08

- Whole Health (https://www.va.gov/wholehealth/)
- Cancer screening, prevention and treatment (https://www.research.va.gov/topics/cancer.cfm)
- Virtual Mental Health Care (https://telehealth.va.gov/): Veterans can connect with a VA mental health provider through a computer or mobile device from the comfort of their homes or at their nearest VA health facility.
- Infertility

(https://www.womenshealth.va.gov/WOMENSHEALTH/outreachmaterials/reproductivehealth/infertility.asp): VA is committed to helping Veterans navigate challenges that may arise from issues with fertility and the

conception of a child.

LGBTQ+ Veteran Care Coordinators (VCCs)

Veteran Care Coordinators on Transgender and Gender Diverse Visibility at VA



<u>LGBTQ+ Veteran Care Coordinators (https://gcc02.safelinks.protection.outlook.com/?</u> url=https%3A%2F%2Fwww.patientcare.va.gov%2FLGBT%2FVAFacilities.asp&data=05%7C01%7C%7Cab0247bc384 (VCCs) share personal insights about the work they do and the importance of LGBTQ+ visibility at VA. LGBTQ+ VCCs talk about:

- Health care for transgender & gender diverse Veterans at VA
- Their personal commitment to supporting LGBTQ+ Veterans
- · Gender-affirming health care including hormones and prosthetics
- Advocating for LGBTQ+ Veterans and promoting VA policies for respectful care
- Experiences as Veterans that inform their work at VA
- Why LGBTQ+ Veterans should choose VHA care
- Providing connection to community and with VHA
- Training and education for VA staff to create a welcoming environment

• Coordinating with many health specialties for Veteran care

Transgender and gender diverse Veterans face increased health risks and unique challenges in accessing quality health care. The Veterans Health Administration (VHA) is working to be a national leader in health care for LGBTQ+ Veterans and assure that high-quality care is provided in a person-centered, respectful environment. LGBTQ+ VCCs help Veterans get the care they need. VHA providers know about specific risk and protective factors that impact health care based on gender identity, sexual orientation, race, age, and other individual factors. Health care is best when Veterans and their providers have good relationships. LGBTQ+ VCCs are there to support Veterans to make connections with their providers.

Reach out to your local facility's LGBTQ+ Veteran Care Coordinator

today: https://gcc02.safelinks.protection.outlook.com/? url=https%3A%2F%2Fwww.patientcare.va.gov%2FLGBT%2FVAFacilities.asp&data=05%7C01%7C%7Cab0247bc384

Does my sexual orientation or gender identity matter to my health care?

As a result of stigma, stress, and discrimination, LGBTQ+ Veterans face increased health risks and unique challenges in health care. We want you to be comfortable talking with your VA providers about all aspects of your life, so we can offer you the best care possible.

Learn about health risks and why you should talk to your provider about your sexual orientation identity, birth sex, and self-identified gender identity in the fact sheets below.

- Transgender Men & Transmasculine Veterans Health Care Fact Sheet (/LGBT/docs/Transgender-Men-Transmasculine-FINAL-March23.pdf#) (PDF)
- Transgender Women & Transfeminine Veterans Health Care Fact Sheet (/LGBT/docs/Transgender-Women-Transfeminine-FINAL-March23.pdf#) (PDF)
- Veteran Health Care For Lesbian, Gay, Bisexual, & Queer Women (/LGBT/docs/LGBTQ-Lesbian-Gay-Bisexual-Queer-Women.pdf#) (PDF)
- Veteran Health Care For Gay, Bisexual, & Queer Men (/LGBT/docs/LGBTQ-Gay-Bisexual-Queer-Men.pdf#) (PDF)
- Nonbinary Veteran Health Care Fact Sheet (/LGBT/docs/LGBTQ-factsheet-nonbinary-Veterans.pdf#) (PDF)
- Veteran Birth Sex and Self-Identified Gender Identity Fact Sheet (/LGBT/docs/2022/Birth-Sex-Gender-Identity-FactSheet-for-Veterans-2022.pdf#) (PDF)
- Provider Birth Sex and Self-Identified Gender Identity Fact Sheet (/LGBT/docs/2022/Birth-Sex-Gender-Identity-FactSheet-for-Providers-2022.pdf#) (PDF)
- Sexual Orientation and Sexual Health Veteran Fact Sheet (/LGBT/docs/LGBTQ-Sexual-Orientation-Sexual-Health-Factsheet.pdf#) (PDF)

Learn about the resources and support available for LGBTQ+ Veterans who have faced challenges related to coming out or are unsure what services they are eligible for at VA.

- Coming Out to Your Health Care Provider (https://maketheconnection.net/events/coming-out-health-care-provider)
- Lesbian, Gay Bisexual & Transgender Queer Questioning + (LGBTQ+) Service Members and Veterans (https://www.benefits.va.gov/persona/lgbt.asp)
- How to Apply for a Discharge Upgrade (https://www.va.gov/discharge-upgrade-instructions/)

VA Begins Action to Allow for Gender-Affirming Surgeries in VA Health Care Coverage



VA currently provides all medically necessary gender-affirming care to transgender Veterans with the exception of gender-affirming surgical interventions, due to an exclusion in the VA medical benefits package. The LGBTQ+ Health Program is pleased to share that in the summer 2021, VA will be initiating the rulemaking process to modify the Code of Federal Regulations (CFR) to expand VA's care to transgender Veterans to include gender-affirming surgery.

- 1. VA currently provides all medically necessary gender-affirming care to transgender Veterans with the exception of gender-affirming surgical interventions, due to an exclusion in the VA medical benefits package.
- 2. Gender-affirming procedures have been proven effective at mitigating serious health conditions, including suicidality, substance abuse, and dysphoria.
- 3. Removing this exclusion would allow VA to provide transgender and gender diverse Veterans with coordinated, medically necessary, transition-related surgical procedures. In addition, revising the medical benefits package would enable a safe, coordinated continuum of care that is Veteran-centric and consistent with VA's values of equity and respect for all Veterans.
- 4. The entire rulemaking process can take approximately two years and includes a period of public comment. This will allow VA to develop the framework to provide the full continuum of care in a way that is consistent with VA's rigorous standards for quality health care.
- 5. During the rulemaking process, VA will continue to provide or pay for the services it currently offers, including corrective procedures after gender affirming surgeries a Veteran obtains outside VA, hormone therapy, and other gender affirming care.

FAQs: Removing "Gender Alterations" Exclusion from the VA Medical Benefits Package (/LGBT/docs/Transgender-Care-External-FAQs-18June21.pdf#) - (PDF)

Questions (/LGBT/Questions.asp)

Q. <u>Are there any providers specializing in transgender Veteran care in my area?</u> (/LGBT/Questions.asp#specialize)

- Q. How do I get transition-related care at the VA? (/LGBT/Questions.asp#transition)
- Q. Why are there resources devoted to LGBTQ+ Veterans?

(/LGBT/Questions.asp#transition) (/LGBT/Questions.asp)

SEE ALL QUESTIONS

(/LGBT/Questions.asp)

Need Help? LGBTQ+ Veteran Care Coordinator (VCC) Services

There is an <u>LGBTQ+ Veteran Care Coordinator</u> (/LGBT/VAFacilities.asp)(LGBTQ+ VCC) at every facility to help you get the care you need. VHA policies require that your health care is delivered in an affirming and inclusive environment and that VHA employees respect your identity.

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Reach out to your local facility's LGBTQ+ Veteran Care Coordinator today:

https://www.patientcare.va.gov/LGBT/VAFacilities.asp (https://www.patientcare.va.gov/LGBT/VAFacilities.asp)
Not yet a patient at VA? - Apply Now (https://www.va.gov/health-care/how-to-apply/)

*Link will take you outside of the Dept of Veterans Affairs (VA) Website. VA does not endorse and is not responsible for the content of the linked websites. The link will open in a new window for the content of the linked websites.

U.S. Department of Veterans Affairs | 810 Vermont Avenue, NW Washington DC 20420

Last updated October 26, 2023

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF DOCKETING

17-1460 - Fulcher v. Secretary of Veterans Affairs

Date of docketing: January 9, 2017

Petition for review of: United States Department of Veterans Affairs, pursuant to 38 U.S.C. Sec. 502

Petitioner(s): Dee Fulcher, Giuliano Silva, Transgender American Veterans Association

Critical dates include:

- Date of docketing. See Fed. Cir. R. 12 and 15.
- Certified list. See Fed. Cir. R. 17.
- Entry of appearance. (Due within 14 days of the date of docketing.) See Fed. Cir. R. 47.3.
- Certificate of interest. (Due within 14 days of the date of docketing.) See Fed. Cir. R. 47.4.
- Docketing Statement. (*Due within 30 days of the date of docketing*.) [See Fed. Cir. R. 33.1 and the mediation guidelines available at www.cafc.uscourts.gov.]
- Requests for extensions of time. See Fed. Cir. R. 26 and 27. N.B. Delayed requests are not favored by the court.
- Briefs. See Fed. Cir. R. 31. N.B. You will not receive a separate briefing schedule from the Clerk's Office.
- ORAL ARGUMENT SCHEDULE CONFLICTS: Counsel should advise the clerk in writing within 30 days
 once briefing is completed of potential scheduling conflicts or as soon as they are known and should not wait
 until an actual conflict arises. Once scheduled, a case will not be postponed except on motion showing
 compelling reasons. See Practice Note following Fed. Cir. R. 34.

The official caption is reflected on the electronic docket under the listing of the parties and counsel. The Rules of Practice and required forms are available at www.cafc.uscourts.gov.

Peter R. Marksteiner Clerk of Court

cc:

Secretary, Department of Veterans Affairs
Director, Commercial Litigation Branch, Civil Division, U.S. Department of Justice, P.O. Box 480, Ben Franklin Station, Washington, DC 20044
Paul Reinherz Wolfson

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DEE FULCHER, GIULIANO SILVA, and TRANSGENDER AMERICAN VETERANS ASSOCIATION,)))
Petitioners,) PETITION FOR REVIEW PURSUANT TO 38 U.S.C. § 502)
SECRETARY OF VETERANS AFFAIRS,	
Respondent.)))

Pursuant to 38 U.S.C. § 502 and Federal Circuit Rule 47.12, Dee Fulcher ("Ms. Fulcher"), Giuliano Silva ("Mr. Silva"), and the Transgender American Veterans Association ("TAVA") (collectively "Petitioners") hereby petition this Court for review of the denial of their petition for rulemaking by the U.S. Department of Veterans Affairs (the "Department" or "VA"). The petition for rulemaking, *see* Exhibit 1 ("Pet."), requested that the Department initiate rulemaking to amend or repeal rules and regulations excluding sex reassignment surgery as a covered medical benefit for transgender veterans and, in particular, to amend or repeal 38 C.F.R. § 17.38(c)(4) (the "Regulation"), which categorically excludes coverage for "gender alterations."

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STATEMENT OF THE CASE

On May 9, 2016, Petitioners filed a petition for rulemaking pursuant to 5 U.S.C. § 553(e), requesting that the VA "amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4) and any implementing directives, that exclude medically necessary sex reassignment surgery for transgender veterans from the medical benefits package provided to veterans under the health care system of the [Department], and to promulgate regulations expressly including medically necessary sex reassignment surgery for transgender veterans in that medical benefits package." Pet. 1. The Department acknowledged receipt of the petition.

Later in the spring of 2016, the Department announced in the Unified Agenda of Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the federal government, that it was considering issuance of a notice of proposed rulemaking to remove the regulation that prohibits the VA from providing medical services that are considered gender alterations.

On November 10, 2016, the Department informed members of Congress that it was withdrawing consideration of that possible rulemaking from its regulatory agenda. *See* Exhibit 2. Although the Department stated that it "will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding

is available," it made clear that any rulemaking that would allow the VA to perform or pay for such treatment is "not imminent." *Id.* The VA's letter amounts to a denial of the petition. *See Nat'l Parks Conservation Ass'n v. U.S. Dep't of Interior*, 794 F. Supp. 2d 39, 46 (D.D.C. 2011) (holding in part that an agency's letter response, which stated that the agency may engage in future rulemaking but would not initiate rulemaking at that time, constituted a denial of the plaintiffs' petition for rulemaking).

This petition for review is timely because it is filed within 60 days of the VA's letter as required by Federal Circuit Rule 47.12. This Court has jurisdiction pursuant to 38 U.S.C. § 502 to review the VA's denial of the petition for rulemaking. *See Preminger v. Sec'y of Veterans Affairs*, 632 F.3d 1345, 1352 (Fed. Cir. 2011).

PETITIONERS

Pursuant to Federal Circuit Rule 47.12, Petitioners state that each has been adversely affected by the VA's denial of the petition for rulemaking.

Ms. Fulcher is a transgender veteran of the U.S. Marine Corps who has been diagnosed with gender dysphoria and whose VA clinicians have recommended sex reassignment surgery as treatment. Pet. 6. Because of the Regulation, Ms. Fulcher cannot obtain medically necessary procedures that her clinicians have prescribed. Pet. 6.

Mr. Silva is a transgender man who has also been diagnosed with gender dysphoria. He is a veteran of the U.S. Army. Pet. 6. Mr. Silva would undergo both a mastectomy and reconstructive surgery but cannot obtain both because of the Regulation. Pet. 6.

Both Ms. Fulcher and Mr. Silva are members of TAVA, which is a 501(c)(3) organization dedicated "to ensuring that transgender veterans receive appropriate and necessary medical care." Pet. 4. Members of TAVA have been denied access to sex reassignment surgery by the Regulation. TAVA has independent standing to bring this petition because its members are directly harmed by the Regulation, the petition is germane to TAVA's purpose, and the participation of individual members is not required for the relief sought. See Disabled Am. Veterans v. Gober, 234 F.3d 682, 689 (Fed. Cir. 2000) (citing Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977)). Specifically, at least one veteran is a member of TAVA, Pet. 6; advocacy relating to healthcare for transgender veterans is consistent with TAVA's mission, Pet. 5; and, although individual TAVA members are participating in this appeal, their participation is not necessary to obtain the desired relief—namely, an order requiring the VA to engage in the requested rulemaking.

RELIEF SOUGHT

For the foregoing reasons, Petitioners request that this Court review the Department's denial of the petition for rulemaking and direct the VA to undertake a rulemaking to amend or repeal the Regulation.

Dated: January 6, 2017

M. Dru Levasseur LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 120 Wall Street, 19th Floor New York, NY 10005 Telephone: (212) 809-8585 Facsimile: (212) 809-0055

Tara L. Borelli LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 730 Peachtree Street NE, Suite 1070 Atlanta, GA 30308-1210 Telephone: (404) 897-1880 Facsimile: (404) 897-1884 Respectfully submitted,

/s/ Paul R.Q. Wolfson
Paul R.Q. Wolfson
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue
Washington, DC 20006
Telephone: (202) 663-6390
Facsimile: (202) 663-6363

Alan Schoenfeld WILMER CUTLER PICKERING HALE AND DORR LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007 Telephone: (212) 937-7294 Facsimile: (212) 230-8888

Attorneys for Petitioners

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EXHIBIT 1

PETITION FOR RULEMAKING TO PROMULGATE REGULATIONS GOVERNING PROVISION OF SEX REASSIGNMENT SURGERY TO TRANSGENDER VETERANS

SUBMITTED TO

THE UNITED STATES DEPARTMENT OF VETERANS AFFAIRS MAY 9, 2016

Dee Fulcher, Giuliano Silva, and Transgender American Veterans Association

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Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association ("TAVA") (together, "Petitioners") hereby petition the Secretary of Veterans Affairs (the "Secretary") to amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4) and any implementing directives, that exclude medically necessary sex reassignment surgery for transgender veterans from the medical benefits package provided to veterans under the health care system of the Department of Veterans Affairs ("Department" or "VA"), and to promulgate regulations expressly including medically necessary sex reassignment surgery for transgender veterans in that medical benefits package.

I. INTRODUCTION

When Congress enacted the Veterans Health Care Eligibility Reform Act of 1996 (Pub. L. 104-262), establishing the current framework for veteran eligibility for medical benefits under the VA health care system, the United States sought to ensure that the medical needs of all American veterans would be met through the provision of quality health care. To implement that directive, the Department has promulgated a series of regulations establishing robust coverage for the panoply of medical needs that veterans of our armed services might confront. But in contravention of that directive, the Department also has promulgated a discriminatory regulation that singles out transgender veterans and bars the provision of medically necessary sex reassignment surgery to treat gender dysphoria. *See* 38 C.F.R. § 17.38(c)(4) (prohibiting coverage for "gender alterations") (the "Regulation").

That bar has remained in place notwithstanding the existence of a broad medical consensus about the need for sex reassignment surgery for many transgender people, and notwithstanding the United States' own evolving policies on the ability of transgender people to serve openly in the military. The Department's exclusion for sex reassignment surgery was not supported by medical evidence when it was implemented in 1999, and it is even more

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indefensible today. The Department should eliminate the categorical exclusion of sex reassignment surgery as a treatment for gender dysphoria, and expressly include sex reassignment surgery in the medical benefits package available to veterans, either as an exercise of the Secretary's discretion or in recognition of the fact that the exclusion is both arbitrary and capricious and unconstitutional.

Providing sex reassignment surgery to transgender veterans for whom it is medically indicated is required by the Department's stated policy of providing medically necessary care to all veterans. That sex reassignment surgery is a medically necessary treatment for gender dysphoria is not in dispute within the medical community; all major medical associations recognize this treatment as such. Providing sex reassignment surgery to transgender veterans is essential to relieving the serious distress caused by gender dysphoria. Our Nation owes transgender veterans this treatment in the same way it owes all other veterans medically necessary care for their serious medical conditions. Finally, although the Department has never justified the exclusion for sex reassignment surgery on cost grounds, it bears emphasis here that any marginal increase in the Department's total expenditures on medical care—which should be negligible—should be offset in whole or in part by the reduced costs of long-term health care that would otherwise be necessary for some transgender veterans denied surgical treatment.

Including sex reassignment surgery in the medical benefits package is legally required, and the refusal to do so would constitute arbitrary and capricious agency action, subject to reversal by the federal courts. The established medical consensus plainly requires the inclusion of sex reassignment surgery in the medical benefits package, on equal footing with medical treatments that address other similarly serious and treatable medical conditions. Indeed, the Department recognizes the seriousness of gender dysphoria as a medical condition: It offers

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other treatments that may be necessary (but not sufficient) to ameliorate that condition, such as hormone therapy, and it offers ancillary treatments supporting sex reassignment surgery, such as pre- and post-surgical care, for the few who can pay for the surgery on their own. Nor does the Department appear to have any rational objection to the forms of surgery involved in sex reassignment surgery: The Department's regulations and directives offer surgeries identical or substantially similar to those constituting sex reassignment surgery to veterans with other medical conditions. And, finally, the VA excluded sex reassignment surgery without examining any relevant data and without giving any public explanation for the exclusion. All of this lays bare the arbitrariness of the exclusion at issue here.

The Fifth Amendment to the Constitution likewise bars the exclusion. To offer certain medically necessary surgeries to veterans for some conditions, yet to deny the same or substantially similar surgeries to transgender veterans to treat gender dysphoria, constitutes unconstitutional discrimination on the basis of sex and transgender status, and the regulations implementing this discrimination fail to survive any level of scrutiny that may be applied. These regulations—lacking any connection to medical consensus or any other rational justification—are also unconstitutional under a long line of Supreme Court cases forbidding discriminatory treatment that appears to be based on "a bare ... desire to harm a politically unpopular group'[.]" *United States v. Windsor*, 133 S. Ct. 2675, 2693 (2013) (quoting *Department of Agriculture v. Moreno*, 413 U.S. 528, 534-35 (1973)).

The amendments this petition seeks are not only good policy and legally required—they also are urgent. The suicide rate for individuals with untreated gender dysphoria is significantly higher than that of the general population, as is the prevalence of depression, self-harm, and drug and alcohol addiction. Appropriate treatment is necessary to prevent such suffering and long-

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term harm. Petitioners respectfully request that the Secretary attend to the urgency of the need of some transgender veterans for sex reassignment surgery in his consideration of this petition.

II. LEGAL AUTHORITY

Congress granted the Secretary of Veterans Affairs the "authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department," which include laws governing veterans' benefits. 38 U.S.C. § 501(a). The Secretary thus has the authority to amend or repeal the rules and regulations that are the focus of this petition, including 38 C.F.R. § 17.38(c)(4), and to issue appropriate rules and regulations in their place.

III. PETITIONERS

Petitioners each have the statutory right to petition the Department for rulemaking pursuant to 5 U.S.C. § 553(e), which requires "[e]ach agency [to] give an interested person the right to petition for the issuance, amendment, or repeal of a rule." Petitioners also satisfy the standing requirements of Article III of the United States Constitution.

TAVA is a 501(c)(3) organization dedicated to ensuring that transgender veterans receive appropriate and necessary medical care. TAVA was founded in 2003 to advocate on behalf of transgender veterans within the VA health care system. Its mission is to work with the VA, Congress, veterans, active-duty military personnel, and LGBT groups to influence the VA and military policy, regulations, and procedures regarding the provision of medical and psychological care to veterans with gender dysphoria. While TAVA primarily focuses on ensuring the fair and equal treatment of transgender individuals, it is committed to improving the health care of all American veterans.

TAVA is a membership organization, and many of its members are transgender veterans currently enrolled in the VA health care system. Affidavit of Evan Young ("Young Aff.") ¶ 11.

Some of those individuals have been diagnosed with gender dysphoria by the VA and have been provided some medical care related to their diagnosis. *Id.* However, members who have sought sex reassignment surgery through the VA, or coverage of such surgery by the VA, have been denied such surgery or coverage because of the existing regulatory exclusion of "gender alterations" from covered benefits. *Id.* Many of those veterans rely on the VA for provision of their mental and physical health care, and they satisfy all the medical prerequisites for sex reassignment surgery: They have been diagnosed with gender dysphoria (often by VA clinicians), they have spent multiple years living in a gender role consistent with their gender identity and are currently undergoing hormone therapy to assist in their transition, and they have been prescribed sex reassignment surgery by qualified mental health providers as medically necessary treatment for their condition. Id. Nevertheless, these veterans have been unable to obtain medically necessary sex reassignment surgery due to the VA's categorical bar on "gender alterations." Id. These veterans are currently, concretely, and directly harmed by the VA's bar on sex reassignment surgery; granting the petition and repealing or amending the Regulation as requested herein would provide them with redress.

TAVA's purpose in submitting this petition is to advocate on behalf of its members who have been denied medically necessary treatment as a result of the VA's regulations. Young Aff. ¶ 12. This petition directly advances one of TAVA's central organizational goals—to achieve reform of the VA's policies regarding coverage of sex reassignment surgery and other medical procedures related to gender dysphoria. *Id.* If the VA were to amend its regulations to include coverage of sex reassignment surgery, such an amendment would significantly improve the physical and mental health of TAVA members and of other transgender veterans with gender dysphoria. *Id.*

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Although the relief requested by TAVA in this petition does not require the participation of TAVA's individual members, *see, e.g., Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362, 1369 (Fed. Cir. 2007), TAVA is joined in this petition by Dee Fulcher and Giuliano Silva, individual transgender veterans whose interests are directly affected by the VA's exclusion of sex reassignment surgery.

Dee Fulcher is a veteran of the U.S. Marine Corps and a member of TAVA. Affidavit of Dee Fulcher ("Fulcher Aff.") ¶ 2. Dee is a transgender woman. *Id.* She was first diagnosed with gender dysphoria by a physician outside of the VA health care system. *Id.* ¶ 6.

Ms. Fulcher's diagnosis of gender dysphoria has been confirmed by a clinical mental health social worker and a board certified physician in internal medicine, both at the Southeast Louisiana Veterans Healthcare System (part of the VA health care network). *Id.* ¶¶ 6-7. Ms. Fulcher's VA clinicians have both recommended that she receive sex reassignment surgery as the next step in her treatment for gender dysphoria. *Id.* If that were covered by the VA, Ms. Fulcher would pursue such surgery, including penectomy, vaginoplasty, facial feminization, breast augmentation, and electrolysis. *Id.* ¶ 8. Yet due to the VA's exclusion of sex reassignment surgery, Ms. Fulcher cannot receive this medically necessary treatment that her physician and mental health provider have prescribed for her.

Giuliano Silva is a veteran of the U.S. Army and a member of TAVA. Affidavit of Giuliano Silva ("Silva Aff.") ¶ 2. Mr. Silva is a transgender man and has been diagnosed with gender dysphoria by medical providers at the Miami VA Healthcare System. *Id.* ¶ 10. While Mr. Silva would seek sex reassignment surgery (in particular, a mastectomy) if that surgery were covered, Mr. Silva also has suffered, and continues to suffer, from additional effects of the VA's exclusion of sex reassignment surgery on the medical practices of VA healthcare providers.

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Id. ¶ 15. The VA's exclusion of sex reassignment surgery has had the effect of preventing Mr. Silva from receiving a mastectomy, which a VA physician has recommended to Mr. Silva to treat his severe back pain and related problems. Id. ¶ 11. The surgeon to whom this physician referred Mr. Silva appears to have determined that Mr. Silva is seeking the mastectomy primarily as transition-related surgery, rather than as a surgery to address his severe back problems, and has consequently determined that the surgery is not covered. Id. In Mr. Silva's experience, the VA's exclusion of sex reassignment surgery has left VA doctors skeptical of the medical needs of transgender veterans and outwardly hostile to treating them. Id. ¶ 12.

IV. BACKGROUND: THE CURRENT REGULATORY FRAMEWORK, GENDER DYSPHORIA, AND SEX REASSIGNMENT SURGERY

A. The VA's Provision of Medical Care

Under 38 U.S.C. § 1710, the Secretary "shall furnish" "medical services" that the Secretary determines to be "needed" by several classes of veterans, including those with a service-connected disability, former prisoners of war, veterans of World War I, and all veterans who are unable "to defray the expenses of necessary care," which include all veterans who qualify for Medicaid, receive a qualifying pension, or meet specified income thresholds.

38 U.S.C. §§ 1710(a)(1)-(2), 1722 (a)(1)-(3). In addition, under § 1710, the Secretary is authorized to provide "needed" "medical services" to all veterans "to the extent resources and facilities are available." 38 U.S.C. § 1710(a)(3). Thus, all veterans are eligible to receive medically necessary health care, as determined by the Secretary, as long as the VA has the resources to provide or pay for such care. As President Clinton explained in signing the current enabling statute into law, it "authorizes the Department of Veterans Affairs to furnish comprehensive medical services to all veterans." Presidential Statement on Signing Veterans Legislation, 32 Weekly Comp. Pres. Doc. 2018 (Oct. 9, 1996).

Veterans who enroll in the VA health care system (as well as certain other veterans meeting other criteria¹) are entitled to a "medical benefits package" as defined by regulation (the "Medical Benefits Package"). 38 C.F.R. § 17.36. The regulation sets forth a broad and overarching directive for the provision of veterans' health care: Veterans are meant to receive a given medical treatment "if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice." 38 C.F.R. § 17.38(b). Care is deemed "to promote health" if "the care will enhance the quality of life or daily functional level of the veteran." *Id.* at 17.38(b)(1). To that end, the regulation broadly covers inpatient and outpatient medical, surgical, and mental health care. *See* 38 C.F.R. § 17.38(a).

B. Gender Dysphoria and Sex Reassignment Surgery

At issue in this petition is the VA's coverage of medically necessary health care for veterans with gender dysphoria. By way of background, "gender identity" is an established medical concept, referring to one's intrinsic understanding of oneself as being a particular gender. Declaration of Dr. Randi C. Ettner ("Ettner Decl.") ¶ 11. Gender identity is an innate aspect of personality that is firmly established, generally by the age of four, although individuals vary in the age at which they come to understand and express that identity. *Id.* Typically, people who are designated female at birth based on the appearance of their genitalia identify as girls or women, and people who are designated male at birth identify as boys or men. *Id.* ¶ 12. For transgender individuals, however, the person's gender identity differs from the sex assigned to

Under 38 C.F.R. § 17.37, even veterans who are not enrolled in the VA health care system may receive the care in the Medical Benefits Package, or some subset thereof, if they fall within one of certain specified classes. For example, veterans with service-connected disabilities that meet specified severity criteria are entitled to all the care in the Medical Benefits Package (§ 17.37(a)), and a veteran with a compelling medical need to complete a course of VA treatment started when the veteran was enrolled in the VA health care system may continue to receive that treatment regardless of the veteran's continuing enrollment status (§ 17.37(d)).

that person at birth.² The medical diagnosis for that feeling of incongruence is gender dysphoria, which can cause severe distress if untreated. *Id.* ¶ 13.

The major medical associations and diagnostic manuals uniformly recognize gender dysphoria as a serious medical condition. For example, the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition—on which the VA regulations governing ratings for disability relating to mental disorder rely, *see* 38 C.F.R. § 4.130—dedicates an entire chapter to the diagnosis of gender dysphoria.³ Other manuals too, such as the *International Classification of Diseases*, provide for a diagnosis of gender dysphoria (albeit using different terminology).⁴ Major medical organizations—including the American Psychiatric Association, the American Medical Association, the Endocrine Society, and the American Psychological Association—likewise recognize gender dysphoria, and provide for its diagnosis and full treatment, including through sex reassignment surgery where necessary. Declaration of Dr. Marci L. Bowers ("Bowers Decl.") ¶ 36; Ettner Decl. ¶¶ 11, 13-14, 18, 24, 35.

In May 2012, the American Psychiatric Association ("APA") issued an official Position

Statement on Access to Care for Transgender and Gender Variant Individuals, which:

(1) recognizes that appropriately evaluated transgender and gender variant individuals can benefit greatly from medical and surgical gender transition treatments; (2) advocates for removal

A transgender man is a person who was assigned the sex of female at birth but whose gender identity is male. A transgender woman is a person who was assigned the sex of male at birth but whose gender identity is female.

The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition ("DSM" or "DSM-5"), is used throughout the world as the authoritative guide to the diagnosis of mental disorders and includes gender dysphoria. The DSM "provides a common language for clinicians to communicate about their patients and establishes consistent and reliable diagnoses that can be used in the research of mental disorders." American Psychiatric Association, DSM Development, *available at* http://www.dsm5.org/about/Pages/faq.aspx.

World Health Organization, "Gender Identity Disorders," International Statistical Classification of Diseases and Related Health Problems, 10th Revision (2016), at F64, *available at* http://apps.who.int/classifications/icd10/browse/2016/en#/F64.0.

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of barriers to care and supports both public and private health insurance coverage for gender transition treatment; and (3) opposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician.⁵

The protocol for diagnosing and treating gender dysphoria is well established and generally accepted by the medical community. The Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People promulgated by the World Professional Association for Transgender Health ("WPATH Standards" or "Standards of Care") set forth the accepted protocol for the diagnosis and treatment of gender dysphoria, and are recognized as authoritative standards of care by the American Psychiatric Association, the Endocrine Society, and the American Psychological Association. Ettner Decl. ¶ 18.

The Standards of Care identify the following treatment protocols for treating individuals with gender dysphoria:

- Changes in gender expression and role (which may involve living part-time or full-time in another gender role, consistent with one's gender identity);
- Psychotherapy (individual, couple, family, or group) for purposes such as
 exploring gender identity, role, and expression; addressing the negative
 impact of gender dysphoria and stigma on mental health; alleviating
 internalized transphobia; enhancing social and peer support; improving body
 image; or promoting resilience;
- Hormone therapy to feminize or masculinize the body; and

American Psychiatric Association, Position Statement on Access to Care for Transgender and Gender Variant Individuals (2012), *available at* http://www.psychiatry.org/File%20Library/Learn/Archives/Position-2012-Transgender-Gender-Variant-Access-Care.pdf.

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 Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring).

Sex reassignment surgery is a well-established, effective, and often critical treatment for gender dysphoria. Bowers Decl. ¶¶ 31-38; Ettner Decl. ¶¶ 15, 19-34. While not all individuals with gender dysphoria require sex reassignment surgery, the WPATH Standards recognize that hormone therapy and psychotherapy may be inadequate to treat severe cases of gender dysphoria, and in those cases, failure fully to treat gender dysphoria through sex reassignment surgery may cause serious mental and physical health issues for the patient. Bowers Decl. ¶¶ 34, 37; Ettner Decl. ¶ 19-20. Without treatment, individuals with severe gender dysphoria experience anxiety, depression, suicidality, and other attendant mental health issues. Bowers Decl. ¶ 37; Ettner Decl. ¶ 15. Many such individuals carry a burden of shame and low selfesteem, attributable to a feeling of being inherently "defective," and as a result become socially isolated. Ettner Decl. ¶ 15. This isolation in turn leads to the stigmatization of such individuals, which over time proves ravaging to healthy personality development and interpersonal relationships. *Id.* As a result, without treatment, many such individuals are unable to function effectively in occupational, social, or other important areas of daily living. *Id.* A recent survey shows a 41% rate of suicide attempts among transgender people, far above the baseline rates for North America. *Id.* As with the diagnosis of gender dysphoria, there is a consensus within the medical community that sex reassignment surgery may be the only adequate treatment for some cases of gender dysphoria. *Id.* ¶¶ 21, 23; Bowers Decl. ¶ 34.

Courts too have recognized that gender dysphoria is a serious medical condition and that sex reassignment surgery may be medically necessary to treat certain individuals with gender

dysphoria. In *Soneeya v. Spencer*, for example, the court held that a prisoner's gender dysphoria constituted a "serious medical need" that the Massachusetts Department of Correction ("MDOC") was required under the Eighth Amendment to address adequately. Moreover, although the MDOC had provided the prisoner with psychotherapy and hormone treatment, offering such treatment alone was inadequate, as the MDOC also was required to "consider whether sex reassignment surgery ... [was] medically indicated." Likewise, in *Fields v. Smith*, the court found that gender dysphoria was a "serious medical need" within the meaning of the Eighth Amendment, and held that a statutory prohibition on hormone therapy and sex reassignment surgery for inmates was unconstitutional on its face because it deprived inmates of access to "medically necessary" treatment.

In a recent Tax Court case, *O'Donnabhain v. Commissioner*, the court conducted a trial and an in-depth review of the medical evidence regarding treatment of gender dysphoria. ⁹ The court noted the broad acceptance of the WPATH Standards throughout the psychiatric profession, as evidenced by multiple psychiatric and medical reference texts and court opinions, all concluding that sex reassignment surgery is medically necessary to ensure the health of some patients suffering from gender dysphoria. ¹⁰ Other courts to consider the necessity of surgery to treat gender dysphoria have reached similar conclusions. ¹¹

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⁸⁵¹ F. Supp. 2d 228, 231-232, 252 (D. Mass. 2012).

⁷ *Id.* at 252.

⁸ 712 F. Supp. 2d 830, 844 (E.D. Wis. 2010).

⁹ See O'Donnabhain v. Commissioner, 134 T.C. 34, 65-70 (2010).

¹⁰ *Id*.

See, e.g., De'lonta v. Johnson, 708 F.3d 520, 526 (4th Cir. 2013) (noting that sex reassignment surgery is an "accepted, effective, medically indicated treatment for GID").

Sex reassignment surgery often may be the only adequate treatment for gender dysphoria. In certain cases, sex reassignment surgery—which can include, depending upon the circumstances, removal or construction of the breasts, penectomy, vaginoplasty, phalloplasty, and penile and testicular implants—is medically necessary to treat the symptoms of gender dysphoria, and indeed may be the only medically adequate treatment.¹²

The VA's categorical ban on sex reassignment surgery in all instances, no matter how necessary it may be for an individual, flies in the face of the medical consensus on this subject. This categorical exclusion is all the more irrational because the VA recognizes that gender dysphoria is a serious medical condition that requires treatment. For example, the VA will provide, where medically necessary, hormone treatment to address gender dysphoria. The VA also will provide pre- and post-operative care for veterans who have undergone sex reassignment surgery outside the VA system. Thus, the VA appears to have no *medical* objection to sex reassignment surgery. Yet the VA irrationally continues to exclude coverage for sex reassignment surgery—no matter how medically necessary.

C. The VA's Current Provision of Surgeries Constituting Sex Reassignment Surgery To Treat Other Conditions

The VA already provides each of the surgeries that constitute sex reassignment surgery. The VA provides these surgeries for a variety of reasons, including to address certain intersex conditions, to repair traumatic injuries, and to treat cancer, but the VA denies those same procedures to transgender veterans for the treatment of gender dysphoria. For example, VA policy covers surgery for intersex veterans "in need of surgery to correct inborn conditions related to reproductive or sexual anatomy." VHA Directive 2013-003 (Feb. 8, 2013) ("VHA

See id. (noting, in the Eighth Amendment context, that providing some treatment consistent with the WPATH Standards does not mean that constitutionally adequate treatment has been provided); see also Norsworthy v. Beard, 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015) (granting preliminary injunction where plaintiff was likely to succeed in establishing that surgery was "the only way to treat her persistent symptoms of gender dysphoria").

Directive 2013-003" or "Directive 2013-003"), at 2. Under 38 C.F.R. § 17.38(a)(1)(x), the VA offers veterans "[r]econstructive (plastic) surgery required as a result of disease or trauma," which under VHA Directive 1091 (Feb. 21, 2014) ("Directive 1091") includes "those surgical procedures performed for the revision of external bodily structures which deviate from normal either from congenital or acquired causes."

Under 38 C.F.R. § 17.38(a)(1)(x) and Directive 1091, the VA offers breast reconstruction to cisgender ¹³ women who have had a mastectomy, and penile and testicular implants to cisgender males whose penises or testes have been damaged. Hysterectomy and mastectomy are offered to cisgender females for, among other reasons, reduction of cancer risk. The VA also offers cisgender males orchiectomies, scrotectomies, and penectomies for various medical reasons. Moreover, under the clear language of Directive 2013-003, the VA offers various procedures, including vaginoplasty and phalloplasty, for certain intersex individuals born with ambiguous genitalia.

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[&]quot;Cisgender" is a term used to describe a person whose self-identity conforms to the sex he or she was assigned at birth—*i.e.*, someone who is not transgender. *See Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1120 n.9 (N.D. Cal. 2015).

See Leong et al., Effective Breast Reconstruction in Female Veterans, 198(5) Am. J. Surg. 658-63 (Nov. 2009) (addressing outcomes of breast reconstruction performed at VA hospitals); Shimansky v. West, 17 Vet. App. 90, 90 (1999) (patient received a penile prosthesis at the Wilmington, Delaware VA Medical Center); Brewer v. Nicholson, 21 Vet. App. 420, 420 (2006) (patient received a penile prosthesis at the Jackson, Mississippi VA Medical Center); Board of Veteran's Appeals, Docket No. 96-07-121 (Sept. 26, 1997) (stating patient received a "testicular prosthetic implantation" at a VA hospital).

See Gardella et al., Prevalence of Hysterectomy and Associated Factors in Women Veterans Affairs Patients, 50(3) J. Reprod. Med. 166, 166-72 (Mar. 2005) (estimating the prevalence of hysterectomies provided by the VA Puget Sound Health Care System); Hynes et al., Breast Cancer Surgery Trends and Outcomes: Results from a National Department of Veterans Affairs Study, 198(5) J. of the Am. College of Surgeons 707-16 (Mar. 2004) (examining trends in breast cancer surgery performed at VA hospitals).

See Norvell v. Peake, 22 Vet. App. 194, 195 (2008) (noting that the patient underwent a bilateral orchiectomy at Lexington, Kentucky, VA Medical Center), aff'd sub nom. Norvell v. Shinseki, 333 F. App'x 571 (Fed. Cir. 2009); Corman et al., Fournier's Gangrene in a Modern Surgical Setting: Improved Survival with Aggressive Management, BJU International, 84: 85-88 (July 1999) (noting that all patients covered in the survey had received scrotectomies for Fournier's Gangrene and that some of the patients had been treated at West Los Angeles Veterans Administration Hospital); Board of Veterans Appeals, Docket No. 05-31 519 (Oct. 25, 2007) (noting that the patient had undergone a total penectomy at a VA hospital due to cancer).

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These procedures are excluded from coverage, however, if they are necessary to treat a transgender veteran's gender dysphoria. The regulation at issue here, *i.e.*, 38 C.F.R. § 17.38(c)(4), expressly excludes "[g]ender alterations" from the Medical Benefits Package. VHA Directive 2013-003 clarifies that this exclusion constitutes an absolute bar to coverage for "sex reassignment surgery," which the Directive defines to include "any of a variety of surgical procedures (including vaginoplasty and breast augmentation in MtF transsexuals and mastectomy and phalloplasty in FtM transsexuals) done simultaneously or sequentially with the explicit goal of transitioning from one sex to another." VHA Directive 2013-003 at 2. Heedless of the current medical consensus regarding the medical necessity of sex reassignment surgery for some individuals suffering from gender dysphoria, the Directive puts such surgery on equal footing with "plastic reconstructive surgery for strictly cosmetic purposes." It does this even though, as noted above, substantively identical procedures are available to intersex veterans under the clear language of the Directive, and to other veterans for various reasons, including to repair traumatic injuries and to treat cancer.

The illogic of the exclusion on sex reassignment surgery is underscored not only by the fact that the VA provides its constituent procedures to other veterans to treat other conditions, but also by the fact that the VA covers *other* aspects of transgender health, including hormone therapy and post-sex-reassignment-surgery health care. Specifically, the VA provides mental health care, hormone therapy, and preoperative evaluation for transgender veterans, as well as continuing hormone replacement therapy and post-operative care to veterans who have received sex reassignment surgery outside the VA health care system. VHA Directive 2013-003 at 2. The VA clearly views those treatments as medically necessary, but irrationally excludes only surgical treatments needed to treat gender dysphoria.

D. The Critical Need for Sex Reassignment Surgery in the Transgender Veteran Population

Recent empirical studies show that the estimated prevalence of transgender individuals in the Nation's military is five times greater than the estimated prevalence in the civilian population. As of May 2014, there are an estimated 129,700 transgender veterans of the U.S. Military, as well as 4,600 retired transgender members of the U.S. Reserves and National Guard. Approximately 15,500 transgender individuals currently serve as members of the U.S. Armed Forces, Reserves, and Guard. The population of transgender veterans is so significant that since 2015, clinics have opened in Cleveland, Ohio and Tucson, Arizona to specialize in providing medical care to these veterans. Similarly, the VA Boston Healthcare System has formed the Interdisciplinary Transgender Treatment Team, which provides medical care tailored to the needs of transgender veterans.

Moreover, recent progress in policies affecting transgender military personnel suggests that the population of transgender active-duty military and veterans is likely only to increase. In July 2015, United States Secretary of Defense Ashton B. Carter issued a directive to devise new rules to allow transgender individuals to serve openly in the military.²¹ These rules are expected to reverse the military's longstanding policy of preventing transgender individuals from serving

Blosnich et al., Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care, 103(10) Am. J. of Public Health e27 (2001).

Gates & Herman, *Transgender Military Service*, Williams Institute (May 2014).

Albrecht, VA's First Transgender Clinic Opens in Cleveland, Cleveland.com (Nov. 2015); Jenkins, New VA Clinic Opens for Transgender Vets, National Public Radio (Dec. 29, 2015).

Dep't of Veterans Affairs, VA Boston Healthcare Sys. (Mar. 3, 2016).

Somashekhar & Whitlock, *Military To Allow Transgender Members To Serve Openly*, Wash. Post, July 13, 2015.

and reflect a growing recognition on the part of the federal government as a whole that transgender individuals deserve fair and equal treatment under the law.²²

While the percentage of veterans who are transgender is very significant compared to the percentage of transgender individuals in the general population, the transgender veteran population nevertheless constitutes only a small percentage of the total veteran population.

Based on the best available data, only 0.6% of the national population of veterans and retirees of the U.S. Armed Forces, Army Reserves, and National Guard is transgender.²³

E. Developments in Health Care Coverage for Transgender Individuals

The VA's categorical exclusion of sex reassignment surgery from the package of medical benefits available to transgender veterans has become increasingly divorced from the practices of other federal agencies and States, which have recognized that sex reassignment surgery may be a medical necessity to treat gender dysphoria. Several federal agencies and state governments have adopted laws and policies to prohibit discrimination against transgender individuals in access to health care. In particular, these agencies and governments have prohibited categorical bars on sex reassignment surgery in coverage determinations made by insurers and health care programs receiving federal and state financial assistance.

At the federal level, the Department of Health and Human Services ("HHS") recently issued a proposed rule under Section 1557 of the Affordable Care Act ("ACA") that would prohibit sex discrimination (including on the basis of gender identity) in any health program or activity receiving federal financial assistance. 42 U.S.C. § 18116; *see* Nondiscrimination in

On January 14, 2016, Matthew Allen, a Pentagon spokesperson, stated that he anticipates that the Secretary's final approval of the rules will be issued in spring 2016. Johnson, *Pentagon Expects Decision on Trans Military Ban in Spring*, Wash. Blade, January 14, 2016, *available at* http://www.washingtonblade.com/2016/01/14/pentagon-expects-determination-on-trans-military-ban-in-spring.

Gates & Herman, *supra* note 18 at 4.

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Health Programs and Activities, 80 Fed. Reg. 54,172 (Sept. 8, 2015). That prohibition applies to all covered entities under the ACA that provide or administer health-related insurance or other health-related coverage. Although the prohibition does not apply to the VA, it is nonetheless instructive for the VA as it formulates its own nondiscriminatory practices. The proposed rule clarifies that the statutory bar on sex discrimination includes discrimination on the basis of gender identity, and voids any explicit categorical exclusion for coverage of health services related to gender transition, such as the one at issue here. The rule also would prohibit denial of any specific health services related to gender transition "where such a denial or limitation results in discrimination against a transgender individual." 80 Fed. Reg. at 54,190. For example, a health care plan may be discriminatory if it generally provides coverage of hysterectomies but denies coverage of a hysterectomy needed to treat gender dysphoria. See id.

Additionally, the HHS Departmental Appeals Board recently overturned a thirty-year-old National Coverage Determination ("NCD") denying Medicare coverage of all sex reassignment surgery as a treatment for gender dysphoria.²⁴ An NCD is "a determination by the Secretary [of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under [title XVIII (Medicare)]." Social Security Act §§ 1862(1)(6)(A), 1869(f)(1)(B); see also 42 C.F.R. § 400.202 (NCD "means a decision that [the Centers for Medicare & Medicaid Services] makes regarding whether to cover a particular service nationally under title XVIII of the Social Security Act."). NCDs "describe the clinical circumstances and settings under which particular [Medicare items and] services are reasonable and necessary (or are not reasonable and necessary)." 67 Fed. Reg. 54,534, 54,535 (Aug. 22, 2002). The Appeals Board found that the exclusion of coverage of sex reassignment surgery was unreasonable in

See Decision No. 2576, Department of Health and Human Services, Departmental Appeals Board (May 30, 2014), available at http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.

light of significant and unchallenged empirical evidence supporting the safety, effectiveness, and necessity of that treatment for certain individuals with severe gender dysphoria.²⁵

Other federal agencies and multiple States have acknowledged the need to establish clear policies that recognize the medical consensus that sex reassignment surgery may be medically necessary for a number of transgender individuals. For example, the Office of Personnel Management ("OPM") recently issued a letter to health insurance carriers participating in the Federal Employees Health Benefits Program stating that no carrier "may have a general exclusion of services, drugs or supplies related to gender transition or 'sex transformations.'"²⁶ The guidance from OPM recognizes "the evolving professional consensus that treatment may be medically necessary to address a diagnosis of gender dysphoria."²⁷ And an increasing number of States, including California, Colorado, Connecticut, Illinois, Maryland, Massachusetts, Minnesota, Nevada, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington, as well as the District of Columbia, have adopted laws and policies that recognize the discriminatory nature of health care programs that deny necessary coverage for the treatment of gender dysphoria.²⁸ These recent policy revisions and clarifications focus on the inappropriateness of blanket exclusions of sex reassignment surgery and other treatments for

²⁵ *Id*.

U.S. Office of Personnel Management, FEHB Program Carrier Letter, Letter No. 2015-12 (June 23, 2015), available at https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-12.pdf.

²⁷ *Id*.

See Pennsylvania Ins. Dep't, Notice Regarding Nondiscrimination, Pa.B. Doc. No. 16-762, 46 Pa.B. 2251 (Apr. 30, 2016), available at http://www.pabulletin.com/secure/data/vol46/46-18/762.html; 80 Fed. Reg. at 54,189; Rhode Island Office of the Health Ins. Comm'r, Bulletin No. 2015-3 (Nov. 23, 2015), available at http://www.ohic.ri.gov/documents/Bulletin-2015-3-Guidance-Regarding-Prohibited-Discrimination.pdf; Minnesota Dep't of Commerce, Administrative Bulletin 2015-5 (Nov. 24, 2015), available at http://mn.gov/commerce-stat/pdfs/bulletin-insurance-2015-5.pdf; Maryland Ins. Admin., Bulletin 14-02 (Jan. 27, 2014), available at http://insurance.maryland.gov/Insurer/Documents/bulletins/bulletin-1402-transgender.pdf.

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gender dysphoria while still preserving providers' ability to make medical necessity determinations on an individual basis.

The VA is quickly becoming an outlier among health care providers in its failure to provide full coverage of the treatment necessary for patients with gender dysphoria.

V. THE VA SHOULD AMEND THE REGULATION TO COVER SEX REASSIGNMENT SURGERY

The VA should offer sex reassignment surgery to transgender veterans, first and foremost, because doing so is good policy. The VA may adopt a new policy if it "is permissible under the statute, [] there are good reasons for it, and [] the agency *believes* it to be better, which the conscious change adequately indicates." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Offering sex reassignment surgery is clearly permissible under 38 U.S.C. § 1710, which broadly authorizes the Secretary to provide "needed" medical care to veterans, and there are good reasons for this policy change: providing this surgery is consistent with, and mandated by, the VA's mission, would impose at most only a relatively minor burden on the VA health care system, and would provide medically necessary care to alleviate the physical suffering, depression, and suicidal ideation of transgender veterans who, in the absence of such care, are likely to be gravely afflicted with such conditions.

Providing sex reassignment surgery is required by the VA's mission to promote the health of veterans through coverage of medically accepted treatments that enhance the quality of life or daily functional level of veterans. The Secretary is charged with providing hospital care and medical services to veterans. *See* 38 U.S.C. § 1710. The VA has determined that this mandate includes care that is "needed to promote, preserve, or restore the health of the individual and is consistent with generally accepted standards of medical practice." 38 C.F.R. § 17.38(b). Care is deemed "to promote health" if "the care will enhance the quality of life or daily

functional level of the veteran," *id.* § 17.38(b)(1), and care is deemed to "preserve health" if the care will maintain the current quality of life or daily functional level of the veteran," including by "extend[ing] lifespan," *id.* § 17.38(b)(2). Notwithstanding its categorical exclusion for some of the most essential medical care for transgender veterans, VHA Directive 2013-003 states that "[i]t is the VHA policy that medically necessary care is provided to enrolled or otherwise eligible intersex and transgender veterans." VHA Directive 2013-003 at 2.²⁹

As discussed above, there is no genuine dispute within the medical community that sex reassignment surgery is a medically necessary component of treatment for some individuals with gender dysphoria. Indeed, the VA implicitly acknowledges the necessity of sex reassignment surgery by providing preoperative assessment and post-operative care to veterans who may undergo, or who have already undergone, such surgery. Not all individuals suffering from gender dysphoria require surgery, yet those who do may be some of the most vulnerable to related complications from lack of access to care—namely, depression and suicide. Transgender individuals who need but do not receive sex reassignment surgery are significantly more susceptible than the general population to depression and suicide.³⁰

Relative to the extraordinarily salubrious effect of providing medically necessary sex reassignment surgery to those in need of it, a change in VA policy would impose an immaterial cost burden on the VA health care system. Only a small absolute number of veterans are

Notably, in addition to preventing transgender veterans from receiving medically necessary care, the VA's exclusion of sex reassignment surgery from coverage appears to be having other unfortunate effects, evidently causing some providers to be skeptical of the medical needs of transgender veterans that are unrelated to gender transition, and outwardly hostile to treating them. *See* Silva Aff. ¶¶ 11-12.

See Ettner Decl. ¶ 15 ("A recent survey shows a 41% rate of suicide attempts among transgender people, far above the baseline rates for North America. (Haas et al., 2014)."); Blosnich et al., Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care," 103 Am. J. Pub. Health e27 (Oct. 2013), available at http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301507 (the "rate of suicide-related events among GID-diagnosed VHA veterans was more than 20 times higher than were rates for the general VHA population.").

transgender, and likely only a fraction of them will require sex reassignment surgery.³¹ And sex reassignment surgery is no more expensive than substantially identical surgeries included in the Medical Benefits Package for cisgender veterans. *See, e.g.*, Bowers Decl. ¶ 20. Moreover, the VA's failure to treat gender dysphoria fully in a given patient leads to collateral consequences, both for the individual veteran who experiences continued mental and physical impairment from his or her partially treated condition, and for the VA health care system itself, which must continue to pay for such veterans' mental health care, sometimes indefinitely. In fact, a recent study shows that the upfront costs of sex reassignment surgery are negligible when compared with the ongoing costs associated with treatment of long-term depression in individuals with cases of gender dysphoria for which surgery is appropriate.³²

The California Department of Insurance likewise recently conducted an assessment of the economic impact of covering transition-related health care and determined that "transgender insureds who have access to treatment see rates of depression drop and anxiety decrease," and that "[t]his overall improvement in mental health and reduction in utilization of mental health

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See supra note 18 and accompanying text. The WPATH Standards of Care reference available studies of individuals who "present for gender-transition-related care at specialist gender clinics," and notes that these studies estimate the prevalence of such individuals in the general population at between "1:11,900 to 1:45,000 for male-to-female individuals ... and 1:30,400 to 1:200,000 for female-to-male ... individuals." Some researchers have suggested that, given the sources of the study participants, the figures in these studies approximate the prevalence of individuals who undergo sex reassignment surgery. See Olyslager & Conway, "On the Calculation of the Prevalence of Transsexualism" (Sept. 2007), at 1 (paper presented at the WPATH 20th International Symposium), available at http://www.changelingaspects.com/ PDF/2007-09-06-Prevalence of Transsexualism.pdf.

The New York Times has reported that a recent yet currently unreleased study commissioned by the Department of Defense and conducted by the RAND Corporation predicted that between only 29 and 129 active service members would seek transition-related medical care annually. The study also found that given these low numbers, the cost of providing transition-related care to active duty service members would be negligible. Editorial Board, *The Military's Transgender Policy, Stalled*, N.Y. Times, Apr. 6, 2016.

Padula et al., Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis, J. of General Internal Medicine (Oct. 19, 2015).

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services could be a source of cost savings for employers, insurers, and insureds."³³ Citing the California assessment, HHS agreed in its proposed rule on Section 1557 of the Affordable Care Act that "providing transgender individuals non-discriminatory insurance coverage and treatment ... will have minimal impact on the overall cost of care and on health insurance premiums."³⁴

Finally, offering sex reassignment surgery to transgender veterans is the right thing to do. Offering sex reassignment surgery to transgender veterans can be a life-saving treatment to treat the serious distress associated with gender dysphoria. Bowers Decl. ¶¶ 34-35, 37; Ettner Decl. ¶¶ 15-16, 21. The VA implicitly acknowledges what the broader medical community does not question—that sex reassignment surgery is medically necessary for some patients—yet the VA refuses to provide this medically necessary care to those patients. Our Nation owes transgender veterans this life-changing treatment in the same way it owes all other veterans medically necessary care for their most significant medical conditions. It is time for the VA to take the next step and provide complete treatment to transgender veterans.

VI. THE EXISTING REGULATION IS ARBITRARY AND CAPRICIOUS

Under the Administrative Procedure Act, a court may hold unlawful and set aside final agency action, such as a regulation or a denial of a petition for rulemaking or to amend existing rules, that it finds to be, *inter alia*, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. To comply with the requirements of the Act, the agency "must examine the relevant data and articulate a satisfactory explanation for its action." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 552, (2009) (quoting *Motor Vehicles Mfrs*.

California Department of Insurance, "Economic Impact Assessment of Gender Nondiscrimination in Health Insurance," Reg. File No. REG-2011-00023 (Apr. 13, 2012), available at http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.

Notice of Proposed Rulemaking Nondiscrimination in Health Programs and Activities, Medicare & Medicaid Guide 220954, 80 Fed. Reg. 54,171, 54,206 (Sept. 8, 2015).

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Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983)). That explanation must "includ[e] a rational connection between the facts found and the choice made." State Farm, 463 U.S. at 42-43. "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise[.]" Fox Television, 556 U.S. at 552 (quoting State Farm, 463 U.S. at 42-43). Moreover, "it is well-established that 'an agency action is arbitrary when the agency offer[s] insufficient reasons for treating similar situations differently." SKF USA Inc. v. United States, 263 F.3d 1369, 1382 (Fed. Cir. 2001) (quoting Transactive Corp. v. United States, 91 F.3d 232, 237 (D.C. Cir. 1996)).

A denial of this petition would be arbitrary and capricious for three reasons: (1) the VA already recognizes that gender dysphoria is a treatable medical condition and currently provides some treatments for it, yet arbitrarily excludes sex reassignment surgery from the covered treatments; (2) the VA covers certain treatments for cisgender and intersex veterans yet arbitrarily denies the same or analogous treatments for transgender veterans; and (3) the VA excluded sex reassignment surgery without examining any relevant data and without giving any public explanation for the exclusion, while the overwhelming medical consensus supports the inclusion of sex reassignment surgery.

It is the height of arbitrary and capricious action to recognize gender dysphoria as a treatable medical condition and provide some treatments for it, while denying other equally necessary medical treatments. The VA's current policy with respect to the provision of medical care to transgender veterans states:

VHA policy [requires] that medically necessary care [be] provided to enrolled or otherwise eligible intersex and transgender Veterans, including hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery. Sex reassignment surgery cannot be performed or funded by VA.

VHA Directive 2013-003 at 2.³⁵ Thus, VA policy clearly recognizes that medically necessary care must be provided to transgender veterans, and also recognizes that some level of care related to sex reassignment surgery is medically necessary. For example, the VA currently provides mental health care coverage and hormonal therapy—which, like surgery, is specifically designed to assist transgender individuals in treating their dysphoria by making their bodies congruent with their gender. VA policy likewise provides transgender individuals with therapies, namely "preoperative evaluation, and medically necessary post-operative and long-term care following sex-reassignment surgery," that are specifically tailored to assist individuals seeking sex reassignment surgery with the pre- and post-surgical aspects of such surgery. And VA policy recognizes as medically necessary evaluations of transgender individuals performed prior to their obtaining sex reassignment surgery (namely, preoperative evaluation). Thus, the VA recognizes the medical necessity of *every aspect of care* for transgender veterans undergoing sex reassignment surgery, except surgery itself. That policy is incoherent because it is internally inconsistent, and therefore arbitrary and capricious.

The arbitrary and capricious nature of the VA's policy is underscored by the fact that the VA offers the same or substantially similar surgeries to cisgender and intersex veterans for other medically necessary conditions. As explained above, sex reassignment surgery is an umbrella term referring to a compliment of surgeries that may include, penectomy, vaginoplasty, chest reconstruction, phalloplasty, hysterectomy, and/or mastectomy.

See also, Dep't of Veterans Affairs, Patient Care Services, (Mar. 3, 2016), available at http://www.patientcare.va.gov/Lesbian Gay Bisexual and Transgender LGBT Veteran Care.asp.

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Under the clear language of the VA regulations and directives, each of these surgeries is provided as a matter of VA policy to cisgender and intersex veterans for other conditions that the VA recognizes to be medically necessary. VA policy grants surgery to intersex individuals "to correct inborn conditions related to reproductive or sexual anatomy," and so provides penectomy and vaginoplasty to certain intersex individuals born with ambiguous genitalia. VHA Directive 2013-003 at 2. Hysterectomy and mastectomy are offered to cisgender females for, among other reasons, reduction of cancer risk, but the same surgeries are denied to transgender males. *See supra*, note 15. The VA offers, and so deems medically necessary, breast reconstruction to cisgender women who have had a mastectomy, but denies a substantially identical surgery, breast augmentation, to transgender women. *See supra*, note 14. The VA offers penile and testicular implants to cisgender males whose penises or testes have been damaged, but refuses very similar treatment to transgender men. *See id*.

In each of these comparisons, the VA offers certain surgeries to cisgender or intersex individuals for their conditions, but refuses to cover the same or substantially similar surgeries to transgender individuals for their conditions. The VA cannot justify this inconsistent treatment by claiming that these surgeries are medically necessary for treatment of some conditions, but not medically necessary for the treatment of gender dysphoria—as explained above, *see supra* Section IV.B, there is no genuine dispute within the medical community that sex reassignment surgery is medically necessary for certain patients. Accordingly, the VA's current policy amounts to offering certain surgeries when they are medically necessary, only not when those surgeries are medically necessary to treat gender dysphoria. This policy is incoherent and unjustifiable, and the VA's action in continuing it would be arbitrary and capricious. *See SKF USA Inc.*, 263 F.3d at 1382.

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Finally, the VA has given no public explanation for excluding from coverage sex reassignment surgery for transgender veterans. Neither the proposed nor the final Regulation explained the exclusion or offered any evidence that the VA had "examine[d] the relevant data" in arriving at its decision to exclude this surgery from coverage. *State Farm*, 463 U.S. at 42-43; *see* 63 Fed. Reg. 37,299 (July 10, 1998) (proposed rule); 64 Fed. Reg. 54,207 (Oct. 6, 1999) (final regulation). The subsequent VHA directives that implemented the exclusion of sex reassignment surgery from the Medical Benefits Package likewise contained no explanation. *See* VHA Directive 2011-024 (June 9, 2011); VHA Directive 2013-003 (Feb. 8, 2013). The VA has therefore failed thus far even to attempt to "articulate a satisfactory explanation for its action" in excluding sex reassignment surgery from the Medical Benefits Package, or to offer a "rational connection between [] facts found and the choice made." *State Farm*, 463 U.S. at 42-43; *see also Michigan v. E.P.A.*, 135 S. Ct. 2699, 2706 (2015) ("Federal administrative agencies are required to engage in 'reasoned decisionmaking.") (citation omitted).

As explained above, if the VA were to examine data relevant to its policy of excluding sex reassignment surgery from the Medical Benefits Package, the VA would find that such data clearly support reversing this exclusion. The medical community has reached consensus that sex reassignment surgery is a medically necessary treatment for a significant number of individuals with gender dysphoria—medically necessary in the same way as any other medical treatment that is required "to promote, preserve, or restore" the well-being of the patient. VHA Directive 1091 (Feb. 21, 2014), at 1; *see also* Bowers Decl. ¶ 34-37; Ettner Decl. ¶ 21, 23. No major medical association considers sex reassignment surgery to be a form of cosmetic surgery. Bowers Decl. ¶ 35; Ettner Decl. ¶ 23. As discussed above, the costs of providing sex reassignment surgery are negligible in context. *See supra* Section V at 21-22.

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For these reasons, a denial of this petition to amend the Regulation to include sex reassignment surgery in the Medical Benefits Package would constitute unlawful, arbitrary and capricious agency action.

VII. THE EXISTING REGULATION VIOLATES THE EQUAL PROTECTION COMPONENT OF THE FIFTH AMENDMENT

A denial of this petition to amend the Regulation to include sex reassignment surgery in the Medical Benefits Package would also violate the Equal Protection component of the Fifth Amendment. The Federal Circuit is required to "hold unlawful and set aside" any VA regulation "contrary to constitutional right, power, privilege, or immunity." 38 U.S.C. § 7292(d)(1)(B). The Regulation violates those guarantees by discriminating against transgender veterans on the basis of their sex and their transgender status, without any compelling, or even arguably permissible, government interest.

A. Discrimination Against Transgender People Receives Heightened Scrutiny

1. Discrimination Against Transgender People Is Sex Discrimination

It is "firmly established" that laws or policies that discriminate based on sex are evaluated under close scrutiny. *Mississippi Univ. for Women v. Hogan*, 458 U.S. 718, 723 (1982). Discrimination against transgender people receives the same scrutiny. In fact, since *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989), every court of appeals to consider the question has concluded that prohibitions against sex discrimination protect transgender people.

In *Price Waterhouse*, the Supreme Court held that discrimination on the basis of gender stereotypes is sex-based discrimination. In that case, a female employee with the Price Waterhouse firm had been denied partnership in the firm because she was considered too "macho" and was told she needed to "walk more femininely, talk more femininely, dress more femininely, wear make-up, have her hair styled, and wear jewelry." 490 U.S. at 235. Six

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members of the Supreme Court agreed that that kind of discrimination due to failure to conform to sex stereotypes constituted sex discrimination. *Id.* at 250-251 (plurality opinion); *id.* at 258-261 (White, J., concurring); *id.* at 272-273 (O'Connor, J., concurring).

Since that decision, federal courts have been nearly unanimous in holding that discrimination against transgender people is also a form of sex discrimination under *Price Waterhouse*. *See, e.g.*, *G.G. ex rel. Grimm v. Gloucester Cnty. Sch. Bd.*, No. 15-2056, __ F.3d __, 2016 WL 1567467, at *4-8 (4th Cir. Apr. 19, 2016); *Glenn v. Brumby*, 663 F.3d 1312, 1316-1320 (11th Cir. 2011); *Smith v. City of Salem*, 378 F.3d 566, 571-575 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-216 (1st Cir. 2000); *Schwenk v. Hartford*, 204 F.3d 1187, 1201-1202 (9th Cir. 2000); *see also Schroer v. Billington*, 577 F. Supp. 2d 293, 303-306 (D.D.C. 2008).

As the Eleventh Circuit observed in *Glenn*, "[a] person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes" and there is therefore "a congruence between discriminating against transgender and transsexual individuals and discrimination on the basis of gender-based behavioral norms." 663 F.3d at 1316.

Schroer offered another formulation of why discrimination against transgender people must be understood as sex discrimination, posing a helpful analogy:

Imagine that an employee is fired because she converts from Christianity to Judaism. Imagine too that her employer testifies that he harbors no bias toward either Christians or Jews but only "converts." That would be a clear case of discrimination "because of religion." No court would take seriously the notion that "converts" are not covered by the statute. Discrimination "because of religion" easily encompasses discrimination because of a *change* of religion.

577 F. Supp. 2d at 306. Applying that logic, the court held that the discrimination against a transgender job applicant because she disclosed her intent to transition from male to female "was *literally* discrimination because of ... sex." *Id.* at 308; *see also Fabian v. Hosp. of Cent.*

Conn., No. 3:12-cv-1154, 2016 WL 1089178, at *28 (D. Conn. Mar. 18, 2016) ("[D]iscrimination on the basis of gender stereotypes, or on the basis of being transgender, or intersex, or sexually indeterminate ... is literally discrimination 'because of sex.'").

Recognizing that no responsible argument to the contrary remains, the federal government has adopted the position that discrimination against transgender people is sex discrimination. In *Macy v. Holder*, the Equal Employment Opportunity Commission ("EEOC") held unanimously that discrimination against a transgender person is, "by definition," a form of sex discrimination.³⁶ E.E.O.C. Appeal No. 0120120821, 2012 WL 1435995, at *11 (Feb. 24, 2012); *see also* Memorandum from the Attorney General, Treatment of Transgender Employment Discrimination Claims Under Title VII of the Civil Rights Act of 1964 (Dec. 15, 2014) (announcing that the Department of Justice will take the position that discrimination against transgender people violates Title VII); U.S. Department of Labor, Office of Federal Contract Compliance Programs, Directive 2014-02 (Aug. 19, 2014) (clarifying that sex discrimination "under Executive Order 11246 ... includes discrimination on the bas[is] of ... transgender status").³⁷

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Macy was decided under Title VII, but "the showing a plaintiff must make to recover on a disparate treatment claim under Title VII mirrors that which must be made to recover on an equal protection claim." Smith, 378 F.3d at 577; see also Glenn, 663 F.3d at 1316-1318 (reviewing Title VII precedent to conclude that the Fourteenth Amendment prohibits discrimination against transgender employees).

The U.S. Department of Education also has made clear that "Title IX's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity." Dep't of Educ., Office of Civil Rights, *Questions and Answers on Title IX and Sexual Violence* (Apr. 29, 2014), at 5, *available at* http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf. Numerous federal courts have agreed. *See, e.g., G.G.*, 2016 WL 1567467, at *7; *Pratt v. Indian River Cent. Sch. Dist.*, 803 F. Supp. 2d 135, 151-152 (N.D.N.Y. 2011); *Doe v. Brimfield Grade Sch.*, 552 F. Supp. 2d 816, 823 (C.D. Ill. 2008); *Montgomery v. Independent Sch. Dist. No. 709*, 109 F. Supp. 2d 1081, 1090 (D. Minn. 2000); *see also Rumble v. Fairview Health Servs.*, No. 14-cv-2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (holding that Section 1557 of the Affordable Care Act, which incorporates Title IX's prohibition on sex-based discrimination, "protects plaintiffs ... who allege discrimination based on 'gender identity'").

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2. Discrimination Based on Transgender Status Also Receives Heightened Scrutiny

Even aside from its inextricable connection to sex discrimination, discrimination based on transgender status is separately entitled to heightened scrutiny. If a classification disadvantages certain groups, it may be considered "suspect" or "quasi-suspect," and therefore scrutinized with extra care. The Supreme Court consistently has applied heightened scrutiny where the classified group has suffered a history of discrimination, and the classification has no bearing on a person's ability to perform in society. See, e.g., Massachusetts Bd. of Ret. v. Murgia, 427 U.S. 307, 313 (1976) (heightened scrutiny is warranted where a classified group has "experienced a 'history of purposeful unequal treatment' or been subjected to unique disabilities on the basis of stereotyped characteristics not truly indicative of their abilities"). In addition, the Supreme Court has sometimes considered whether the group is a minority or relatively politically powerless, and whether the characteristic is defining or "immutable" in the sense of being beyond the group member's control or not one the government has a right to insist an individual try to change. See, e.g., Lyng v. Castillo, 477 U.S. 635, 638 (1986); see also Kerrigan v. Comm'r of Pub. Health, 957 A.2d 407, 425-28 (Conn. 2008) (analyzing federal equal protection law to conclude that history of discrimination and ability to contribute to society are the two central considerations, and collecting authorities). While not all considerations need point toward heightened scrutiny, Plyler v. Doe, 457 U.S. 202, 216 n.14, (1982); Golinski v. Office of Pers. Mgmt., 824 F. Supp. 2d 968, 983 (N.D. Cal. 2012), here all demonstrate that laws that discriminate based on transgender status should be subjected to heightened review.

Under any faithful application of that standard, discrimination against transgender people must receive heightened review. In recent decisions, federal courts have recognized that discrimination against transgender people—beyond its connection to discrimination based on

sex—must be evaluated under heightened scrutiny. *See, e.g., Adkins v. City of New York*, ___ F. Supp. 3d ___, No. 14 Civ. 7519, 2015 WL 7076956, at *3-4 (S.D.N.Y. Nov. 16, 2015); *Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1119 (N.D. Cal. 2015). In *Adkins*, the court found that all four of the hallmarks of heightened scrutiny were present with respect to the transgender community. It found that "transgender people have [inarguably] suffered a history of persecution and discrimination," 2015 WL 7076956, at *3;³⁸ that "transgender status bears no relation to ability to contribute to society," *id.*; that "transgender status is a sufficiently discernible characteristic to define a discrete minority class," *id.*; and that "transgender people are a politically powerless minority," noting that "there have [n]ever been any transgender members of the United States Congress or the federal judiciary," *id.* at *4. The court therefore concluded that transgender people constituted a "quasi-suspect class" entitled to intermediate scrutiny. *Id.* at *4.

Another federal court examined the same question in a case challenging a health care policy—like the VA's here—that denied transgender people access to sex reassignment surgery. *Norsworthy*, 87 F. Supp. 3d at 1119. That court noted the recent federal decisions indicating that discrimination based on sexual orientation must be evaluated with heightened scrutiny, holding that such conclusion "applies with at least equal force to discrimination against transgender people, whose identity is equally immutable and irrelevant to their ability to contribute to society, and who have experienced even greater levels of societal discrimination and marginalization." *Id.* at 1119 n.8. As a result, the court held squarely that "discrimination based

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See also Sears et al., Documenting Discrimination on the Basis of Sexual Orientation and Gender Identity in State Employment, Williams Institute (2009), available at http://williamsinstitute.law.ucla.edu/research/workplace/documenting-discrimination-on-the-basis-of-sexual-orientation-and-gender-identity-in-state-employment; Grant et al., Injustice at Every Turn: A Report of the National Transgender Discrimination Survey (2011), available at http://www.thetaskforce.org/downloads/reports/reports/ntds full.pdf.

on transgender status ... qualifies as a suspect classification under the Equal Protection Clause." *Id.* at 1119.

B. The Regulation Cannot Survive Any Level of Review

The Regulation is plainly discriminatory: It denies transgender veterans treatments critical for their health, while providing the same treatments for other veterans. To state the obvious, an exclusion of coverage for surgeries related to "gender alteration," which the VA applies *only* to transgender veterans, targets transgender veterans for differential treatment.

38 C.F.R. § 17.38(c)(4); VHA Directive 2013-003 at 2 (defining the prohibited surgery to apply to transgender, but not intersex, veterans). That is facial discrimination based on sex and transgender status. Because there is no permissible justification for that exclusion, the Regulation is unconstitutional.

Under the heightened scrutiny standard applicable to claims of discrimination based on sex or transgender status, the challenged action must "serve important governmental objectives" and be "substantially related to the achievement of those objectives." *Craig v. Boren*, 429 U.S. 190, 197 (1976); *see also United States v. Virginia*, 518 U.S. 515, 531, 533 (1996) (under intermediate scrutiny, government "must demonstrate an exceedingly persuasive justification for that action," the burden for which "is demanding and ... rests entirely on the state") (internal quotation marks and citations omitted).

No such "important" objective can be advanced by denying transgender veterans the same medically necessary treatments that are provided to other veterans. For example, the facts of this case are nearly identical to those in *Norsworthy*. That case challenged the policy of a state prison that sex reassignment surgery could never be provided to transgender people in prison, although the prison did provide the same treatments for non-transgender individuals, and it did provide mental health and hormone treatments to transgender individuals. The state was

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unable to identify any "important governmental interest, much less describe how their gender classification—which makes it more difficult for a transgender person to receive vaginoplasty than it is for a cisgender woman—[could be] substantially related to that interest." 87 F. Supp. 3d at 1120. The court therefore concluded that a state policy of "treat[ing a transgender woman] differently from a similarly situated non-transgender woman in need of [the same] medically necessary surgery" would violate her right to equal protection. *Id*.

Even under the most deferential standard of review, however, the policy cannot stand. Governmental action that "neither burdens a fundamental right nor targets a suspect class" will be upheld only "so long as it bears a rational relation to some legitimate end." *Romer v. Evans*, 517 U.S. 620, 631 (1996). That test is not "toothless." *Mathews v. Lucas*, 427 U.S. 495, 510 (1976). In particular, the review must be meaningful when the policy at issue targets a vulnerable group. *See Romer*, 517 U.S. at 634-635 (invalidating law that burdened the "politically unpopular group" of lesbian, gay, and bisexual people); *Lawrence v. Texas*, 539 U.S. 558, 580 (2003) (O'Connor, J., concurring) ("When a law exhibits such a desire to harm a politically unpopular group, we have applied a more searching form of rational basis review to strike down such laws under the Equal Protection Clause."); *Kelo v. City of New London*, 545 U.S. 469, 490-491 (2005) (Kennedy, J., concurring) (distinguishing between the rational basis test applied to "economic regulation" versus classifications discriminating against a particular group of people).

As discussed above, because the VA already provides the same or similar treatments to non-transgender and intersex veterans, there is no conceivable non-discriminatory basis for excluding coverage for transgender veterans alone. The Regulation and its implementing directives do not deny transgender veterans surgical treatments for gender dysphoria because of

concerns about medical necessity, or because it is expensive (which it is not),³⁹ or because it is impractical or difficult to provide—if any of those were the case, the VA would bar provision of those treatments for *any* veteran, not just transgender veterans. And the reason cannot be that the VA disagrees with the necessity of medical treatments for gender dysphoria generally—because if that were the case, the VA would not provide the many other medical treatments it *does* provide for transgender veterans, such as hormone therapy and pre- and post-operative care.

Accordingly, the only conceivable explanation for the transgender-specific surgery exclusion appears to be the fear of potential political controversy that could result from extending care to this vulnerable minority, which is not a permissible consideration under any standard of review. *See U.S. Dep't of Ag. v. Moreno*, 413 U.S. 528, 534 (1973) (intention to exclude a "politically unpopular group" from receiving benefits "cannot constitute a legitimate governmental interest"); *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 448 (1985) ("mere negative attitudes, or fear, unsubstantiated by factors which are properly cognizable ... are not permissible bases" for differential treatment of a vulnerable group).

VIII. CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Secretary of Veterans Affairs amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4), that exclude sex reassignment surgery for transgender veterans from the Medical Benefits Package provided to veterans under the Veterans Affairs health system, and promulgate regulations expressly

Because the population of transgender veterans affected by the Regulation is small compared to the overall population, cost concerns have no basis in reality. But regardless, the Fifth Amendment does not safeguard equality only when it is costless. Seeking to justify the Regulation as a budgetary matter would do what the Supreme Court has condemned: attempt to "protect the public fisc by drawing an invidious distinction between classes of its citizens." *Memorial Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 263 (1974); *see also Graham v. Richardson*, 403 U.S. 365, 374-375 (1971).

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Package.

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Dated: May 9, 2016

By: Man Schoonfell / At

Alan Schoenfeld Austin Van

WILMER CUTLER PICKERING HALE AND DORR LLP

7 World Trade Center 250 Greenwich Street New York, NY 10007

Telephone: (212) 937-7294 Facsimile: (212) 230-8888

Paul R.Q. Wolfson
Andrew Jaco
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue
Washington, DC 20006
Telephone: (202) 663-6390
Facsimile: (202) 663-6363

ġ: ;

Respectfully submitted,

M. Dru Leyasseur

LAMBDA LEGAL DEFENSE AND

EDUCATION FUND, INC. 120 Wall Street, 19th Floor

New York, NY 1005

Telephone: (212) 809-8585

Facsimile: (212) 809-0055

Tara L. Borelli LAMBDA LEGAL DEFENSE AND

EDUCATION FUND, INC.

730 Peachtree Street NE, Suite 1070

Atlanta, GA 30308-1210 Telephone: (404) 897-1880 Facsimile: (404) 897-1884

11 m/

Ilona Turner Sasha Buchert

TRANSGENDER LAW CENTER 1629 Telegraph Avenue, Suite 400

Oakland, CA 94612

Telephone: (415) 865-0176 Facsimile: (877) 847-1278

Attorneys for Petitioners

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EXHIBIT 2

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DEPARTMENT OF VETERANS AFFAIRS Under Secretary for Health Washington DC 20420

November 10, 2016

The Honorable Mike Quigley U.S. House of Representatives Washington, DC 20515

Dear Congressman Quigley:

This is in response to your September 12, 2016, letter to the Department of Veterans Affairs (VA) asking for an update on the Notice of Proposed Rulemaking (NPRM) regarding the removal of gender alteration restrictions from VA's medical benefits package. I am responding on behalf of the Department.

VA regularly reviews regulations across the full spectrum of medical services to provide the highest quality health care to our Nation's Veterans. Where there is new data, research, or changes to health care policies across Federal agencies that suggest a need for review, VA makes every effort to examine the circumstances and openly discuss actions that could improve Veteran health care. We note that VA has not published a NPRM to remove the exclusion of gender alterations from VA's medical benefits package, but rather announced it was considering issuance of such a NPRM in the Unified Agenda of Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the Federal Government.

VA currently provides many services for transgender Veterans to include hormone therapy, mental health care, preoperative evaluation, and long-term care following sex reassignment surgery. Increased understanding of both gender dysphoria and surgical techniques in this area has improved significantly and is now widely accepted as medically necessary treatment. VA has been and will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding is available. Therefore, this regulation will be withdrawn from the Fall 2016 Unified Agenda. While VA has begun considering factors impacting this rulemaking process, it is not imminent.

Should you have further questions, please have a member of your staff contact Ms. Angela Prudhomme, Congressional Relations Officer, at (202) 461-6471 or by email at Angela.Prudhomme@va.gov.

Thank you for your continued support of our Nation's Veterans.

Sincerely,

David J. Shulkin, M.D.

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DEPARTMENT OF VETERANS AFFAIRS Under Secretary for Health Washington DC 20420

November 10, 2016

The Honorable Michael M. Honda U.S. House of Representatives Washington, DC 20515

Dear Congressman Honda:

This is in response to your September 12, 2016, letter to the Department of Veterans Affairs (VA) asking for an update on the Notice of Proposed Rulemaking (NPRM) regarding the removal of gender alteration restrictions from VA's medical benefits package. I am responding on behalf of the Department.

VA regularly reviews regulations across the full spectrum of medical services to provide the highest quality health care to our Nation's Veterans. Where there is new data, research, or changes to health care policies across Federal agencies that suggest a need for review, VA makes every effort to examine the circumstances and openly discuss actions that could improve Veteran health care. We note that VA has not published a NPRM to remove the exclusion of gender alterations from VA's medical benefits package, but rather announced it was considering issuance of such a NPRM in the Unified Agenda of Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the Federal Government.

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Should you have further questions, please have a member of your staff contact Ms. Angela Prudhomme, Congressional Relations Officer, at (202) 461-6471 or by email at Angela.Prudhomme@va.gov.

Thank you for your continued support of our Nation's Veterans.

Sincerely,

David J. Shulkin, M.D.

Case: 44-1480 Posemaeht2122 Pagge246 Filed: 01/05/2024



DEPARTMENT OF VETERANS AFFAIRS Under Secretary for Health Washington DC 20420

November 10, 2016

The Honorable Raúl M. Grijalva U.S. House of Representatives Washington, DC 20515

Dear Congressman Grijalva:

This is in response to your September 12, 2016, letter to the Department of Veterans Affairs (VA) asking for an update on the Notice of Proposed Rulemaking (NPRM) regarding the removal of gender alteration restrictions from VA's medical benefits package. I am responding on behalf of the Department.

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Thank you for your continued support of our Nation's Veterans.

Sincerely.

David J. Shulkin, M.D.

Case: 44-1480 Documenti2122 Pagge243 Filed: 01/05/2024



DEPARTMENT OF VETERANS AFFAIRS Under Secretary for Health Washington DC 20420

November 10, 2016

The Honorable Bonnie Watson Coleman U.S. House of Representatives Washington, DC 20515

Dear Congresswoman Watson Coleman:

This is in response to your September 12, 2016, letter to the Department of Veterans Affairs (VA) asking for an update on the Notice of Proposed Rulemaking (NPRM) regarding the removal of gender alteration restrictions from VA's medical benefits package. I am responding on behalf of the Department.

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Thank you for your continued support of our Nation's Veterans.

Sincerely,

David J. Shulkin, M.D.

Case: 44-1480 Documenti2122 Pagge238 Filed: 01/05/2024



DEPARTMENT OF VETERANS AFFAIRS Under Secretary for Health Washington DC 20420

November 10, 2016

The Honorable Eleanor Holmes Norton U.S. House of Representatives Washington, DC 20515

Dear Congresswoman Norton:

This is in response to your September 12, 2016, letter to the Department of Veterans Affairs (VA) asking for an update on the Notice of Proposed Rulemaking (NPRM) regarding the removal of gender alteration restrictions from VA's medical benefits package. I am responding on behalf of the Department.

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Thank you for your continued support of our Nation's Veterans.

Sincerely,

David J. Shulkin, M.D.

Case: 44-1480 Documenti2122 Pagge239 Filed: 01/05/2024



DEPARTMENT OF VETERANS AFFAIRS Under Secretary for Health Washington DC 20420

November 10, 2016

The Honorable Jackie Speier U.S. House of Representatives Washington, DC 20515

Dear Congresswoman Speier:

This is in response to your September 12, 2016, letter to the Department of Veterans Affairs (VA) asking for an update on the Notice of Proposed Rulemaking (NPRM) regarding the removal of gender alteration restrictions from VA's medical benefits package. I am responding on behalf of the Department.

VA regularly reviews regulations across the full spectrum of medical services to provide the highest quality health care to our Nation's Veterans. Where there is new data, research, or changes to health care policies across Federal agencies that suggest a need for review, VA makes every effort to examine the circumstances and openly discuss actions that could improve Veteran health care. We note that VA has not published a NPRM to remove the exclusion of gender alterations from VA's medical benefits package, but rather announced it was considering issuance of such a NPRM in the Unified Agenda of Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the Federal Government.

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Thank you for your continued support of our Nation's Veterans.

Did J Shill MD

David J. Shulkin, M.D.

United States Court of Appeals for the Federal Circuit



Key Rule Changes

Key changes to the Federal Circuit local rules are included below as a courtesy to assist you in perfecting your appeal. For complete details, please review the current rules and potential future changes by visiting the Court's online Rules and Notices pages at: www.cafc.uscourts.gov.

December 1, 2016 Changes

Cases opened on or after December 1, 2016 must comply with the updated rules.

The revisions to the Federal Circuit Rules ("Rules") and Federal Rules of Appellate Procedure ("FRAP") will change page limitations to word limitations for various documents submitted to the court, if those documents were prepared using a computer word processing program (abbreviated below as: "computer"):

- FRAP 27(d)(2): A motion or a response to a motion may not exceed 5,200 words.
 - o A reply may not exceed 2,600 words.
- FRAP 28(j): A citation of supplemental authority may not exceed 350 words.
- Rule 29(b): The United States or its officer or agency or a state may file an amicus curiae brief during consideration of whether to grant rehearing without the consent of the parties or leave of court.
- *Rule 39(b)*: An objection to the bill of costs must not exceed 1,300 words.
- FRAP 35(b)(2) & 40(b): A Petition for Rehearing may not exceed 3,900 words.
- Rule 40(e): A response to a petition for rehearing must not exceed 3,900 words.
- Rule 40(g): An amicus brief on rehearing must not exceed 2,600 words.

April 1, 2016 Changes

Cases opened on or after April 1, 2016 must comply with the below rules.

Appeals, New Rule 12 - Practice Notes: Clarifies that any objection to an official caption should be made **promptly** after docketing of the appeal.

Briefs

• *Rule 28(a)(11):* A document that is included in both the addendum and appendix must have the same page numbering. For example, if in the appendix a judgment in question is numbered Appx7-10, it must also be numbered Appx7-10 in the addendum.

Citations

• Rule 28(a)(11) and 28(f): Requires appendices, supplemental appendices and addendum material to be numbered using the abbreviation "Appx" or "SAppx" followed by the page number, and to be referenced in the briefs accordingly. Review the <u>Appendix Reference</u>
<u>Formatting Best Practices Guide</u>, on the CM/ECF Reference Materials page of our public web

Case: 247-10860 Documentin 2-2-3 Page; 241 Filled: 01/25/2024

site www.cafc.uscourts.gov:

• Rule 30(b)(4)(E): Requires the use of Bates numbering for all pages of an appendix or supplemental appendix. Refer to the <u>Adding Bates Number Guide</u> available on the CM/ECF web page, Reference Materials.

Confidential Material Rule 27(m) and Rule 28(d): No material in a brief, motion, response, or reply shall be marked confidential — The exceptions are as follows: Each brief, motion, response, or reply may mark confidential up to fifteen (15) words if the information (1) was treated in the matter under review as confidential pursuant to a judicial or administrative protective order and (2) such marking is authorized by statute, administrative regulation, or court rule (such as Federal Rule of Civil Procedure 26(c)(1)). A 50-word limit applies in cases arising under 19 U.S.C. § 1516a or 28 U.S.C. § 1491(b).

- A motion, response or reply including confidential material must be accompanied by a certificate that the motion, response or reply complies with the word limitation. The form can be embedded within the brief or filed separately.
- Federal Circuit Form 31 is a suggested form of the certificate of compliance with this rule. It is the responsibility of the filing party to ensure that its certificate of compliance is accurate.

When you file a confidential document in CM/ECF, you will be asked to confirm that your document is compliant with all confidentiality requirements and/or that you have simultaneously filed a motion to waive the confidentiality requirements, if applicable (see *Figure 1* below).

• To confirm, simply select the check box as indicated in *Figure 1* and then select **OK**.



Figure 1. Confidential Brief Tendered Event

Entry of Appearance (EOA) Rule 47.3: If an attorney's entry of appearance is first submitted after a case is assigned to a merits panel, the appearance will be treated as a motion to appear. Counsel must immediately file an updated EOA if representation changes. This included a change in contact information. Electronic filers must also report a change in contact information to the PACER Service Center.

Oral Argument *Rule 34 – Practice Notes:* Shortens the time to 7 days from notification by the Clerk's Office (via Notice of Docket Activity) that the case is fully briefed in which counsel must advise the Clerk's Office of schedule conflicts; Clarifies argument time per side (not per attorney).

Filed: 01/25/2024 Case: 24-108 Document: 2-2 Page: 242

No. 2017-1460

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DEE FULCHER, GIULIANO SILVA, AND THE TRANSGENDER AMERICAN VETERANS ASSOCIATION,

Petitioners,

 ν .

SECRETARY OF VETERANS AFFAIRS,

Respondent.

On Petition for Review from the United States Department of Veterans Affairs

BRIEF FOR PETITIONERS

ILONA M. TURNER M. Dru Levasseur SHAWN THOMAS MEERKAMPER LAMBDA LEGAL DEFENSE Transgender Law AND EDUCATION FUND. INC. 120 Wall Street, 19th Floor CENTER P.O. Box 70976 New York, NY 10005 (212) 809-8585 Oakland, CA 94612 (510) 587-9696

ALAN SCHOENFELD WILMER CUTLER PICKERING HALE AND DORR LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007 (212) 937-7294

TARA L. BORELLI LAMBDA LEGAL DEFENSE AND LAMBDA LEGAL DEFENSE EDUCATION FUND, INC. 730 Peachtree Street NE, Suite 640 Atlanta, GA 30308-1210 (404) 897-1880

SASHA J. BUCHERT AND EDUCATION FUND, INC. 1875 I Street NW Washington, D.C. 20006 (202) 999-8083

PAUL R.Q. WOLFSON MICHAEL POSADA WILMER CUTLER PICKERING HALE AND DORR LLP 1875 Pennsylvania Avenue Washington, DC 20006 (202) 663-6390

June 21, 2017

Attorneys for Petitioners

CERTIFICATE OF INTEREST

Counsel for Petitioners, Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association, certifies the following:

1. The full name of every party or amicus represented in this appeal is:

Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association

- 2. The names of the real parties in interest represented in this appeal are: Not applicable.
- 3. The names of all parent corporations and any publicly held companies that own 10 percent of the party represented are:

None.

4. The names of all law firms and the partners or associates that are expected to appear in this appeal for Petitioners are:

Lambda Legal Defense and Education Fund, Inc.: Tara L. Borelli, Sasha J. Buchert, M. Dru Levasseur

TRANSGENDER LAW CENTER: Ilona M. Turner, Shawn Thomas Meerkamper

WILMER CUTLER PICKERING HALE AND DORR LLP: Michael Posada, Alan E. Schoenfeld, Paul R.Q. Wolfson

5. The following law firms and counsel formerly appeared in the district court in prior phases of the case:

None.

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD

June 21, 2017

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RELATED CASES

No appeal in this case was previously before this Court or any other court.

Petitioners submitted a petition for rulemaking to the U.S. Department of Veterans

Affairs ("VA" or "Department") on May 9, 2016.

JURISDICTION

This Court has jurisdiction under 38 U.S.C. §502 to review the denial of a petition for rulemaking. *See Preminger v. Secretary of Veterans Affairs*, 632 F.3d 1345, 1352 (Fed. Cir. 2011). The petition was denied on November 10, 2016, and Petitioners filed a petition for review on January 9, 2017, within 60 days of the denial, as required by Circuit Rule 47.12.

ISSUES PRESENTED

On May 9, 2016, Petitioners filed a petition for rulemaking requesting that the Department amend its regulations excluding "medically necessary sex reassignment surgery for transgender veterans from the[ir] medical benefits package." Appx74. The VA acknowledged receipt but never directly responded to the petition. The VA did respond, however, to inquiries from Members of Congress about its treatment of transgender veterans, stating in a letter that although the VA would "continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding is available," any rulemaking that would

allow the VA to perform or pay for such treatment is "not imminent." Appx1. The questions presented are:

- 1. Whether the VA's refusal to initiate rulemaking is subject to judicial review at this time.
- 2. If so, whether the VA's denial of the petition for rulemaking must be set aside as arbitrary and capricious or because the VA's policy excluding medically necessary sex reassignment surgery from the veterans' benefits package is contrary to constitutional right or otherwise not in accordance with law.

STATEMENT

A. The VA's Medical Benefits Package

Veterans "risk[] both life and liberty in their military service to this country." *Sneed v. Shinseki*, 737 F.3d 719, 728 (Fed. Cir. 2013). In return for their service, the United States provides a comprehensive benefits scheme that is "imbued with special beneficence from a grateful sovereign." *Id.* (quoting *Bailey v. West*, 160 F.3d 1360, 1370 (Fed. Cir. 1998) (en banc) (Michel, J., concurring)). "A veteran, after all, has performed an especially important service for the Nation, often at the risk of his or her own life." *Shinseki v. Sanders*, 556 U.S. 396, 412 (2009).

As part of the benefits scheme, the Secretary of Veterans Affairs is directed to "furnish hospital care and medical services which the Secretary determines to be

needed." 38 U.S.C. §1710. As relevant here, the Secretary has implemented that directive by establishing the veterans' medical benefits package, which "explain[s] what care would and would not be provided to veterans enrolled in the VA healthcare system." Enrollment—Provision of Hospital and Outpatient Care to Veterans, 63 Fed. Reg. 37,299, 37,300 (July 10, 1998). The benchmark for inclusion in the package is generally whether the particular care is "medically needed"—that is, "care that is determined by appropriate healthcare professionals to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice." Id. (codified at 38 C.F.R. §17.38(b)). Applying that definition, the VA regulation establishing the benefits package (the "Regulation") enumerates an array of health care services available to veterans through the VA, including nutrition education, vaccines, surgical care, substance abuse counseling, prescription-drug coverage, bereavement counseling, and prosthetic equipment. 38 C.F.R. §17.38(a); Appx48-50.

B. VA's Exclusion Of Medically Necessary Surgical Procedures For Transgender Veterans

This case involves the VA's decision to exclude specific surgical procedures from its benefits package only when they are used for a specific reason: to relieve a transgender veteran's gender dysphoria by facilitating the veteran's gender transition.

According to recent estimates, there are more than 130,000 transgender veterans of the United States Military, the United States Reserves, and the National Guard. Appx89. Typically, people designated female at birth based on the appearance of their genitalia identify as girls or women, and people who are designated male at birth identify as boys or men. Appx143. For transgender individuals, the person's gender identity differs from the sex assigned at birth. Appx142-143. The medical diagnosis for the distress that incongruence often causes is gender dysphoria, which major medical associations and diagnostic manuals uniformly recognize as a serious medical condition. Appx143; see also Appx305; Appx321. As treatment for gender dysphoria, individuals may undergo a gender transition, which is a "[p]eriod of time when individuals change from the gender role associated with their sex assigned at birth to a different gender role" and "may or may not include feminization or masculinization of the body through hormones or other medical procedures." Appx288. "The nature and duration of transition is variable and individualized." Id.

The Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People ("Standards of Care"), promulgated by the World Professional Association for Transgender Health, set forth the protocol accepted by medical professionals for the diagnosis and treatment of gender dysphoria.

Appx231-298. The Standards of Care—recognized as authoritative by other

professional medical societies, including the American Medical Association, the Endocrine Society, and the American Psychological Association, Appx145—identify the following treatment protocols for individuals with gender dysphoria:

- Changes in gender expression and role (which may involve living part-time or full-time in another gender role, consistent with one's gender identity);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience;
- Hormone therapy to feminize or masculinize the body; and
- Surgery to change primary and/or secondary sex characteristics (*e.g.*, removal or construction of the breasts, penectomy, vaginoplasty, phalloplasty, and penile and testicular implants), often referred to as sex reassignment surgery.

Appx237.

Major medical associations uniformly recognize sex reassignment surgery as an effective treatment for gender dysphoria—and indeed one that is critical for some transgender individuals. Appx133; Appx147. Although not all individuals

with gender dysphoria require such surgery, the Standards of Care recognize that hormone therapy and psychotherapy may be inadequate to treat severe cases of gender dysphoria. Appx265; Appx146-147. In those cases, failure to provide sex reassignment surgery may cause the patient serious mental and physical health issues—including anxiety, depression, and suicidality. *Id*.

The VA's policies and practices recognize that gender dysphoria is a serious medical condition requiring treatment. See, e.g., Appx1 (November 2016 letter from the VA to members of Congress); Appx305 (VA draft proposed rule regarding "Removing Exclusion of Gender Alterations from the Medical Benefits Package"); Appx321 (impact analysis for proposed rule); Appx330 (memorandum from VHA CFO regarding impact analysis for proposed rule). For that reason, the VA provides mental health counseling and hormone therapy for transgender veterans experiencing gender dysphoria. Appx57-58 (VHA Directive 2013-003). The VA also provides preoperative evaluation for transgender veterans, as well as continuing hormone replacement therapy and postoperative care to veterans who have received sex reassignment surgery outside the VA health care system. *Id*. Indeed, reflecting its commitment to provide medically needed care to transgender veterans, the VA has recently opened clinics in Cleveland and Tucson that specialize in providing medical care to those veterans. Appx89. In addition, the VA Boston Healthcare System has formed the Interdisciplinary Transgender

Treatment Team, which provides medical care tailored to the needs of transgender veterans. *Id*. As the VA also has acknowledged, the agency actually provides "the majority" of the care needed for transgender veterans—without any specific appropriation from Congress. Appx323 (impact analysis for proposed rule).

Nonetheless, the VA categorically refuses to provide sex reassignment surgery, even though it acknowledges that the surgery is now "widely accepted" as "medically necessary" to treat gender dysphoria. See, e.g., Appx1; Appx305; Appx321; Appx330. In particular, the Regulation expressly excludes "[g]ender alterations" from the medical benefits package. 38 C.F.R. §17.38(c)(4). VHA Directive 2013-003 (the "Directive") clarifies that this exclusion constitutes an absolute bar to coverage for "sex reassignment surgery," which the Directive defines to encompass "any of a variety of surgical procedures ... done simultaneously or sequentially with the explicit goal of transitioning from one sex to another." Appx57. The excluded procedures include "vaginoplasty and breast augmentation in MtF [male-to-female] transsexuals and mastectomy and phalloplasty in FtM [female-to-male] transsexuals." *Id.* Despite the overwhelming medical consensus that sex reassignment surgery is not cosmetic and is medically necessary for some individuals suffering from gender dysphoria, the Directive puts

such surgery on equal footing with "plastic reconstructive surgery for strictly cosmetic purposes." Appx61.¹

The VA harbors no medical objection to the *procedures* that constitute sex reassignment surgery. Indeed, it already provides surgeries similar to those that constitute sex reassignment surgery—when done for reasons other than to treat gender dysphoria. Appx53 (VHA Directive 2011-024); Appx324 (impact analysis for proposed rule). For example, the VA offers veterans "[r]econstructive (plastic) surgery required as a result of disease or trauma," Appx49, which under VHA Directive 1091 (Feb. 21, 2014) includes "those surgical procedures performed for the revision of external bodily structures which deviate from normal either from congenital or acquired causes," Appx70. Under 38 C.F.R. §17.38(a)(1)(x) and VHA Directive 1091, the VA offers breast reconstruction to cisgender (*i.e.*, nontransgender) women following a mastectomy, as well as penile and testicular implants to cisgender males whose penises or testes have been damaged.²

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As originally promulgated, the Regulation prohibited the surgical implantation of penile prostheses. *See* 63 Fed. Reg. at 37,307. That exclusion was subsequently removed, *see* Enrollment—Provision of Hospital and Outpatient Care to Veterans, 64 Fed. Reg. 54,207, 54,210 (Oct. 6, 1999), and penile prostheses remain available to veterans under the benefits package—so long as the prosthesis is not sought in connection with a veteran's being transgender.

[&]quot;Cisgender" is a term used to describe a person whose gender identity conforms to the sex assigned at birth—*i.e.*, someone who is not transgender. *See Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1120 n.9 (N.D. Cal. 2015).

Appx87; *see also* Appx49; Appx70. Hysterectomy and mastectomy are offered to cisgender females for, among other reasons, reduction of cancer risk. Appx87. The VA also provides orchiectomies, scrotectomies, and penectomies to cisgender males for various medical reasons. Appx87. Yet it denies those same procedures to transgender veterans when needed for purposes of treating gender dysphoria. Finally, VA policy covers surgery for intersex veterans "in need of surgery to correct inborn conditions related to reproductive or sexual anatomy." Appx57; Appx61.³

To sum up: The VA recognizes that gender dysphoria is a serious medical condition that requires treatment, and it provides transgender veterans with an array of medically needed care, including preoperative and postoperative care for sex reassignment surgery performed outside the VA system. The VA categorically refuses, however, to provide transgender veterans with health care coverage that includes sex reassignment surgery itself or to pay for it—regardless of the medical

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[&]quot;Intersex' is an umbrella term used to describe a wide range of natural bodily variations. Intersex people are born with sex characteristics that do not fit conventional binary notions of bodies designated 'male' or 'female.' In some cases, intersex traits are visible at birth, while in others they are not apparent until puberty. Some variations may not be visibly apparent at all." *Zzyym v. Kerry*, 220 F. Supp. 3d 1106, 1110 n.1 (D. Colo. 2016) (quoting plaintiff's complaint); *see also* Ben-Asher, *The Necessity of Sex Change: A Struggle for Intersex and Transsex Liberties*, 29 Harv. J. L. & Gender 51, 51 n.2 (2006) ("The intersex category today covers: (1) chromosomal variations, (2) gonadal variations (atypical ovaries or testes), (3) hormonal variations, and (4) external morphologic variations (genitalia that is neither clearly male nor female).").

need for such surgery in any particular case, and even though it provides substantively identical procedures to intersex veterans and other veterans for various reasons.

C. Treatment Of Sex Reassignment Surgery By Other Agencies, Insurers, And Employers

The VA's position is not only internally incoherent, it also is divorced from an ever-growing consensus among federal and state agencies, insurance carriers, and private businesses regarding coverage for sex reassignment surgery. Perhaps most relevant here, the Defense Department has stated that it would provide sex reassignment surgery (among other transition-related care) to some transgender active-duty servicemembers. Other federal agencies have taken a similar tack. For example, in 2014, the Department of Health and Human Services ("HHS") Departmental Appeals Board overturned a thirty-year-old policy denying Medicare coverage for sex reassignment surgery. See Decision No. 2576, HHS Departmental Appeals Board (May 30, 2014); Appx150. The Board deemed the exclusion unreasonable in light of significant and unchallenged contemporary

See Kime, Pentagon to cover sex-reassignment surgery for transgender active-duty troops, MilitaryTimes, Sept. 19, 2016, http://www.militarytimes.com/articles/defense-department-covers-gender-reassignment-surgery; see also U.S. Department of Defense, Transgender Service in the U.S. Military, An Implementation Handbook (Sept. 30, 2016); Interim Guidance for Service of Transgender Navy Personnel, NAVADMIN 248/16 ("Transition medical treatment differs for each individual and may include any or all of the following: behavioral health counseling, cross-sex hormone therapy, surgery, and real-life experience.").

empirical evidence supporting the safety, effectiveness, and necessity of that treatment for certain individuals with severe gender dysphoria.

More broadly, federal and state agencies have taken a dim view of categorical exclusions for coverage of health services related to gender transition, such as the VA's Regulation. For example, the Office of Personnel Management, recognizing "the evolving professional consensus that treatment may be medically necessary to address ... gender dysphoria," stated in a letter to health insurance carriers participating in the Federal Employees Health Benefits Program that no carrier "may have a general exclusion of services, drugs or supplies related to gender transition." Appx92. An increasing number of states, including California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington, as well as the District of Columbia, have adopted similar statutes, rules, and directives prohibiting such categorical exclusions of care. See Appx92; Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,189-54,190 (Sept. 8, 2015).⁵

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See also Delaware Dep't of Ins., Domestic/Foreign Insurers Bulletin No. 86 (Mar. 23, 2016); Haw. Rev. Stat. §§432D, 432:1, 431:10A; Mich. Dep't of Ins. & Fin. Servs., Bulletin 2016-10-INS (Mar. 14, 2016); Mont. Comm'r of Secs. & Ins., Advisory Memorandum: Requirements for Health Plan Form Filings and Qualified Health Plan Certification (Mar. 31, 2016).

Federal courts also have recognized both the seriousness of gender dysphoria, see Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1, F.3d , 2017 WL 2331751, at *11 (7th Cir. May 30, 2017); Evancho v. Pine-Richland Sch. Dist., F. Supp. 3d , 2017 WL 770619, at *5 n.12 (W.D. Pa. Feb. 27, 2017); Board of Educ. of Highland Local Sch. Dist. v. U.S. Dep't of Educ., 208 F. Supp. 3d 850, 855 (S.D. Ohio 2016), and the medical need for sex reassignment surgery. The Tax Court, for example, held that expenses associated with the surgery were medically necessary and therefore deductible for federal tax purposes. O'Donnabhain v. Commissioner, 134 T.C. 34, 65-70 (2010). Courts have also struck down categorical bans on sex reassignment surgery, deeming them deliberately indifferent to a prisoner's medical needs in violation of the Eighth Amendment. See, e.g., De'lonta v. Johnson, 708 F.3d 520, 523, 526 (4th Cir. 2013); Fields v. Smith, 712 F. Supp. 2d 830, 863-864 (E.D. Wis. 2010), aff'd, 653 F.3d 550 (7th Cir. 2011).

Finally, private businesses and insurance carriers increasingly cover sex reassignment surgery as part of the complement of benefits provided to employees.

According to one 2016 study, nearly a third of large employers nationwide include

the surgery as part of their employee health benefits packages.⁶ The nation's largest insurers likewise cover surgery.⁷

D. Petitioners' Military Service And Medical Need For Sex Reassignment Surgery

Petitioners Dee Fulcher and Giuliano Silva served with distinction as members of the U.S. Armed Forces. As veterans, they participate in the VA medical benefits package; as transgender veterans, they are deprived by the Regulation of care that their VA health care practitioners have determined is medically necessary as part of their gender transition.

Ms. Fulcher is a veteran of the Marine Corps. Appx116 (affidavit of Dee Fulcher). She received a diagnosis of gender dysphoria from her physician and mental health social worker at the VA, and her clinicians have since recommended that she receive sex reassignment surgery, including a penectomy and a vaginoplasty, as part of her gender transition. Appx118. However, because of the Regulation, Ms. Fulcher cannot receive this prescribed treatment through the VA. *Id.*

See Japsen, More Employers Cover Transgender Surgery As Politics Shift, Forbes.com (May 17, 2016).

See, e.g., Aetna Policy No. 0615 (Gender Reassignment Surgery); Anthem Blue Cross Blue Shield Clinical Guideline CG-SURG-27 (Sex Reassignment Surgery); Cigna Medical Coverage Policy No. 0266 (Treatment of Gender Dysphoria); UniCare Clinical Guideline CG-SURG-27 (Sex Reassignment Surgery).

Mr. Silva is a veteran of the U.S. Army. Appx124 (affidavit of Giuliano Silva). He has also received a diagnosis of gender dysphoria from his VA physicians but could not receive necessary sex reassignment surgery as treatment under the Regulation.

Ms. Fulcher and Mr. Silva are members of petitioner Transgender American Veterans Association ("TAVA"), a non-profit organization that advocates for transgender veterans within the VA health care system. Appx111 (affidavit of Evan Young, National President of TAVA); Appx116; Appx124. TAVA works with veterans, active duty servicemembers, Congress, and LGBT organizations to influence VA and military policy, regulations, and procedures regarding the provision of health care to veterans with gender dysphoria. Appx111-112. TAVA members "experience extreme and sometimes life-threatening hardships because they cannot obtain coverage for these health care services that their doctors deem to be medically necessary." Appx114.

E. Agency Proceedings

Pursuant to 5 U.S.C. §553(e), Ms. Fulcher, Mr. Silva, and TAVA submitted a petition for rulemaking on May 9, 2016, requesting that the VA amend or repeal the rules and regulations—including 38 C.F.R. §17.38(c)(4) and any implementing directives—that exclude medically necessary sex reassignment surgery from the medical benefits package. *See* Appx72-109. Petitioners argued that the VA's

policies regarding treatment of transgender veterans were both internally inconsistent and in conflict with the emerging consensus among federal and state agencies concerning coverage for sex reassignment surgery. Appx93-96.

Petitioners further argued that the Regulation is arbitrary and capricious and violates the equal protection component of the Fifth Amendment's Due Process

Clause because it discriminates against transgender people and is not supported by any rational justification. Appx96-109. The VA acknowledged receipt of the petition but never directly responded to it.

In the spring of 2016—the exact date is unclear from the record—the VA drafted a Notice of Proposed Rulemaking ("NPRM") proposing to amend or repeal the Regulation by removing the exclusion of "gender alterations" from the medical benefits package. Appx305-315. As the draft NPRM explained, that exclusion had been enacted in 1999 on the theory that sex reassignment surgery was "not considered medically needed" for transgender veterans. Appx307. Even if that rationale had been tenable seventeen years earlier, the VA explained, it was no longer consistent with the statute and regulation under which the agency provided the medical benefits package, given intervening medical developments:

Increased understanding of both gender dysphoria and surgical techniques in this area have improved significantly, and surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria. Additionally, recent medical research shows that the failure to provide transition

surgeries to certain patients suffering from gender dysphoria can have severe medical consequences.

Appx305. "In light of these medical advances and the evolving standard of care," the NPRM explained, the VA "propose[d]" to "revise its medical benefits package regulation to remove this exclusion." *Id.* With the exclusion removed, "the treating VA healthcare provider [could] determine, in the exercise of his or her clinical judgment, that such services are medically necessary in a particular clinical case and so offer them to the patient." Appx308.

In the summer of 2016—again, the precise date is not clear from the record—the VA announced that it would include the NPRM in the Fall 2016 Unified Agenda for Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the federal government. *See* Appx1.

In conjunction with the draft NPRM, the VA conducted an economic impact analysis of the proposed removal of the exclusion for sex reassignment surgery. Appx320-330. It concluded that projected costs for 2018-2020 would be approximately \$18 million, depending on patient interest in and awareness of the procedures. Appx329. Given that the VA already provided certain aspects of transition-related care, the analysis observed that "[f]ortunately, the addition of medically necessary transition-related procedures is viewed as an event-based expense per unique veteran, rather than ongoing medical expense to the system."

Appx323. That is, the VA would incur no incremental fixed costs, but only the expense associated with each procedure sought and provided.

Moreover, the analysis observed that those costs might be offset by efficiencies introduced by the VA's provision of sex reassignment surgery through its own network of providers. See Appx327. For example, the VA explained that "[m]any Veterans" had undergone sex reassignment surgery abroad, with little or no planned post-surgical care. *Id.* That arrangement not only imposed significant hardship on the affected veterans—requiring them, for example, to "sit[] on the surgical site for an extended airline trip" and consequently requiring visits to VHA emergency rooms, id.—but also imposed significant cost on the VA: Because the VA provides post-surgical care regardless of where the surgery takes place, it is obligated to address—and bear the financial consequence of—"post-operative complications related to international travel from surgical centers and poor surgical care." Id. By removing the exclusion, the analysis explained, "these types of complications can be reduced and continuity of care will be enhanced." Id. The agency further explained that "transition-related surgery has been proven effective at mitigating serious health conditions including suicidality, substance abuse and dysphoria that, left untreated, impose treatment costs on the [VA]." Id.

The chief financial officer of the Veterans Health Administration concurred in the financial analysis. Appx330.

During the summer and fall of 2016, Members of Congress sent letters to the VA requesting information about the status of the proposed rulemaking. Some wrote to the VA to express "serious concerns" about the proposal to cover sex reassignment surgery. Appx316-319. Those Members argued that the provision of non-service-connected medical care to veterans was "misguided" given "challenges" the VA was facing "in delivering health care to those veterans whose service directly resulted in their need for medical treatments." Appx316. (Those Members did not take issue, however, with the fact that the VA provides extensive care for non-service-connected conditions to veterans.) Others wrote to urge the VA to move forward on the proposed NPRM. Appx331-336. Those Members emphasized that other federal agencies "recognized [a] de minimis fiscal impact in findings in final regulations prohibiting such exclusions [of sex reassignment surgery] for Marketplace health plans and for employee plans of federal contractors." Appx334.

On November 10, 2016, the VA sent an identical letter to each of the 47 Members of Congress who had written to the agency about the NPRM. Appx1-47. Signed by respondent David J. Shulkin, M.D.—then the Under Secretary for Health and now the Secretary of Veterans Affairs—the letter acknowledged both that the VA "currently provides many services for transgender Veterans to include hormone therapy, mental health care, preoperative evaluation, and long-term care

following sex reassignment surgery," and that "[i]ncreased understanding of both gender dysphoria and surgical techniques in this area has improved significantly and is now widely accepted as medically necessary treatment." Appx1. The letter nonetheless disclosed that the VA was withdrawing the NPRM from the Fall 2016 Unified Agenda. *Id.* Then-Under Secretary Shulkin explained that the "VA has been [exploring] and will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package," but only "when appropriated funding is available." *Id.* Any future rulemaking on the subject, moreover, was "not imminent." *Id.*

On January 19, 2017, after the petition for review was filed in this Court, the VA reissued VHA Directive 2013-003, reiterating the Department's categorical position that "[s]ex reassignment surgery cannot be performed or funded by VA." Appx57. According to the reissued Directive, this is the VA's position until at least February 28, 2018. *Id*.

SUMMARY OF ARGUMENT

I. The VA has denied the petition for rulemaking, and that final agency action is ripe for this Court's review. In official correspondence between the agency and Congress, the VA stated unequivocally that it does not intend to engage in rulemaking. That correspondence reflects both the consummation of the agency's decisionmaking process and the agency's definitive decision to deny the

petition. Nothing more is required to present agency action for this Court's review. If this Court determines that the November 10 letter was not a denial, then the Court should nonetheless compel the VA to engage in rulemaking because the agency's one-year delay is unreasonable and unjustified. The agency has no basis for further delay, which will result in grave harm to the transgender veterans affected by the Regulation.

This Court should set aside the denial and compel the VA to engage in II. rulemaking. First, the agency's action is arbitrary and capricious. The VA's proposed rulemaking materials in the record, as well as its own policies, indicate that the VA understands the medical necessity of sex reassignment surgery—yet the VA has refused to engage in rulemaking to address the inconsistency caused by its policy of refusing to provide that surgery. The VA's stance is also directly contrary to the medical community's understanding that sex reassignment surgery is a medically necessary treatment for gender dysphoria, an understanding that an ever-growing number of courts have embraced. In its letter to Members of Congress, the VA claimed that it requires "appropriated funding" to engage in rulemaking, but there is no support for that claim. In fact, the proposed rulemaking materials and other documents considered by the agency in the record undermine the VA's proffered reason for the denial.

III. The VA's denial of the petition should also be set aside on the independent ground that the Regulation discriminates against transgender veterans on the basis of sex and transgender status, in violation of both the equal protection component of the Fifth Amendment's Due Process clause and Section 1557 of the Affordable Care Act. Although the VA provides medically necessary care to nontransgender veterans, it withholds substantially similar medically necessary procedures from transgender veterans on the basis of their sex and transgender status alone. Numerous courts have held that discrimination against transgender individuals is discrimination on the basis of sex or transgender status and that classifications based on transgender status (like those based on sex) are suspect and thus subject to strict or at least heightened scrutiny. Regardless of the level of scrutiny applied, the Regulation cannot survive because the VA cannot present any government interest—including cost considerations—to justify it. Accordingly, the VA's denial should be set aside, the VA should be compelled to engage in rulemaking to protect and preserve the health of transgender veterans.

STANDARD OF REVIEW

This Court will set aside an administrative agency's denial of a petition for rulemaking if the denial was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Preminger v. Secretary of Veterans Affairs*, 632 F.3d 1345, 1353 (Fed. Cir. 2011) (quoting *Massachusetts v. EPA*, 549)

U.S. 497, 527-528 (2007)); see also 5 U.S.C. §706(2)(A). A reviewing court must ensure that "the [agency] has adequately explained the facts and policy concerns it relied on and ... satisfy [itself] that those facts have some basis in the record." *Preminger*, 632 F.3d at 1353 (citation omitted). In addition, this Court must "hold unlawful and set aside" any VA action "contrary to constitutional right." 5 U.S.C. §706(2)(B); see also Griffin v. Secretary of Veterans Affairs, 288 F.3d 1309, 1317 (Fed. Cir. 2002).

ARGUMENT

I. THE VA HAS DENIED THE PETITION FOR RULEMAKING

The Secretary's November 10 letter makes clear that the VA has denied the petition for rulemaking. That denial is final agency action susceptible to this Court's review.

A. The November 2016 Letter Demonstrates That The VA Has Denied The Petition For Rulemaking

As the Supreme Court has explained, for agency action to be "final" and therefore fit for judicial review, "the action must mark the 'consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature" and "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177-178 (1997) (citations omitted); *see also Systems*

Application & Techs., Inc. v. United States, 691 F.3d 1374, 1384 (Fed. Cir. 2012). The VA's November 10, 2016 letter satisfies both requirements.

The letter reflects the consummation of the agency's decisionmaking process. By mid-2016, the VA had drafted an NPRM, conducted an extensive internal analysis to gauge the proposed rule's financial impact, and undertaken to include the NPRM in the Fall 2016 Unified Agenda. *See supra* pp. 15-16. The November 2016 letter announced conclusively that the draft NPRM had been withdrawn from the Unified Agenda and that any future rulemaking was "not imminent." Appx1. The subsequently reissued VHA Directive 2013-003 confirmed that the ban on coverage for sex reassignment surgery would remain through at least February 28, 2018. Appx56. In short, all the preliminary steps necessary to engage in rulemaking had been completed, and yet the agency made the decision not to go forward.

Nothing more is required to finalize the agency's determination. The absence of any formal statement that the petition was denied is immaterial. *WildEarth Guardians v. Salazar*, 741 F. Supp. 2d 89, 104 (D.D.C. 2010). Nor does it matter that the VA did not foreclose the possibility of future regulatory action. An agency cannot render its decision non-final by promising to consider the issue again at some future point. *See Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1037-1038 (D.C. Cir. 2002) ("[T]he Commission argues that the *1998*

Report is not final because the agency intends to continue considering the ownership rules. That, however, does not mean the determination is not 'final' as a matter of law."), opinion modified in part on reh'g on other grounds, 293 F.3d 537 (D.C. Cir. 2002); cf. Henley v. FDA, 873 F. Supp. 776, 783, 786 (E.D.N.Y. 1995) (reviewing FDA denial of a petition for rulemaking that expressly left open the possibility of different agency action in the future), aff'd, 77 F.3d 616 (2d Cir. 1996).

A particularly instructive decision on this point is *National Parks*Conservation Association v. United States Department of Interior, 794 F. Supp. 2d
39 (D.D.C. 2011). Citing unreasonable delay, the plaintiffs there moved to compel
a response from two federal agencies after receiving letters from the agencies
opining that the existing regulations adequately addressed the plaintiffs' concerns
and that the agencies reserved the right to revisit their determinations in the future
if necessary. *Id.* at 43-44. The court found that it was "clear from the face of the
response letters ... that [the agencies] have reached a 'definitive decision' to deny
Plaintiffs' petitions." *Id.* at 45. The court also rejected the plaintiffs' argument
that the possibility of undetermined future action rendered their responses nonfinal: "Although it is true that [the agencies] left open the possibility that they may
initiate the type of rulemaking Plaintiffs want in the future," the court explained,

"they have also made clear that they are denying Plaintiffs' petitions at this time." *Id.* at 46.

Likewise here, the VA has reached a "definitive decision" to deny the petition for rulemaking "at this time," and the agency's suggestion that it might reinitiate rulemaking "when appropriated funding is available" does not somehow make its denial non-final. That conclusion is underscored by the VA's January 2017 decision to reissue VHA Directive 2013-003, reiterating the categorical exclusion of sex reassignment surgery from the medical benefits package and declaring, again, that this would be the agency's policy at least through February 28, 2018. See supra p. 19. In other words, having withdrawn its proposed rulemaking in November 2016, the VA elected to reconfirm its policy in January 2017. That is final (indeed, decisive) agency action. Were it otherwise, an agency could perpetually evade judicial review of denials of petitions for rulemaking merely by suggesting that it would revisit issues at an unspecified time in the future.

Any argument that the November 2016 letter was mere correspondence and thus does not reflect a final denial of the petition for review would be meritless.

Courts regularly review denials of petitions for rulemaking embodied in correspondence. *See American Horse Prot. Ass'n, Inc. v. Lyng*, 812 F.2d 1, 5

(D.C. Cir. 1987) (reviewing a denial in the form of letters to the plaintiff

association and two litigation affidavits provided by an agency officials); *Henley*, 873 F. Supp. at 780, 783 (reviewing an agency's letters denying the petition and affirming denial on reconsideration). Although in those cases the correspondence was directed to the petitioning party or expressly referred to the petition (or both), that distinction is not meaningful. A letter to Congress by a high-ranking agency official, after all, is not just any correspondence; it is an official act by the agency with respect to another branch of government. The letter here reflects an authoritative statement of the VA's position, sent in response to official inquiries by Members of Congress specifically regarding the NPRM, all of which were sent after Petitioners filed their petition. That the VA chose to state its denial of the petition by writing to Congress rather than responding directly to Petitioners (as it should have) does not render its decision any less final.

B. At A Minimum, The VA's Year-Long Delay In Addressing The Petition Is Unreasonable

Even if the Court concludes that the November 2016 letter did not finally deny the petition, it should nonetheless compel the VA to act. Under the Administrative Procedure Act, an agency is required to proceed on a matter before it "within a reasonable time." 5 U.S.C. §555(b). If the agency fails to do so, a reviewing court "shall ... compel agency action." *Id.* §706(1).

1. "[T]here is no per se rule as to whether a given delay is reasonable"; rather, "courts must determine the reasonableness of delay based on the totality of

the circumstances." Families for Freedom v. Napolitano, 628 F. Supp. 2d 535, 541 (S.D.N.Y. 2009). Relevant factors in making that determination include not only the length of time elapsed, but also whether the relevant statute provides any justification; the nature and extent of the interests prejudiced by the delay—and in particular whether the delay affects economic interests or health and welfare; and the effect that compelling agency action will have on other agency priorities. See Telecommunications Research & Action Ctr. v. FCC, 750 F.2d 70, 80 (D.C. Cir. 1984). A court need not find ill motive behind the delay in order to hold that a delay is unreasonable. Id.

Here, all the factors support a finding of unreasonable delay. First, even if the VA has not officially denied the petition, it nonetheless has failed to act for more than a year. That is unreasonable given that the VA was able to draft a proposed rulemaking and conduct an impact analysis within a few months of receiving the petition. The VA has received and prepared all necessary materials to respond to the petition but has nonetheless unjustifiably failed to provide any indication as to when it may respond. *See Khan v. Johnson*, 65 F. Supp. 3d 918, 929 (C.D. Cal. 2014) ("Courts have ... been less likely to favor the government ... when [it] has 'fail[ed] to provide any indication of when' adjudication of the application might take place.").

Second, there is no basis in either 38 U.S.C. §1710 or the Regulation warranting the VA's prolonged delay in responding to the petition. Indeed, the delay is antithetical to the relevant statute's goal of providing veterans with medically needed care. *Cf. Public Citizen Health Research Grp. v. Commissioner, FDA*, 740 F.2d 21, 34 (D.C. Cir. 1984) ("In response to a request that the court 'compel agency action ... unreasonably delayed' pursuant to 5 U.S.C. §706(1), the court should review the pace of the agency decisional process to ensure that it is not lagging unreasonably in light of the nature and extent of public health considerations." (ellipsis in original)).

Third, the delay worsens "grave health and safety problems for the intended beneficiaries of the statutory scheme." *National Customs Brokers & Forwarders Ass'n of America, Inc. v. United States*, 883 F.2d 93, 103 (D.C. Cir. 1989). The VA's own documents reflect the agency's recognition of the severe health concerns implicated by the Regulation. In particular, the VA has concluded based on sound medical authority that failure to provide sex reassignment surgery when it is medically indicated "can lead to serious medical problems, including 'clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death." Appx308-309 (draft NPRM); *see also* Appx327 (VA economic impact analysis for draft NPRM stating that "transition-related surgery

has been proven effective at mitigating serious health conditions including suicidality, substance abuse and dysphoria that, left untreated, impose treatment costs on the [VA]."). While the agency delays, therefore, transgender veterans are denied critical medical care—in contravention of both Congress's statutory directive, and the agency's own regulatory goal of providing medical care "to promote, preserve, or restore the health of the individual." 38 C.F.R. §17.38(b).

Lastly, the VA has no plausible claim that addressing the petition will unduly burden the agency or divert its resources. The Department has already laid the groundwork for the rulemaking by drafting the NPRM and conducting a thorough financial impact analysis. Only minor work remains to be done to formally initiate the rulemaking.

2. The ordinary remedy for an agency's unreasonable delay in responding to a petition for rulemaking is for the Court to direct a response. *See, e.g., McHugh v. Rubin,* 220 F.3d 53, 61 (2d Cir. 2000); *Families for Freedom,* 628 F. Supp. 2d at 541. Such an order would be futile here, however. As discussed, the VA has unambiguously decided—as announced in public correspondence with Congress—not to initiate a rulemaking. Hence, "[a] remand to the agency for further proceedings would serve no purpose and would only add to the delay already encountered." *Public Citizen v. Heckler,* 653 F. Supp. 1229, 1241 (D.D.C. 1986). This Court should therefore simply direct the VA to initiate rulemaking.

Cf. 5 U.S.C. §555(b) ("With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency *shall* proceed to conclude a matter presented to it." (emphasis added)).

As the court explained in *Heckler*, courts will "overturn an agency judgment not to institute rulemaking ... 'if a significant factual predicate of a prior decision on the subject (either to promulgate or not to promulgate specific rules) has been removed." 653 F. Supp. at 1241 (quoting WWHT, Inc. v. FCC, 656 F.2d 807, 818 (D.C. Cir. 1981)). Those admittedly "rare and compelling circumstances," id., are present here. The draft NPRM explains that the exclusion of sex reassignment surgery from the medical benefits package was based on the VA's 1999 view that surgery was "not considered medically needed." Appx307. That "factual premise" has now been removed; the VA acknowledges that "surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria." Appx305. Because "[t]here is no longer any question of fact as to whether" sex reassignment surgery is medically needed in some cases, Heckler, 653 F. Supp. at 1241, this Court should order the VA to initiate rulemaking to reconsider its categorical exclusion of such surgery from the medical benefits package.

II. THE VA'S DENIAL OF THE PETITION FOR RULEMAKING IS ARBITRARY AND CAPRICIOUS

An agency's denial of a petition for rulemaking is reviewed under the familiar Administrative Procedure Act standard to determine "whether the agency's decision was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Preminger v. Secretary of Veterans Affairs, 632 F.3d 1345, 1353 (Fed. Cir. 2011) (quoting *Massachusetts v. EPA*, 549 U.S. 497, 526-527 (2007)). Although "an agency's refusal to institute rulemaking proceedings is at the high end of the range of levels of deference given to agency action under th[at] standard," the Court must nonetheless ensure that the agency "has adequately explained the facts and policy concerns it relied on and ... that those facts have some basis in the record." *Id.* (alteration in original) (citation omitted). "In other words, a court 'look[s] to see whether the agency employed reasoned decisionmaking in rejecting the petition." *Id.* (alteration in original) (citation omitted); see also Service Women's Action Network v. Secretary of Veterans Affairs, 815 F.3d 1369, 1374 (Fed. Cir. 2016); Level the Playing Field v. FEC, F. Supp. 3d , 2017 WL 437400, at *11 (D.D.C. Feb. 1, 2017) (applying quoted standard and remanding to the agency for reconsideration of petition).

The VA's unreasoned denial of Petitioners' rulemaking request is arbitrary and capricious. As the VA recognized when it was poised to open a rulemaking in this matter, the Regulation and its implementing directives are inconsistent with

the statute requiring the agency to provide for veterans' medically necessary care. Appx305. The VA's regulatory exclusion of sex reassignment surgery from the medical benefits package contradicts accepted medical standards as well as the agency's professed goal of promoting, preserving, and restoring veterans' health. The VA's only proffered justification for maintaining the exclusion—that "appropriated funding" is not yet available—is unsupported by the record and in any event insufficient. The VA conducted a comprehensive financial analysis of a proposed rule to remove the exclusion for sex reassignment surgery. That analysis recognized that the projected cost entailed in offering sex reassignment surgery to veterans would be relatively minor and that the VA would realize cost savings from doing so. That analysis also included a proposed three-year cost-allocation pilot designed to better understand the costs (and, presumably, any offsetting financial benefits) associated with providing sex reassignment surgery. Appx326. Having previously proposed a pilot program without any mention of the need for appropriations, the VA cannot now be heard to claim that providing sex reassignment surgery simply cannot be done without specific appropriated funds.

A. The VA's Denial Of The Petition Is Unreasoned

In determining whether an agency's action was arbitrary and capricious, the Court asks "whether the agency employed reasoned decisionmaking in rejecting the petition." *Service Women's Action Network*, 815 F.3d at 1374 (citation

omitted). Here, the answer is no, because the relevant facts, factors, and policy concerns all militate in favor of amending the Regulation to remove the exclusion for sex reassignment surgery—and, at a minimum, in favor of opening a rulemaking to receive comments on such a proposal.

1. The Regulation is contrary to the statutory directive to provide "needed" care to veterans

As the VA acknowledges, 38 U.S.C. §1710 "requires VA to 'furnish hospital care and medical services which the Secretary determines to be needed' for eligible veterans." Appx306-307 (draft NPRM (quoting statute)). The agency has implemented that statutory directive by providing an operative definition of the statutory term "needed"—namely "medically needed," which the agency in turn defines to mean "care that ... appropriate healthcare professionals [determine] to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice." Appx307 (alteration in original) (quoting 63 Fed. Reg. 37,299, 37,300 (July 10, 1998)); see also 63 Fed. Reg. at 37,300 ("The Secretary has authority to provide healthcare as determined to be medically needed." (citing 38 U.S.C. §1710)).

As the draft NPRM explained, the exclusion of sex reassignment surgery was introduced in 1999 based on the view that the surgery was "not considered medically needed." Appx307. That rationale, the VA recognizes, has now been thoroughly debunked: "[M]ultiple medical professional organizations, including

the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the American Congress of Obstetricians and Gynecologists, and the World Professional Association for Transgender Health have all issued statements affirming that transition surgery is medically necessary care for some patients." Appx309. Yet the VA's categorical exclusion of sex reassignment surgery remains in place, even as "other provisions of this regulation have been modified over the years." Appx307.

The VA's recognition that sex reassignment surgery is sometimes medically necessary is consistent with a wall of medical authority on the point. "Indeed, every psychiatric reference text that has been established as authoritative in this case endorses sex reassignment surgery as a treatment for [gender dysphoria] in appropriate circumstances," and "[n]o psychiatric reference text has been brought to the Court's attention that fails to list, or rejects ... sex reassignment surgery as the accepted treatment regimen for [gender dysphoria]." *O'Donnabhain*, 134 T.C. at 65-66; *see supra* pp. 4-6. In recognition of that medical consensus, multiple federal agencies—including the Department of Defense—have either expressed a willingness to provide sex reassignment surgery for covered transgender people or direct participating providers or insurance carriers to do so in appropriate cases. *See supra* p. 10. A growing number of state agencies take the same approach (*see*

supra p. 11), as do an increasing number of private businesses and insurance carriers. Yet the VA clings to its categorical exclusion.

As this Court has explained, even under the "narrow" scope of review applicable to an agency's denial of a petition for rulemaking, the "agency's decision not to initiate a rulemaking" will be set aside where there has been "a fundamental change in the factual premises previously considered by the agency." *Service Women's Action Network*, 815 F.3d at 1375 (citation omitted). Those circumstances are clearly met here, as the agency itself has recognized that the factual premise for its current regulation—which it reissued after denying the petition for rulemaking—has been "fundamental[ly] change[d]." *Id.* The VA's decision to deny the petition should be set aside for this reason alone.

2. The VA's illogical approach to transition-related care is arbitrary and capricious

The Regulation and its implementing directives are independently arbitrary and capricious because they result in a regimen for transition-related care that is incoherent and contrary to the VA's professed goal of promoting, preserving, and restoring veterans' health. As explained (*see supra* pp. 6-7), the VA recognizes that gender dysphoria is a serious medical condition that requires treatment—including, in some cases, sex reassignment surgery. The VA accordingly provides transgender veterans with treatments such as "hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-

term care following sex reassignment surgery to the extent that the appropriate health care professional determines that the care is needed to promote, preserve, or restore the health of the individual." Appx53. The VA categorically refuses, however, to provide transgender veterans with sex reassignment surgery—irrespective of the medical need for it in a particular case, and notwithstanding that it provides substantively identical procedures to intersex veterans and to other veterans for various reasons. *Id.* The rulemaking petition expressly challenged that irrational state of affairs, and the VA's denial offered no justification for this irrationality. That failure to adequately explain or defend the agency's regime warrants setting aside the denial.

Moreover, as the VA recognized in the draft NPRM, the Regulation strips VA clinicians of the ability to determine whether sex reassignment surgery is medically necessary on a case-by-case basis. Because that categorical bar is contrary to "the medical literature," the VA proposed that "surgical procedures currently available to aid individuals in gender transitioning may be reasonably determined by a treating VA healthcare provider to be ... in accord with generally accepted standards of medical practice." Appx308. "In other words, we would permit the treating VA healthcare provider to determine, in the exercise of his or her clinical judgment, that such services are medically necessary in a particular clinical case and so offer them to the patient." *Id.* The agency's denial of the

rulemaking petition means that notwithstanding the VA's apparent recognition that the categorical exclusion runs contrary to medical judgment, it remains in place.

The VA's decision to maintain that exclusion is not only unreasoned, but also contrary to a line of cases holding that categorical bans on sex reassignment surgery are improper because they refuse medically necessary treatment. Several courts have held these bans invalid because they preclude an "individualized medical evaluation" of the need for sex reassignment surgery, contrary to "prudent professional standards" and the Standards of Care. *Fields*, 712 F. Supp. 2d at 858-862 (internal quotation marks omitted); *see also De'lonta*, 708 F.3d at 523, 526 ("[J]ust because Appellees have provided De'lonta with *some* treatment consistent with the [gender dysphoria] Standards of Care, it does not follow that they have necessarily provided her with *constitutionally adequate* treatment."). The VA's refusal to reconsider its contrary view is arbitrary and capricious.

B. The VA's Proffered Reason For Denying The Petition Is Meritless The VA denied the petition on the sole ground that it would wait until "appropriated funding is available." Appx1. That is inadequate.

To the extent the VA means to say that it cannot even initiate the rulemaking process absent funding, that is incorrect. The VA does not require any additional funding to issue an already-drafted NPRM, solicit and respond to comments, and issue a final rule. In fact, given that all the groundwork—including the proposed

rule and financial impact analysis—has been laid, lack of funding is a particularly illegitimate reason to refuse even to open the rulemaking process.

If the VA instead means that it cannot or will not undertake a rulemaking because funding is not yet available to cover the expected demand for sex reassignment surgery in the event the categorical exclusion is removed, that justification fails because it has no basis in the record.

First, as explained, the agency recognizes the medical needs of transgender veterans and has provided transition-related care for years—without the need for specific rulemaking or appropriations from Congress. The VA offers no explanation why appropriated funding is uniquely warranted to provide transgender veterans with sex reassignment surgery. That is particularly the case in view of the agency's determination that "the addition of medically necessary transition-related procedures is viewed as an event-based expense per unique veteran, rather than ongoing medical expense to the system." Appx323 (economic impact analysis). The VA has not explained why specific appropriated funds are necessary to cover this incremental event-based expense.

Second, as also discussed, the VA already provides procedures substantially similar to those constituting sex reassignment surgery, so long as the medical need is not related to a veteran's gender transition. See supra pp. 8-9. The VA thus will not need to develop new technologies or acquire new equipment to meet the needs

of transgender veterans. This further undermines the agency's apparent position that removing the categorical bar would impose some material cost on the agency that demands specifically appropriated funds.

Third, the VA's own financial analysis of the proposed rule—drafted by agency staff and concurred in by the CFO of the Veterans Health Administration—concluded that projected costs for 2018 through 2020 would be approximately \$18 million. Appx329. That figure represents less than 0.01% of the VA's \$186.5 annual budget for 2018, far too little to justify withholding medically necessary care. Moreover, as the financial analysis makes clear, that figure would likely be offset substantially by eliminating costs associated with (1) serious health consequences from untreated gender dysphoria and (2) post-operative care needed by veterans who receive sex reassignment surgery from non-VA (and often low-quality) providers. Appx327. Confirming this point, the petition cited a recent analysis demonstrating that the upfront costs of sex reassignment surgery would be far outweighed by these savings. Appx95. Yet the VA denied the petition without

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Annual Budget Submission, Office of Budget, U.S. Department of Veterans Affairs, https://www.va.gov/budget/products.asp (last visited June 18, 2017) ("The President's 2018 Budget includes \$186.5 billion in budget authority for VA in 2018. This includes \$82.1 billion in discretionary resources and \$104.3 billion in mandatory funding."); Rein, Veterans Affairs budget is in line to grow by 6 percent, The Washington Post (Mar. 16, 2017), http://wapo.st/2muumtJ? tid=ss_mail ("[President Trump's] first spending plan would boost VA's budget by \$4.4 billion, to \$78.9 billion.").

making any effort to reconcile the projected costs and financial benefits of removing the exclusion. Cf. Heckler, 653 F. Supp. at 1239 ("No evidence has been presented which shows that to additionally require the regulation of certified raw milk, contrary to the Secretary's bare assertion that resources will be diverted from truly national problems, will impose a significant burden on the agency's budget or personnel."). While an agency has "broad discretion" in its decision to engage in rulemaking, that discretion "should not be construed as providing a blanket exception to APA review in any matter involving the allocation of agency resources." Compassion Over Killing v. U.S. Food & Drug Administration, 849 F.3d 849, 857 (9th Cir. 2017). Thus, "[i]n denying a petition for rulemaking, an agency must, at a minimum, clearly indicate that it has considered the potential problem identified in the petition and provide a 'reasonable explanation as to why it cannot or will not exercise its discretion' to initiate rulemaking." Id. Here, the VA has failed to provide any reasonable explanation of why the minimal costs involved in providing sex reassignment surgery require denial of the petition, particularly in view of the corresponding efficiencies and offsets.

III. THE VA'S DENIAL OF THE PETITION MUST BE SET ASIDE BECAUSE THE REGULATION DISCRIMINATES AGAINST TRANSGENDER VETERANS

This Court must "hold unlawful and set aside" any VA action that is either "contrary to constitutional right" or otherwise "not in accordance with law." 5 U.S.C. §706(2)(A), (B). That mandate provides an independent basis to invalidate

the VA's denial of the petition, because the Regulation and its implementing directives discriminate against transgender veterans on the basis of sex and transgender status, in violation of both the equal protection component of the Fifth Amendment's Due Process Clause and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116.

A. The Regulation Discriminates On The Basis Of Sex And Transgender Status

The Regulation and its implementing directives deny transgender veterans medically necessary care that is available to non-transgender veterans to meet their medical needs. Under the Regulation, for example, a transgender woman may not receive vaginoplasty through the medical benefits package if it is intended to treat her gender dysphoria. See supra p. 7. By contrast, the VA would provide a cisgender woman that same procedure to treat an array of medical needs, including for "genital reconstruction due to blast injuries." Appx324 (economic impact analysis). That differential treatment is plainly discriminatory. See, e.g., Norsworthy v. Beard, 87 F. Supp. 3d 1104, 1120 (N.D. Cal. 2015) (California regulation is "facially discriminatory because it explicitly distinguishes between treatment for transsexual women that is designated as presumptively 'not medically necessary' ... and the same treatments for non-transgender women ..., which are explicitly exempted from this bar"); Denegal v. Farrell, No. 1:15-cv-01251, 2016 WL 3648956, at *7 (E.D. Cal. July 8, 2016) (plaintiff stated equal

protection claim based on allegation that prison "discriminate[d] against transgender women by denying surgery (vaginoplasty) that is available to cisgender women"); *Cruz v. Zucker*, 195 F. Supp. 3d 554, 581 (S.D.N.Y. 2016) (holding that a state's blanket ban on sex reassignment procedures constituted a "categorical exclusion on treatments of gender dysphoria" and discriminated on the basis of "sex"), *modified in part on reconsideration*, 218 F. Supp. 3d 216 (S.D.N.Y. 2016). Excluding from coverage procedures necessary for "gender alteration"—which by definition only transgender veterans would use—imposes a distinct and discriminatory burden on transgender people. *See, e.g., International Union v. Johnson Controls, Inc.*, 499 U.S. 187, 199 (1991) (company's "use of the words 'capable of bearing children' ... as the criterion for exclusion ... must be regarded, for Title VII purposes, in the same light as explicit sex discrimination").

1. Discrimination based on a person's transgender status is itself discrimination based on sex. The decision to treat a woman who is transgender differently from a woman who is cisgender is necessarily taken on the basis of whether the woman's gender matches her sex assigned at birth, and is thus based on sex. *See Macy v. Holder*, No. 0120120821, 2012 WL 1435995, at *7 (EEOC Apr. 20, 2012) ("When an employer discriminates against someone because the person is transgender, the employer has engaged in disparate treatment 'related to the sex of the victim." (citing *Schwenk v. Hartford*, 204 F.3d 1187, 1202 (9th Cir.

2000))). Thus, as both agencies and courts have recognized, "discrimination based on transgender status" is "cognizable" as a form of "sex discrimination." *Id.* at *4.

Moreover, "discrimination against a transgender individual on the basis of an intended, ongoing, or completed gender transition is literally discrimination because of [that person's] sex." *Macy*, 2012 WL 1435995, at *14 n.10 (internal quotation marks omitted). As the EEOC has explained, analogizing religious conversion to gender transition:

Imagine that an employee is fired because she converts from Christianity to Judaism. Imagine too that her employer testifies that he harbors no bias toward either Christians or Jews but only "converts." That would be a clear case of discrimination "because of religion." No court would take seriously the notion that "converts" are not covered by the [antidiscrimination] statute. Discrimination "because of religion" easily encompasses discrimination because of a change of religion.

Macy, 2012 WL 1435995, at *11 (citing *Schroer v. Billington*, 577 F. Supp. 2d 293, 306 (D.D.C. 2008)). By the same rationale, discrimination against a person on account of his or her transition from male to female or female to male is definitionally discrimination "because of sex."

Here, the VA provides certain procedures to veterans to treat an array of medical needs—except for needs associated with gender transition.

Discriminatory treatment based on gender transition—as on the face of the Regulation's exclusion for "gender alterations"—is direct evidence of sex discrimination. *See Glenn v. Brumby*, 663 F.3d 1312, 1320-1321 (11th Cir. 2011)

("Brumby['s] admitt[ing] that his decision to fire Glenn was based on 'the sheer fact of the transition' ... provides ample direct evidence to support the district court's conclusion" that sex discrimination occurred; "If this were a Title VII case, the analysis would end here."); Schroer, 577 F. Supp. 2d at 306 ("[T]he Library's refusal to hire Schroer after being advised that she planned to change her anatomical sex by undergoing sex reassignment surgery was literally discrimination 'because of ... sex.'"); Macy, 2012 WL 1435995, at *5 (discrimination claim based on "gender transition/change of sex" was "simply [a] different way[] of stating the same claim of discrimination 'based on ... sex,' a claim cognizable under Title VII"); see also Chavez v. Credit Nation Auto Sales, LLC, 641 F. App'x 883, 890-892 (11th Cir. 2016) (employer's concerns about employee's "gender transition" sufficient to demonstrate pretext for discrimination on the basis of sex).9

As the EEOC's decision in *Macy* explains, while there are several different ways to view discrimination against transgender people as a form of sex discrimination, each constitutes "disparate treatment 'related to the sex of the victim." *Macy*, 2012 WL 1435995, at *7 (quoting *Schwenk*, 204 F.3d at 1202). In particular, the same conclusion obtains "regardless of whether an employer discriminates against an employee because the individual has expressed his or her gender in a non-stereotypical fashion, because the employer is uncomfortable with the fact that the person has transitioned or is in the process of transitioning from one gender to another, or because the employer simply does not like that the person is identifying as a transgender person." *Id*.

Finally, under a distinct but related theory, the First, Sixth, Seventh, Ninth, and Eleventh Circuits have recognized that discrimination against transgender individuals is impermissible discrimination because of sex under the Equal Protection Clause of the Constitution and federal civil rights statutes. See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1, F.3d , 2017 WL 2331751, at *9-11 (7th Cir. May 30, 2017); Glenn, 663 F.3d at 1316-1320; Smith v. City of Salem, 378 F.3d 566, 572-575 (6th Cir. 2004); Rosa v. Park W. Bank & Trust Co., 214 F.3d 213, 215-216 (1st Cir. 2000); Schwenk, 204 F.3d at 1200-1203. As these courts have explained, discrimination on the basis of sex encompasses disparate treatment based on an individual's nonconformity with assumptions about how men and women should look and behave. See, e.g., Price Waterhouse v. Hopkins, 490 U.S. 228, 250-252 (1989). Because transgender individuals' "outward behavior and inward identity do not meet social definitions" associated with their sex assigned at birth, Schwenk, 204 F.3d at 1201, there is inherently "a congruence between discriminating against transgender ... individuals and discrimination on the basis of gender-based behavioral norms," Glenn, 663 F.3d at 1316. As a result, any discrimination against transgender people because they are transgender—i.e., against "individuals who, by definition, do not conform to gender stereotypes—is ... discrimination on the basis of sex." Finkle v. Howard County, Maryland, 12 F. Supp. 3d 780, 788 (D. Md. 2014); see also Evancho v. Pine-Richland Sch. Dist.,

F. Supp. 3d , 2017 WL 770619, at *11 (W.D. Pa. Feb. 27, 2017) ("[D]iscrimination based on transgender status in these circumstances is essentially the epitome of discrimination based on gender nonconformity, making differentiation based on transgender status akin to discrimination based on sex for these purposes."); accord Fabian v. Hospital of Central Connecticut, 172 F. Supp. 3d 509, 526-527 (D. Conn. 2016) ("Discrimination on the basis of the 'peculiarities' that 'typically' manifest as maleness and femaleness ... would surely include discrimination on the basis of gender stereotypes, and just as surely discrimination on the basis of gender identity."); Rumble v. Fairview Health Servs., No. 14-cv-2037, 2015 WL 1197415, at *2 (D. Minn. Mar. 16, 2015) ("Because the term 'transgender' describes people whose gender expression differs from their assigned sex at birth, discrimination based on an individual's transgender status constitutes discrimination based on gender stereotyping.").

2. Discrimination against transgender people is independently impermissible discrimination on the basis of transgender status. The Supreme Court has recognized that certain classifications are inherently invidious, such as those that single out certain groups through a suspect classification. *Massachusetts Board of Retirees v. Murgia*, 427 U.S. 307, 312-313 (1976). Because transgender people have been "saddled with such disabilities, or subjected to such a history of purposeful unequal treatment, or relegated to such a position of political

powerlessness as to command extraordinary protection from the majoritarian political process," *id.* (citation omitted), several courts have concluded that transgender status is a suspect classification, and accordingly subjected statutes and regulations that discriminate on the basis of that status to heightened scrutiny, *see*, *e.g.*, *Board of Educ. of Highland Local Sch. Dist. v. U.S. Dep't of Educ.*, 208 F. Supp. 3d 850, 873-874 (S.D. Ohio 2016); *Norsworthy*, 87 F. Supp. 3d at 1119; *Adkins v. City of N.Y.*, 143 F. Supp. 3d 134, 138-140 (S.D.N.Y. 2015).

Those courts' conclusion is correct. The Supreme Court consistently has applied heightened scrutiny where the group subject to the classification at issue has suffered a history of discrimination and the classification has no bearing on a person's ability to perform in society. See, e.g., Murgia, 427 U.S. at 313 (heightened scrutiny is warranted where a classified group has "experienced a 'history of purposeful unequal treatment' or been subjected to unique disabilities on the basis of stereotyped characteristics not truly indicative of their abilities"). The Court has also sometimes considered whether the group is a minority or relatively politically powerless, and whether the characteristic is defining or "immutable." See, e.g., Lyng v. Castillo, 477 U.S. 635, 638 (1986); see also Kerrigan v. Commissioner of Public Health, 957 A.2d 407, 425-429 (Conn. 2008) (analyzing federal equal protection law to conclude that history of discrimination and ability to contribute to society are the two central considerations, and

collecting authorities). While not all considerations need point toward heightened scrutiny, *Golinski v. Office of Personnel Management*, 824 F. Supp. 2d 968, 983 (N.D. Cal. 2012), here all demonstrate that laws that discriminate based on transgender status should be subjected to heightened review.

"There is no denying that transgender individuals face discrimination, harassment, and violence because of their gender identity." *Whitaker*, 2017 WL 2331751, at *12; *see also Adkins*, 143 F. Supp. 3d at 139-140; Scholars Who Study The Transgender Population Amicus Br. Indeed, "[t]he hostility and discrimination that transgender individuals face in our society today is well-documented," *Brocksmith v. United States*, 99 A.3d 690, 698 n.8 (D.C. 2014)," and "this history of persecution and discrimination is not yet history," *Adkins*, 143 F. Supp. 3d at 139. Today, transgender people face staggering rates of harassment, discrimination, or other mistreatment at school and at work, as well as in access to employment, housing, and healthcare. *See Whitaker*, 2017 WL 2331751, at *12; *Adkins*, 143 F. Supp. 3d at 139-140; Scholars Who Study The Transgender Population Amicus Br.

Transgender people have "immutable [and] distinguishing characteristics that define them as a discrete group, or as the Second Circuit put it ... 'the characteristic of the class calls down discrimination when it is manifest."

Highland, 208 F. Supp. 3d at 874 (quoting Windsor v. United States, 699 F.3d 169,

183 (2d Cir. 2012)); see also Adkins, 143 F. Supp. 3d at 139-140 ("mismatch" between sex assigned at birth and gender identity "calls down discrimination"). A person's transgender status is "inherent in who they are as people," Evancho, 2017 WL 770619, at *13, and "so fundamental" to their identity that they "should not be required to abandon" it, Hernandez-Montiel v. INS, 225 F.3d 1084, 1093 (9th Cir. 2000), overruled on other grounds, Thomas v. Gonzales, 409 F.3d 1177 (9th Cir. 2005). And, as the service of thousands of transgender soldiers in our Nation's defense makes clear, an individual's transgender status has no relation to that person's ability to contribute to society. See Highland, 208 F. Supp. 3d at 874.

Finally, "as a tiny minority of the population, whose members are stigmatized for their gender non-conformity in a variety of settings, transgender people are a politically powerless minority group." *Highland*, 208 F. Supp. 3d at 873-874. Transgender people's lack of "strength to politically protect themselves from wrongful discrimination" is self-evident. *Windsor*, 699 F.3d at 184; *Adkins*, 143 F. Supp. 3d at 140 ("Particularly in comparison to gay people at the time of *Windsor*, transgender people lack the political strength to protect themselves.").

B. The Regulation Cannot Survive Any Level Of Review

Although the Regulation and its implementing directives could not (as discussed below) satisfy even rational-basis review, the fact that they discriminate on the basis of sex and transgender status means they are subject to strict or at least

heightened scrutiny. See Craig v. Boren, 429 U.S. 190, 197 (1976) (sex); Adkins, 143 F. Supp. 3d at 140 (transgender status). Accordingly, they require a compelling or "exceedingly persuasive justification"—and must be narrowly or "substantially related to the achievement of those objectives." Berkley v. United States, 287 F.3d 1076, 1082 n.1 (Fed. Cir. 2002) (quoting United States v. Virginia, 518 U.S. 515, 533 (1996)). The burden to satisfy heightened scrutiny "is demanding and ... rests entirely on the [government]," Virginia, 518 U.S. at 531, and the justifications on which the VA relies "must be genuine, not hypothesized or invented post hoc in response to litigation," id. at 533. Further, as the Supreme Court recently explained, a classification subject to heightened scrutiny "must serve an important governmental interest today, for 'new insights and societal understandings can reveal unjustified inequality ... that once passed unnoticed and unchallenged." Sessions v. Morales-Santana, No. 15-1191, S. Ct. , 2017 WL 2507339, at *2 (June 12, 2017) (quoting Obergefell v. Hodges, 135 S. Ct. 2584, 2603 (2015)).

The required showings are absent here. Neither the proposed nor the final Regulation offered any justification for the exclusion of sex reassignment surgery. *See* 63 Fed. Reg. 37,299 (July 10, 1998) (proposed rule); 64 Fed. Reg. 54,207 (Oct. 6, 1999) (final regulation). Nor did implementing directives. *See* Appx52-70. As discussed, however, the VA has explained that the exclusion was based on the

VA's 1999 view that "such services were not considered medically needed."

Appx307 (draft NPRM). Given the VA's own subsequent rejection of that view, it obviously cannot satisfy strict or even heightened scrutiny.

Nor is the explanation in the VA's denial letter sufficient. Although the cost associated with regulatory action may in some instances be relevant to the "arbitrary and capricious" inquiry, it has no bearing on the constitutional question presented here. The Supreme Court has long made clear that cost cannot justify discrimination; in the Court's words, the government cannot "protect the public fisc by drawing an invidious distinction between classes of its citizens." *Memorial Hospital v. Maricopa County*, 415 U.S. 250, 263 (1974); *see also Graham v. Richardson*, 403 U.S. 365, 374-375 (1971); *Shapiro v. Thompson*, 394 U.S. 618, 633 (1969), *overruled in part on other grounds*, *Edelman v. Jordan*, 415 U.S. 651 (1974).

More broadly, no legitimate governmental objective is served by withholding medically necessary treatment from transgender veterans while providing the same treatment to other veterans. As discussed, the VA has never offered any explanation for that illogical arrangement. *Cf. Norsworthy*, 87 F. Supp. 3d at 1120 (government was unable to identify any "important governmental interest" in policy barring sex reassignment surgery, "much less describe how their gender classification—which makes it more difficult for a transgender person to

receive vaginoplasty than it is for a cisgender woman—[could be] substantially related to that interest"). That failure confirms that "treat[ing a transgender person] differently from a similarly situated non-transgender [person] in need of [the same] medically necessary surgery" violates equal protection. *Id*.

Indeed, the Regulation cannot survive even rational-basis review. As the Supreme Court has explained, "even in the ordinary equal protection case calling for the most deferential of standards, we insist on knowing the relation between the classification adopted and the object to be attained." *Romer v. Evans*, 517 U.S. 620, 632 (1996); *see also Heller v. Doe by Doe*, 509 U.S. 312, 321 (1993) (under rational basis review, the classification must "find some footing in the realities of the subject addressed by the legislation"). This Court's review, in other words, is not "toothless," *Matthews v. Lucas*, 427 U.S. 495, 510 (1976), particularly given that the policy in question targets a vulnerable group, *see Romer*, 517 U.S. at 634-635 (invalidating law that burdened the "politically unpopular group" of lesbian, gay, and bisexual people).

Applying these standards, the Regulation comes up short. The VA recognizes that the original rationale for the exclusion is now untenable, Appx307-308 (draft NPRM), and the agency has offered no rational reason for providing transgender veterans with some, but not all, medically necessary treatment for gender dysphoria, nor explained why the procedures that constitute sex

reassignment surgery ought to be covered for some medical needs but not others. *Cf. Crawford v. Cushman*, 531 F.2d 1114, 1121-1125 (2d Cir. 1976) (Marine Corps regulation requiring the automatic discharge of pregnant soldiers was unconstitutional on equal protection and due process grounds because Corps had no rational basis for treating pregnant soldiers different from other soldiers with a temporary disability). And the budgetary rationale the agency has put forward is indefensible on its own terms (*see supra* pp. 37-40), and illegitimate as a justification for maintaining a plainly discriminatory rule.

Simply put, there is no rational—much less legitimate or compelling—basis for the rule, and the VA's refusal to revisit it through rulemaking must be set aside.

C. The Regulation Violates The Affordable Care Act

For the same reasons just discussed, the Regulation and directives are also "not in accordance with law" because they violate the statutory prohibition on health care discrimination contained in the Affordable Care Act ("ACA"), 42 U.S.C. §18001 *et seq.* Under Section 1557 of the ACA, no individual may be "excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance ... or under any program or activity that is administered by an Executive Agency" on grounds prohibited by various federal antidiscrimination statutes, including Title IX of the Education Amendments of

1972. 42 U.S.C. §18116. Title IX, in turn, prohibits discrimination in certain programs "on the basis of sex." 20 U.S.C. §1681(a). As explained, that prohibition protects transgender people from discrimination. *See supra* pp. 45-46; *see also Rumble*, 2015 WL 1197415, at *7, *10 (transgender status is covered by "sex" under section 1557). And, again for the reasons discussed above, the VA's exclusion constitutes discrimination against transgender veterans. *See supra* pp. 41-42, 52-53; *see also Cruz*, 195 F. Supp. 3d at 581 ("categorical exclusion on treatments of gender dysphoria" violates section 1557). ¹⁰

Where agency action is inconsistent with a statute, it must be set aside as "not in accordance with law." *See, e.g., New York v. Nuclear Regulatory Commission*, 681 F.3d 471, 476, 481-482 (D.C. Cir. 2012) (setting aside agency action under Nuclear Waste Policy Act for failure to comply with National

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This interpretation of Section 1557 accords with HHS's implementing regulations. As noted, HHS clarified there that discrimination against an individual on the basis of transgender status constitutes discrimination on the basis of sex. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 31,387-31,388 (May 18, 2016); *see also* 45 C.F.R. §92.207(b)(3)-(5). Although HHS's rule does not apply to the VA (which is not a "covered entity" under the rule), it implements a statute that does cover the VA, and it reflects the straightforward proposition that the statutory bar on discrimination in health care prohibits the VA's categorical bar on sex reassignment surgery. A district court has enjoined federal agency enforcement of this portion of the HHS rule, *see Franciscan Alliance, Inc. v. Burwell*, No. 7:16-cv-00108, 2016 WL 7638311 (N.D. Tex. Dec. 31, 2016), but the rule has not been rescinded.

Environmental Policy Act). The VA's denial of the rulemaking petition should therefore be set aside as inconsistent with Section 1557.

CONCLUSION

The Court should direct the Department to undertake a rulemaking to amend or repeal the Regulation.

Respectfully submitted,

M. Dru Levasseur Lambda Legal Defense and Education Fund, Inc. 120 Wall Street, 19th Floor New York, NY 10005 (212) 809-8585

TARA L. BORELLI
LAMBDA LEGAL DEFENSE
AND EDUCATION FUND, INC.
730 Peachtree Street NE,
Suite 640
Atlanta, GA 30308-1210
(404) 897-1880

ILONA M. TURNER
SHAWN THOMAS
MEERKAMPER
TRANSGENDER LAW
CENTER
P.O. Box 70976
Oakland, CA 94612
(510) 587-9696

SASHA J. BUCHERT LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 1875 I Street NW Washington, D.C. 20006 (202) 999-8083

Attorneys for Petitioners

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center

7 World Trade Center 250 Greenwich Street New York, NY 10007 (212) 937-7294

PAUL R.Q. WOLFSON
MICHAEL POSADA
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue
Washington, DC 20006
(202) 663-6390

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DEPARTMENT OF VETERANS AFFAIRS Under Secretary for Health Washington DC 20420

November 10, 2016

The Honorable Elizabeth Warren United States Senate Washington, DC 20510

Dear Senator Warren:

This is in response to your September 22, 2016, letter to the Department of Veterans Affairs (VA) asking for an update on the Notice of Proposed Rulemaking (NPRM) regarding the removal of gender alteration restrictions from VA's medical benefits package. I am responding on behalf of the Department.

VA regularly reviews regulations across the full spectrum of medical services to provide the highest quality health care to our Nation's Veterans. Where there is new data, research, or changes to health care policies across Federal agencies that suggest a need for review, VA makes every effort to examine the circumstances and openly discuss actions that could improve Veteran health care. We note that VA has not published a NPRM to remove the exclusion of gender alterations from VA's medical benefits package, but rather announced it was considering issuance of such a NPRM in the Unified Agenda of Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the Federal Government.

VA currently provides many services for transgender Veterans to include hormone therapy, mental health care, preoperative evaluation, and long-term care following sex reassignment surgery. Increased understanding of both gender dysphoria and surgical techniques in this area has improved significantly and is now widely accepted as medically necessary treatment. VA has been and will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding is available. Therefore, this regulation will be withdrawn from the Fall 2016 Unified Agenda. While VA has begun considering factors impacting this rulemaking process, it is not imminent.

Should you have further questions, please have a member of your staff contact Ms. Angela Prudhomme, Congressional Relations Officer, at (202) 461-6471 or by email at Angela.Prudhomme@va.gov.

Thank you for your continued support of our Nation's Veterans.

Sincerely.

David J. Shulkin, M.D.

Did J Shill MD

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of June, 2017 I filed the foregoing Brief for Petitioners with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this brief complies with the type-volume limitation of Circuit Rule 32(a).

- 1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 12,368 words.
- 2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

June 21, 2017

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2017-1460

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DEE FULCHER, GIULIANO SILVA, AND THE TRANSGENDER AMERICAN VETERANS ASSOCIATION, Petitioners,

V.

SECRETARY OF VETERANS AFFAIRS, Respondent.

On Petition for Review Pursuant to 38 U.S.C. § 502

BRIEF FOR RESPONDENT

CHAD A. READLER

Principal Deputy Assistant Attorney General

ROBERT E. KIRSCHMAN, JR.

Director

Of Counsel:

ALLISON KIDD-MILLER DREW CORNACCHIO **Assistant Director**

Staff Attorney

Health Care Law Group ERIC P. BRUSKIN

Department of Veterans Affairs Senior Trial Counsel

810 Vermont Avenue, NW Commercial Litigation Branch

Office of General Counsel Civil Division, Department of Justice Washington, DC 20420

P.O. Box 480, Ben Franklin Station

Washington, DC 20044

Tel: (202) 307-5958 Fax: (202) 353-0461

Attorneys for Respondent November 28, 2017

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STATEMENT OF RELATED CASES

Pursuant to Rule 47.5, respondent's counsel states that he is unaware of any other appeal in or from this action that was previously before this Court or any other appellate court under the same or similar title. Respondent's counsel also states that he is unaware of any case pending in this or any other court that may directly affect or be directly affected by this Court's decision in this case.

2017-1460

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DEE FULCHER, GIULIANO SILVA, AND THE TRANSGENDER AMERICAN VETERANS ASSOCIATION, Petitioners,

V.

SECRETARY OF VETERANS AFFAIRS, Respondent.

BRIEF FOR RESPONDENT

INTRODUCTION

Petitioners invoke this Court's jurisdiction under 38 U.S.C. § 502 to review "the denial" of their petition for rulemaking, Pet. Br. 1, which asked the Department of Veterans Affairs (VA) to amend its regulations to provide gender alteration surgery to veterans enrolled in VA's health care system. But their petition for review suffers from a fatal defect: VA has neither denied their petition for rulemaking nor taken any other final action with respect to such rulemaking. Absent such a denial, this Court lacks jurisdiction over that claim.

Although petitioners concede that VA "never directly responded to the petition," Pet. Br. 1, they nevertheless ask this Court to construe a letter from VA to individual members of Congress as a denial of their rulemaking petition. But that letter, sent to third parties, did not even mention petitioners' request for rulemaking. Moreover, the letter made clear that VA "will continue to explore a regulatory change that would allow VA to perform gender alteration surgery" as part of the medical benefits package to veterans. Appx1-47. That letter, therefore, cannot reasonably be construed as a denial of petitioners' rulemaking request such that this Court has jurisdiction to review that denial.

Petitioners' alternative claim that VA has unreasonably delayed acting on their rulemaking request lacks merit. Regardless of whether this Court analyzes that claim under mandamus or APA standards, petitioners fail to satisfy the high standard necessary to establish that VA unreasonably delayed in acting on their rulemaking petition, particularly given that the rulemaking petition has only been pending for 18 months and VA has taken active steps in considering whether to change the rule excluding gender alterations from the medical benefits package. But even if petitioners could satisfy that standard, they are mistaken as to the appropriate remedy, which would be to order VA to respond to the petition, not to grant the petition.

STATEMENT OF JURISDICTION

Petitioners invoke this Court's jurisdiction under 38 U.S.C. § 502, alleging that VA denied their rulemaking petition on November 10, 2016. Pet. Br. 1; *see also Preminger v. Sec'y of Veterans Affairs*, 632 F.3d 1345, 1352 (Fed. Cir. 2011) (holding that section 502 vests this Court with jurisdiction "to review the Secretary's denial of a request for rulemaking made pursuant to § 553(e)"). But, as explained below, VA has not denied their petition such that this Court has jurisdiction under section 502 to review that purported denial.

STATEMENT OF THE ISSUES

- 1. Whether this Court lacks jurisdiction under 38 U.S.C. § 502 to review a "denial" of rulemaking when VA has not denied the rulemaking petition.
- 2. Even if this Court construes VA's letter to individual members of Congress as final agency action denying the petition for rulemaking, whether the proper remedy is to remand the petition to the agency for an adequate response.
- 3. Whether this Court should reject petitioners' alternative claim that VA has unreasonably delayed acting on petitioners' rulemaking request.

STATEMENT OF THE CASE SETTING OUT RELEVANT FACTS

I. <u>Nature Of The Case</u>

In May 2016, petitioners Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association filed a petition for rulemaking, asking VA to

amend its regulations to provide gender alteration surgery to veterans enrolled in VA's health care system. Although VA has not denied their request, petitioners nevertheless ask this Court to exercise its jurisdiction under 38 U.S.C. § 502 to review "the denial of a petition for rulemaking." Pet. Br. 1. In the alternative, petitioners claim that the agency has unreasonably delayed acting on their rulemaking request.

II. Statement Of Facts And Course Of Proceedings Below

A. <u>VA's Health Care System</u>

Pursuant to 38 U.S.C. § 1710(a), the Secretary "shall furnish hospital care and medical services which the Secretary determines to be needed" to specified categories of veterans, *see id.* § 1710(a)(1) and (a)(2), and "may" furnish such care to all other veterans "to the extent resources and facilities are available," *id.* § 1710(a)(3). Congress gave the Secretary broad discretion to "determin[e]" the "needed" hospital care and medical services that VA will provide to veterans enrolled in the health care system. *Id.* § 1710(a)(1)-(3); *see also E. Paralyzed Veterans Ass'n v. Sec'y of Veterans Affairs*, 257 F.3d 1352, 1362 (Fed. Cir. 2001).

Following passage of the Veterans Health Care Eligibility Reform Act of 1996 (the 1996 Act), VA promulgated a "medical benefits package" in 1999 to clearly establish the parameters of the care and services that VA will provide to

veterans enrolled in its health care system. *See* 38 C.F.R. § 17.38. At the time, VA explained how it intended to determine care and services that are "needed":

The Secretary has authority to provide healthcare as determined to be medically needed. In our view, medically needed constitutes care that is determined by appropriate healthcare professionals to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice.

Enrollment – Provision of Hospital and Outpatient Care to Veterans, 64 Fed. Reg. 54,207, 54,210 (Oct. 6, 1999); see also 38 C.F.R. § 17.38(b) ("Care referred to in the 'medical benefits package' will be provided to individuals only if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice."). As a result, section 17.38(a)(1) lists the "basic care" services and procedures included in the medical benefits package, and subsection (a)(2) lists the "preventative care" services and procedures included in the package. Finally, section 17.38(c) lists six services or

¹ Veterans may also receive certain types of VA care not included in the medical benefits package if authorized by statute or another regulation (*e.g.*, humanitarian emergency care for which the individual will be billed, compensation and pension examinations, dental care, domiciliary care, nursing home care, readjustment counseling, care as part of a VA-approved research project, seeing-eye or guide dogs, sexual trauma counseling and treatment, and special registry examinations). Appx305-315.

procedures that are excluded from the medical benefits package, including "[g]ender alterations." 38 C.F.R. § 17.38(c)(4).

Although Congress gave the Secretary broad discretion to determine the care and services included in the medical benefits package, VA's provision of health care is nevertheless subject to certain Congressionally-imposed limitations. First, the 1996 Act clarified that the Secretary may provide health care to enrollees only to the extent and in the amount appropriated in advance for such programs. 38 U.S.C. § 1710(a)(4); *see* H.R. REP. No. 104-690, at 6 (1996) ("Finally, the Act would explicitly recognize that the extent of the Secretary's obligations under law are limited by the funds made available in advance by appropriations acts.").

The 1996 Act also directs the Secretary to establish and operate a "system of annual patient enrollment" that enrolls veterans according to eight Congressionally-established priority groups. 38 U.S.C. § 1705(a); *see* H.R. REP. No. 104-690, at 12 (1996). Further, the 1996 Act directs the Secretary to manage the enrollment of veterans in accordance with priorities, and in the order, specified in the law. For example, the first priority for enrollment are "[v]eterans with service-connected disabilities rated 50 percent or greater and veterans who were awarded the medal of honor[.]" 38 U.S.C. § 1705(a)(1). Congress also required the Secretary to establish an enrollment system that "ensure[s] that the provision of care to enrollees is timely and acceptable in quality." 38 U.S.C. § 1705(b)(1). The

legislative history of the 1996 Act makes clear Congress's intent was not only to ensure that all enrollees receive timely, quality health care, but also to tether VA's provision of health care to the availability of appropriations and to limit the enrollment pool:

Section 4 would first add a new section 1705 applicable to managing delivery of care under new section 1710(a)(1) to: (1) require the VA to administer care-delivery through an annual patient enrollment, with a veteran's ability to enroll to be governed by the availability of appropriations and by reference to a system of listed priorities; (2) require that the size of the enrollment pool be governed by the requirement that provision of care to enrollees be timely and acceptable in quality; (3) require that the VA promote cost-effective delivery of care in the most clinically appropriate setting; and (4) require the VA to maintain its capacity to provide for the specialized treatment needs of disabled veterans.

H.R. REP. No. 104-690, at 12 (1996).

In addition, 38 U.S.C. § 1706(a) directs VA to "design, establish and manage health care programs in such a manner as to promote cost-effective delivery of health care services in the most clinically appropriate setting." In doing so, the Secretary is required to "ensure that the Department . . . maintains its capacity to provide for the specialized treatment and rehabilitative needs of disabled veterans . . . within distinct programs or facilities of the Department[.]" 38 U.S.C. § 1706(b).

VA currently provides health care to approximately 8.9 million veterans at more than 1,200 VA Medical Centers and Veterans Health Administration (VHA) outpatient clinics.²

B. Petitioners' Rulemaking Request And VA's Preliminary Actions

On May 9, 2016, petitioners filed a petition for rulemaking to request that VA remove the regulatory exclusion for gender alterations in section 17.38(c)(4) and promulgate a new regulation "expressly including medically necessary sex reassignment surgery for transgender veterans in [the] medical benefits package." Appx71-298.

In the Spring 2016 version of the Semiannual Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda), VA announced that it was considering issuing a notice of proposed rulemaking (NPRM) to remove the exclusion of gender alterations from the medical benefits package.³ VA drafted an

² See https://www.va.gov/health/findcare.asp (last visited November 27, 2017).

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201604&RIN=2900 -AP69 (last visited November 27, 2017). The Unified Agenda is a non-binding, informational document that "communicates agency actions under development or review during the 12 months following publication." Office of Information and Regulatory Affairs, Memorandum: Spring 2017 Call for the Unified Agenda of Federal Regulatory and Deregulatory Actions (2017), *available at* https://www.whitehouse.gov/the-press-office/2017/03/06/memorandum-spring-2017-data-call-unified-agenda-federal-regulatory-and (last visited November 27, 2017).

NPRM, Appx305-315, but did not publish the draft NPRM in the Federal Register or otherwise make it publicly available.

In June 2016, VA initiated an economic impact analysis to consider the impact of the draft proposed rule. Appx321-329. The directors of VA's Lesbian, Gay, Bisexual and Transgender (LGBT) Health Program determined that "[t]he costs estimated during the budget pilot from the publication of the rule through the first 3 years to be just over \$17.9 million." Appx329.

On June 22, 2016, VA received a letter signed by 30 members of the United States House of Representatives and Senate expressing disapproval of VA's consideration of a proposed rule. Appx316-319. Among other issues, the letter expressed concern that VA has struggled within its budgetary constraints to provide the care already included in the medical benefits package. *Id.* The letter requested that VA cease consideration of the rulemaking. *Id.*

On September 12, 2016, VA received two letters from members of the United States Senate urging VA to publish a proposed rule and to provide gender alteration surgery to veterans through its medical benefits package. Appx331-336.

On November 10, 2016, then-Under Secretary for the VHA, David Shulkin, responded to individual members of Congress by sending a separate letter to each member. *E.g.*, Appx1. At the beginning of each letter, Dr. Shulkin told each recipient that he was writing "in response to your . . . letter" "asking for an update

on the Notice of Proposed Rulemaking (NPRM)." *E.g., id.* Dr. Shulkin clarified that "VA has not published a NPRM to remove the exclusion of gender alterations from VA's medical benefits package, but rather announced it was considering issuance of such a NPRM in the Unified Agenda of Federal Regulatory and Deregulatory Actions." *Id.* Dr. Shulkin explained:

VA has been and will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding is available. Therefore, this regulation will be withdrawn from the Fall 2016 Unified Agenda. While VA has begun considering factors impacting this rulemaking process, it is not imminent.

Id.

On January 6, 2017, petitioners filed a petition for review. Appx300-304.

SUMMARY OF THE ARGUMENT

This Court lacks jurisdiction over the petition for review insofar as it seeks review of a denial of petitioners' rulemaking request because VA has not denied the rulemaking petition. Although VA has taken concrete steps in consideration of a possible rulemaking, it has neither completed its formal decision-making process nor provided petitioners with a response, as the APA requires before an agency will be deemed to have made a final, judicially-reviewable decision. *See* Pet. Br. 1 (acknowledging that VA has "never directly responded to the petition"). Without final agency action denying the petition, this Court lacks jurisdiction under 38

U.S.C. § 502. At such time as the agency issues a final decision on the petition, this Court may review that decision with the benefit of a reasoned explanation from the agency and a complete administrative record.

If this Court, however, nevertheless determines that it has jurisdiction—despite the absence of any "direct[] respon[se] to the petition" for rulemaking, Pet. Br. 1—then remand would be required to allow VA to provide a reasoned, formal response to the petition. VA's November 2016 letter to individual members of Congress to "update" them on the draft NPRM did not mention, much less deny, petitioners' specific request for rulemaking. Because the letter was never intended to be a final decision responding to petitioners' request, any explanation contained therein would not provide a reasoned basis to support a denial of petitioners' rulemaking petition. At a minimum, Supreme Court precedent would require a remand so that VA may provide a reasoned explanation.

This Court should reject petitioners' alternative claim that VA unreasonably delayed acting on their rulemaking request, which was filed only 18 months ago. Petitioners have failed to establish that VA's 18-month delay is so egregious as to warrant an order compelling VA to act on their petition. Even assuming that petitioners could demonstrate such a right to relief, the proper remedy would be limited to an order directing the Secretary to respond to the rulemaking request, not to grant it.

<u>ARGUMENT</u>

I. <u>Standard And Scope Of Review</u>

This Court has exclusive jurisdiction to review "[a]n action of the Secretary to which section 552(a)(1) or 553 of title 5 . . . refers." 38 U.S.C. § 502. This Court thus has jurisdiction to review certain rulemaking actions, such as the promulgation or amendment of a rule, *Disabled Am. Veterans v. Gober*, 234 F.3d 682, 688 (Fed. Cir. 2000), as well as to "review the Secretary's denial of a request for rulemaking made pursuant to [5 U.S.C.] § 553(e)." *Preminger*, 632 F.3d at 1351-52; *see also* 5 U.S.C. § 553(e) (providing for "the right to petition for the issuance, amendment, or repeal of a rule").

This Court reviews petitions under section 502 in accordance with the standards set forth in the APA. 38 U.S.C. § 502 ("Such review shall be in accordance with chapter 7 of title 5"); *Nyeholt v. Sec'y of Veterans Affairs*, 298 F.3d 1350, 1355 (Fed. Cir. 2002). This standard permits this Court to review whether the Secretary's decisions are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Preminger*, 632 F.3d at 1353. Although "[r]eview under the 'arbitrary and capricious' tag line . . . encompasses a range of levels of deference to the agency[,]" "an agency's refusal to institute rulemaking proceedings is at the high end of the range." *Am. Horse Protection Ass'n v. Lyng*, 812 F.2d 1, 4 (D.C. Cir. 1987) (citations omitted). Under

section 502 and in accordance with the APA, this Court may review only final agency action. 38 U.S.C. § 502; 5 U.S.C. § 704; *see also Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (discussing standard for final agency action).

II. This Court Lacks Jurisdiction To Review A "Denial" Of A Rulemaking Petition Where The Petition Has Not Been Denied

This Court has exclusive jurisdiction to review "[a]n action of the Secretary to which section 552(a)(1) or 553 of title 5 . . . refers." 38 U.S.C. § 502. In *Preminger*, this Court held that its jurisdiction under section 502 extends to review of "the Secretary's denial of a request for rulemaking made pursuant to [5 U.S.C.] § 553(e)." 632 F.3d at 1352. As this Court explained, 5 U.S.C. § 553(e) "refers" to a petition for rulemaking. *Id.* at 1351 (quoting 38 U.S.C. § 502). This Court held that it has jurisdiction not only in "a case in which the petitioner is somehow denied 'the right to petition,'" *id.* at 1351 (quoting 5 U.S.C. § 553(e)), but also in a case that seeks review of "the Secretary's denial" of the petition itself, *id.* at 1352.

Because VA has *not* denied petitioners' rulemaking request, or taken any other final agency action with respect to that request, however, this Court lacks jurisdiction under 38 U.S.C. § 502 (and this Court's decision in *Preminger*) to review the agency's purported denial of rulemaking. Indeed, nothing in the record remotely resembles a denial of petitioners' request for rulemaking.⁴

⁴ The regulatory exclusion in 38 C.F.R. § 17.38(c)(4) became effective over 18 years ago, and therefore the time for seeking direct review of the regulation has

Ordinarily, when an agency denies a petition for rulemaking, the APA requires the agency to give "[p]rompt notice" of the denial and a brief statement of the grounds for the denial. 5 U.S.C. § 555(e) ("Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding . . . the notice shall be accompanied by a brief statement of the grounds for the denial."); see Nat. Resources Def. Council, Inc. v. SEC, 389 F. Supp. 689, 702 (D.D.C. 1974). Moreover, the APA contemplates that the notice will be provided directly to the petitioning party. Families for Freedom v. Napolitano, 628 F. Supp. 2d 535, 540 (S.D.N.Y. 2009) ("At a minimum, the right to petition for rulemaking entitles a petitioning party to a response to the merits of the petition.") (quoting Richard J. Pierce, Jr., ADMINISTRATIVE LAW TREATISE § 6.10 (4th ed. 2002)); cf. WWHT, Inc. v. FCC, 656 F.2d 807, 814 (D.C. Cir. 1981) (FCC regulations provide that a "petition for rule making will be denied and the petitioner will be notified of the Commission's action with the grounds therefor.").

VA has taken no action that satisfies these requirements. Petitioners concede, in fact, that VA has "never directly responded to the petition." Pet. Br. 1.

long passed. See Fed. Cir. R. 47.12(a) (actions for judicial review under 38 U.S.C. § 502 of a VA rule or regulation "must be filed with the clerk of court within 60 days after issuance[.]"); 64 Fed. Reg. at 54,207 (effective Nov. 5, 1999).

This Court therefore lacks jurisdiction over petitioners' challenge to the alleged denial of rulemaking.

Petitioners counter that the absence of a formal denial is "immaterial," Pet. Br. 23, but this argument is predicated on the supposition that VA's decisionmaking process is nonetheless complete. Nothing in the record supports this conclusion.⁵ Moreover, adopting petitioners' characterization of the APA's response requirement as a mere formality would effectively eviscerate the protections Supreme Court precedent affords agencies in completing their administrative processes by inviting premature judicial intervention. See Ohio Forestry Ass'n, Inc. v. Sierra Club, 523 U.S. 726, 733 (1998) (premature judicial intervention "inappropriately interfere[s] with further administrative action" by hindering an agency's efforts to complete the decision-making process); FTC v. Standard Oil Co. of Cal., 449 U.S. 232, 242 (1980) ("Judicial intervention into the agency process denies the agency an opportunity to correct its own mistakes and to apply its expertise . . . [and] also leads to piecemeal review which at the least is inefficient and upon completion of the agency process might prove to have been unnecessary." (citations omitted)). Indeed, petitioners provide no reason for the

⁵ To the extent petitioners allege, in the alternative, that the agency failed to act on their petition for rulemaking (*i.e.*, that the agency unreasonably delayed), that claim lacks merit for the reasons discussed *infra* pp. 36-42.

Court to casually disregard the APA's requirement of a final denial communicated to petitioners as a predicate for judicial review.

Petitioners ask this Court to construe VA's November 2016 letter to update individual members of Congress on the draft NPRM as a "denial of [their] petition for rulemaking." Pet. Br. 1; *Preminger*, 632 F.3d at 1352. But that letter is not addressed to petitioners and does not even mention their specific rulemaking petition, the purported denial of which is the alleged basis for this Court's jurisdiction. *See* 38 U.S.C. § 502 (granting exclusive jurisdiction to this Court to review "[a]n action of the Secretary to which section 552(a)(1) or 553 of title 5 . . . refers"); 5 U.S.C. § 553(e) (right to petition for rulemaking). The letter was sent "in response to [the various] letter[s]" from individual members of Congress, not in response to the rulemaking petition. Appx1.

Even if the letter had referred to the specific rulemaking petition at issue, it could not possibly be considered final agency action denying the petition. As petitioners acknowledge (Pet. Br. 22), "two conditions must be satisfied for agency action to be 'final'" and therefore subject to judicial review. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). "First, the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature." *Id.* (citations omitted). Second, "the action must be one by which 'rights or obligations have been determined,' or from which 'legal

consequences will flow[.]" *Id.* (quoting *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)). Neither *Bennett* condition is satisfied by the letter.

First, the plain language of VA's letter disclosed that VA's consideration of a regulatory change to permit VA to provide gender alteration surgery remained ongoing. Appx1 ("VA has been and will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding is available."); *id.* (noting that "VA has begun considering factors impacting this rulemaking process"). VA was not merely leaving open the possibility of future regulatory action as petitioners contend, Pet. Br. 23-24, but was informing individual members of Congress that its consideration of the issue remained ongoing ("VA . . . will continue to explore a regulatory change"), even if a proposed rule was not "imminent." Appx1.

At most, VA's letter described preliminary, non-final actions taken in consideration of rulemaking regarding gender alteration surgery. That VA initially listed the draft NPRM on the spring Unified Agenda, and then withdrew it in the fall, underscores that the agency was actively considering whether to even publish a draft NPRM on this issue. Such preliminary agency action, taken to explore possible rulemaking, is not final agency action that can operate as a denial of a

petition for rulemaking. See Indep. Equip. Dealers Ass'n v. EPA, 372 F.3d 420, 427 (D.C. Cir. 2004) ("we have long recognized that the term [agency action] is not so all-encompassing as to authorize us to exercise 'judicial review [over] everything done by an administrative agency." (quoting *Hearst Radio, Inc. v.* FCC, 167 F.2d 225, 227 (D.C. Cir. 1948)); see, e.g., Standard Oil, 449 U.S. at 241 (agency's filing of complaint, which included the agency's statement that it had "reason to believe" there was a violation of section 5 of the Federal Trade Commission Act, was not final agency action reviewable under the APA because it was "not a definitive statement of position" but instead "represents a threshold determination[.]"); Clark v. Busey, 959 F.2d 808, 812-13 (9th Cir. 1992) (the agency's publication of a summary of the rulemaking petition in the Federal Register was a "preliminary" action that "did not amount to a denial of [petitioner's] rulemaking petition."). Indeed, petitioners concede that any "denial" must be final agency action to be reviewable. Pet. Br. 22; see also 38 U.S.C. § 502; 5 U.S.C. § 704. A holding to the contrary would discourage agencies from engaging in such preliminary, exploratory activities, rendering the rulemaking process inflexible and less transparent. In light of these standards, VA's November 2016 letter does not reflect anything more than preliminary action that is "tentative or interlocutory in nature," and therefore is not final under *Bennett*, 520 U.S. at 178.

Second, VA's November 2016 letter did not constitute an action from which "rights or obligations have been determined" or from which "legal consequences will flow." Bennett, 520 U.S. at 177-78. Section 17.38(c)(4), promulgated in 1999, remains in effect until replaced or amended through a new rulemaking. By its own terms, the November 2016 letter merely advised members of Congress that VA was withdrawing the draft NPRM from the Unified Agenda, but that consideration of a regulatory change remained ongoing. Appx1. The letter did not announce the outcome of the agency's decision-making process on the petition, alter the applicable legal regime, or result in any legal consequences. See Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 15 (D.C. Cir. 2005) ("if the practical effect of the agency action is not a certain change in the legal obligations of a party, the action is non-final for the purpose of judicial review."); *Indep.* Equip. Dealers Ass'n, 372 F.3d at 428 (agency letter did not satisfy the second part of the *Bennett* test because "[i]t left the world just as it found it[.]").

Other courts have declined to review similarly non-final agency correspondence. In *Families for Freedom v. Napolitano*, the Department of Homeland Security informed a third party (the American Bar Association) by letter that it supported the plaintiffs' petition for rulemaking. 628 F. Supp. 2d 535, 538 (S.D.N.Y. 2009). The agency subsequently sent a letter to petitioners that neither granted nor denied the petition. *Id.* The district court held that the agency's letters

did not constitute final agency action under the APA because "DHS has not yet responded to plaintiffs' petition within the meaning of the APA[.]" *Id.* at 538, 541; *see also La. State v. U.S. Army Corps of Eng'rs*, 834 F.3d 574, 584 (5th Cir. 2016) (agency's report to Congress was "tentative and interlocutory . . . as it necessarily contemplates future agency action."). Likewise here, because VA has only sent a letter to third parties referencing the same issues raised in the petition (but not even the petition itself), VA cannot reasonably be found to have finally decided the petition.

The cases upon which petitioners rely are inapposite or distinguishable. In National Parks Conservation Association v. United States Department of Interior, the Department of the Interior and Environmental Protection Agency sent letters to the petitioners stating that the agencies were "fully and finally respond[ing] to all of the referenced petitions." 794 F. Supp. 2d 39, 45 (D.D.C. 2011). Plaintiffs argued that the agency letters, which denied their petition, were non-final because they did not "foreclose taking the course of action proposed by Plaintiffs in the future." Id. The court disagreed because (1) the agencies "made clear that they [we]re denying Plaintiffs' petitions at this time," and (2) leaving open the possibility of future action does not necessarily render an otherwise definitive denial non-final. Id. at 46. In contrast, VA did not send the letter to petitioners or reach a "definitive decision" to deny the petition "at this time." Pet. Br. 25. The

letter to members of Congress explained that VA's consideration of the regulatory change remained ongoing. Appx1.

Petitioners also rely upon WildEarth Guardians v. Salazar, 741 F. Supp. 2d 89 (D.D.C. 2010), but it is similarly unhelpful. In WildEarth, the Fish and Wildlife Service sent a formal response to plaintiff denying a request to repeal a prior rule, clearly indicating "that [Fish and Wildlife Service] was not repealing the 1991 Rule and that it was [Fish and Wildlife Services'] 'final decision' on the APA Petition." Id. at 104. Plaintiff argued that the response was not a procedurally adequate denial because it did not use the word "denial" or a variation thereof. Id. The court rejected this overly formal approach to the APA, but did not dispense with the APA's formal response requirement, as petitioners suggest. Pet. Br. 23; WildEarth, 741 F. Supp. 2d at 104 (noting that plaintiff "understood the response to be a denial" and "does not claim that [Fish and Wildlife Service] did not provide a brief statement of the grounds for denial as required under 5 U.S.C. § 555(e)."). Unlike the plaintiff in WildEarth, VA does not contend that its November 2016 letter is non-final because of an overly formal reading of the APA. Instead, the APA requires VA to provide a response to petitioners that explains the basis for the agency's final decision, which it has not yet reached. 5 U.S.C. § 555(e).

Petitioners note that courts routinely review agency correspondence under the APA. Pet. Br. 25. But agency correspondence like VA's November 2016

letter—which was sent to third parties, rather than petitioners, which did not even refer to the petition at issue, and which indicated that VA's consideration of the issue remained ongoing—is not the same type of correspondence that courts have found reviewable under the APA. Families for Freedom, 628 F. Supp. 2d at 538, 541. Petitioners concede that in the cases they cite, "the correspondence was directed to the petitioning party or expressly referred to the petition (or both)," but contend that these distinctions are "not meaningful" because the November 2016 letter was sent from a high-ranking VA official and "reflect[s] an authoritative statement of the VA's position." Pet. Br. 26. Petitioners provide no support for this argument, however, which would sidestep the requirements of the APA and open up countless correspondence from agencies, especially those sent to Congress, to premature judicial review. Thus, petitioners provide no reasoned basis for this Court to overlook the meaningful differences between VA's letter to individual members of Congress and the correspondence deemed ripe for review in Am. Horse Protection Ass'n, 812 F.2d at 3, and Henley v. FDA, 873 F. Supp. 776, 780, 782-83 (E.D.N.Y. 1995), cited by petitioners. Pet. Br. 25-26.

Finally, petitioners argue that the finality of VA's action is demonstrated by VA's subsequent "reissue" of VHA Directive 2013-003, which they contend "reiterate[d] the categorical exclusion of sex reassignment surgery from the medical benefits package and declar[ed], again, that this would be the agency's

policy at least through February 28, 2018." Pet. Br. 25. The record demonstrates that VA did not reissue the directive, however, but simply "revised" it on January 19, 2017 to add the contact information for the VA's LGBT Health Program, which had not been included when VA first issued the directive on February 8, 2013. Appx58. There are no other changes in the revised directive. VA's effort to ensure that veterans have contact information for VA's LGBT Health Program does not lend support to the notion that VA has taken any final action on petitioners' rulemaking request. Indeed, to the extent the revised directive is relevant, VA's decision to leave the directive's original February 28, 2018 expiration date in place, as opposed to extending it, is further evidence that VA's decision-making process is not yet complete.

III. If This Court Nevertheless Concludes That It Has Jurisdiction, It Must Remand To VA To Provide A Reasoned Explanation In Response To The Rulemaking Request

As explained above, the record demonstrates that VA has not taken any final agency action to deny petitioners' rulemaking request. However, if this Court disagrees and concludes that VA's November 2016 letter constitutes a denial of the petition for rulemaking such that it has jurisdiction under 38 U.S.C. § 502, then remand would be the only proper course. Because VA's letter did not respond to, or even reference, petitioners' rulemaking request, that letter would not provide a sufficiently reasoned explanation to support "denial" of petitioners' rulemaking

request. Thus, remand would be required to allow VA to adequately respond to petitioners' rulemaking request.

A. This Court's "highly deferential," "narrow" review of a denial of a petition for rulemaking is "limited to ensuring that the agency has adequately explained the facts and policy concerns it relied on" and that "those facts have some basis in the record." *Preminger*, 632 F.3d at 1353 (alterations and quotation marks omitted). This Court "examine[s] the petition for rulemaking, comments pro and con[,] and the agency's explanation of its decision to reject the petition." *Serv. Women's Action Network v. Sec'y of Veterans Affairs*, 815 F.3d 1369, 1374-75 (Fed. Cir. 2016). "In other words, a court looks to see whether the agency employed reasoned decisionmaking in rejecting the petition." *Preminger*, 632 F.3d at 1354.

Even under this Court's narrow review, the November 2016 letter to individual members of Congress fails to adequately explain any denial of petitioners' rulemaking request. The letter did not mention the petition for rulemaking, nor did it provide "reasoned decisionmaking [for] rejecting the petition." *Preminger*, 632 F.3d at 1354; *see also Am. Horse Protection Ass'n*, 812 F.2d at 4 ("[T]wo conclusory sentences . . . are insufficient to assure a reviewing court that the agency's refusal to act was the product of reasoned decisionmaking."). Therefore, even if this Court were to construe the letter as a

denial of the rulemaking petition, there is no reasoned explanation for this Court to review. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("[A] reviewing court . . . must judge the propriety of [agency] action solely by the grounds invoked by the agency.").

B. Remand is the proper remedy when an agency fails to provide a reasoned explanation for its decision. See, e.g., Am. Horse Protection Ass'n, 812 F.2d at 7 ("This remedy is particularly appropriate when the agency has failed to provide an adequate explanation of its denial [of a rulemaking petition]."); see also Deloach v. Shinseki, 704 F.3d 1370, 1380-81 (Fed. Cir. 2013) (noting that when the Board of Veterans' Appeals "fail[s] to provide adequate reasons and bases" for its decision as required by statute, remand is the proper remedy). "Without an adequate statement, it is impossible to understand the precise basis for the [agency's] decision and conduct informed appellate review." Deloach, 704 F.3d at 1381. Therefore, courts have held that when an agency fails to adequately explain or support the denial of a rulemaking petition, the reviewing court should remand to the agency "to adequately address the petition." Flyers Rights Educ. Fund, Inc. v. FAA, 864 F.3d 738, 747 (D.C. Cir. 2017) (remanding to agency where record was insufficient to support decision); see also, e.g., Am. Horse Protection Ass'n, 812 F.2d at 4, 7 (holding that agency failed to provide reasoned explanation for denial

of rulemaking petition and remanding to give the Secretary "a reasonable opportunity to explain his decision or to institute a new rulemaking").

Remand in these circumstances would be a straightforward application of the "ordinary remand rule," which the Supreme Court has repeatedly applied. See, e.g., Gonzales v. Thomas, 547 U.S. 183, 186 (2006) (per curiam) (summarily reversing Ninth Circuit for failure to follow "ordinary remand rule"); INS v. Ventura, 537 U.S. 12, 18 (2002) (per curiam) (same). The ordinary remand rule provides that when an agency "has not yet considered" a particular issue within its discretion, "the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation." Thomas, 547 U.S. at 186 (quoting Ventura, 537 U.S. at 16); see also Negusie v. Holder, 555 U.S. 511, 524 (2009) (remanding to agency for "initial determination" of statutory-interpretation question); Byron v. Shinseki, 670 F.3d 1202, 1205 (Fed. Cir. 2012) (explaining that remand is "the proper course" "when an agency has not made an initial determination") (quoting *Thomas*, 547 U.S. at 186). The Supreme Court has made clear that the ordinary remand rule also applies when an agency has made a determination that cannot survive APA review. See, e.g., Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 547-58 (2007) ("[W]e note that if the EPA's action was arbitrary and capricious, as the Ninth Circuit held, the proper course would have been to remand to the Agency for clarification of its reasons.")

(citing *Thomas*, 547 U.S. at 186); *Camp v. Pitts*, 411 U.S. 138, 143 (1973) (concluding that if agency decision is not sustainable on the basis of the administrative record, then the matter should be "remanded to [the agency] for further consideration.").

In the context of petitioners' specific rulemaking request, it is particularly important for VA to adequately address the request in the first instance, given the "broad discretion" of the Secretary "to determine the precise hospital or medical services to be supplied." *E. Paralyzed Veterans Ass'n*, 257 F.3d at 1362. Remand would permit the Secretary to decide whether and how to exercise his discretion with respect to gender alteration surgery, and to explain his decision to petitioners. *See Ventura*, 537 U.S. at 16.

C. This case does not present the "rare circumstances" that would justify an exception to the ordinary remand rule. *Ventura*, 537 U.S. at 16. In *SKF USA Inc. v. United States*, 254 F.3d 1022 (Fed. Cir. 2001) (*SKF*), this Court explained that a court may have discretion not to remand "if the agency's request is frivolous or in bad faith," but further clarified that "if the agency's concern is substantial and legitimate, a remand is usually appropriate." *Id.* at 1029.⁶ VA's remand request,

⁶ In *SKF*, this Court discussed the bad-faith exception in the context of particular situations where an agency requests a remand, such as when the agency wishes "to reconsider its previous position" or "believes that its original decision is incorrect on the merits and wishes to change the result." 254 F.3d at 1029. This Court acknowledged that "there may be remand situations that do not fall neatly

which is presented only as an alternative to dismissal for lack of jurisdiction, reflects its good-faith effort to adequately address the rulemaking petition and to provide a reasoned explanation that would facilitate this Court's review.

Moreover, petitioners cannot possibly dispute that there are substantial and legitimate concerns that would justify remand to VA, particularly given their extensive arguments that VA's purported denial is "unreasoned," "insufficient," and "unsupported by the record." Pet. Br. 31-39.

Petitioners suggest that this Court "should simply direct the VA to initiate rulemaking." Pet. Br. 29. As petitioners acknowledge, however, "such a remedy is appropriate only 'in the rarest and most compelling of circumstances." *Flyers Rights Educ. Fund*, 864 F.3d at 747 (quoting *Am. Horse Protection Ass'n*, 812 F.2d at 7); *see also WWHT*, 656 F.2d at 818. In support of this extreme remedy, petitioners first argue that remand would be futile because "the VA has unambiguously decided—as announced in public correspondence to Congress—not to initiate a rulemaking." Pet. Br. 29. As an initial matter, petitioners misread

into" the categories it described, and this case is one such situation. *Id.* Here, the Government argues that the petition should be dismissed for lack of jurisdiction, and seeks a remand in the alternative to adequately address petitioners' rulemaking request *in the first instance*, making this case more analogous to *Thomas* and *Ventura*, in which the Supreme Court held that the failure to remand constituted reversible error. Moreover, as discussed above, remand is the only proper remedy when an agency fails to adequately explain its decision. *See, e.g., Flyers Rights Educ. Fund*, 864 F.3d at 747; *Am. Horse Protection Ass'n*, 812 F.2d at 4, 7; *Deloach*, 704 F.3d at 1380-81.

VA's November 2016 letter, which states that consideration of these issues is ongoing. *See supra* pp. 9-10. In any event, this argument fails to appreciate the purpose of a remand, which is to allow the agency to provide a reasoned explanation of its decision in order to facilitate judicial review. *See Ventura*, 537 U.S. at 17.

Petitioners next argue that the court should order VA to initiate rulemaking because "a significant factual predicate of a prior decision on the subject . . . has been removed." Pet. Br. 30 (quoting Public Citizen v. Heckler, 653 F. Supp. 1229, 1241 (D.D.C. 1986)). This exception is reserved for "extremely rare circumstances," and petitioners cite only one district-court decision in which it has been applied. Public Citizen, 654 F. Supp. at 1241. The D.C. Circuit has made clear that this already-rare exception will seldom apply when "the agency has failed to provide an adequate explanation of its denial." Am. Horse Protection Ass'n, 812 F.2d at 7. If the decision involves issues that "lie within the institutional competence of the Secretary," the D.C. Circuit explained, an agency "must be given a reasonable opportunity to explain [its] decision or to institute a new rulemaking proceeding," even if a "significant factual predicate" has been removed. Id. (emphasis added). Where, as here, the Secretary has "broad discretion" "to determine the precise hospital or medical services to be supplied," E. Paralyzed Veterans Ass'n, 257 F.3d at 1362, the issues raised by the rulemaking

petition are clearly "within the institutional competence of the Secretary," who must be given an opportunity to adequately consider the issue in the first instance, *Am. Horse Protection Ass'n*, 812 F.2d at 7.

Moreover, this case is nothing like *Public Citizen*. In that case, the district court held that "extremely rare circumstances" warranted an order directing the Department of Health and Human Services to promulgate a rule banning the interstate sales of certified raw milk. Public Citizen, 653 F. Supp. at 1241. The record showed that the agency's original decision not to ban the sale of certified raw milk was based on the need for further study regarding the product's safety. *Id.* at 1232, 1241. The agency pledged that if the product were found to be unsafe, "appropriate action [would] be taken." Id. at 1232. The administrative record detailed evidence the agency collected over 13 years, including hearings on the product's safety, which ultimately led the Secretary to concede that the product was unsafe. *Id.* at 1241. The district court held that in light of the undisputed facts in the record, the agency's denial of a rulemaking petition to ban the sale of certified raw milk was arbitrary and capricious. Id. Based on this comprehensive administrative record, the court then concluded that "[i]t [was] unlikely that the issues involved or the proposed rule could become any more focused," and that a remand "would serve no purpose." Id. at 1240-41.

Here, by contrast, the circumstances are not so rare or compelling. Petitioners focus on the question of medical necessity, but the record on that issue is sparse, and pales in comparison to *Public Citizen*'s 13-year administrative record. The record here contains only: (1) a statement from VA in a draft NPRM concerning the reason for the initial promulgation of section 17.38(c)(4), which VA cautioned had "not [been] specifically explained in the preambles to the original proposed and final rules[,]" Appx307; and (2) interlocutory statements concerning VA's evolving view on the medical consensus regarding gender alteration surgery. See, e.g., Appx1, Appx308. Thus, VA's statements do not establish to the degree found in *Public Citizen* that "a significant factual predicate" for the promulgation of section 17.38(c)(4) "has been removed." Pet. Br. 30 (citing WWHT, 656 F.2d at 818). In any event, there is no basis to assume that this factual question is the sole factor in determining how VA will exercise its "broad discretion" "to determine the precise hospital or medical services to be supplied." E. Paralyzed Veterans Ass'n, 257 F.3d at 1362. If this Court determines it has jurisdiction, remand would be the only proper remedy.

D. Because remand would be the proper course, it would be entirely improper for this Court to prematurely address the constitutional questions raised in petitioners' brief. Pet. Br. 40-55. As the D.C. Circuit has explained, when an agency fails to provide a reasoned explanation for denying a petitioner's request, it

is "inappropriate for [a] court to consider the constitutionality of [its] denial[] without affording the agency an opportunity to more fully address [the] request[]." Amerijet Int'l, Inc. v. Pistole, 753 F.3d 1343, 1353 (D.C. Cir. 2014). In Amerijet, the D.C. Circuit held that "the usual remedy of a remand" was "the proper course" because the Transportation Security Administration (TSA) failed to adequately explain its denial of petitioner's requests for alternate security procedures. *Id.* (quotation marks omitted). The D.C. Circuit further concluded that, given the absence of a "meaningful basis upon which to evaluate TSA's denials," it would be "inappropriate" to consider petitioner's equal-protection claim, which was "premised on" those denials. *Id.* The court explained that "[t]here is no way to weigh the viability of [petitioner's] equal protection claim without a clear understanding of the agency's position with respect to the disputed denials." *Id.* Moreover, the court continued, "with our remand of this case, the possibility remains that TSA may reconsider its prior denials or offer adequate explanations for the agency's actions, either of which may moot [petitioner's] equal protection claim." Id. Therefore, the court concluded, the equal-protection claim was "unripe for review." Id.

In this case, it would be particularly "inappropriate for this court to consider the constitutionality" of a denial that *was never made* and therefore was not adequately explained. *Amerijet*, 753 F.3d at 1353. Even if this Court construed

VA's letter to individual members of Congress as a denial of petitioners' rulemaking request, the absence of a reasoned explanation would foreclose review: "There is no way to weigh the viability of [petitioner's] equal protection claim without a clear understanding of the agency's position." *Id.*; *see also El-Ganayni v. U.S. Dep't of Energy*, 591 F.3d 176, 186 (3d Cir. 2010) (equal protection claim under the Fifth Amendment "would inevitably involve scrutiny of the merits of the [agency's] decision."). Here, as in *Amerijet*, there is simply no "meaningful basis" for review of petitioners' equal-protection claim. 753 F.3d at 1353. Indeed, petitioners' opening brief underscores the difficulty of assessing their claims on the current record. *See* Pet. Br. 50-51. The claim is not fit for review. *Amerijet*, 753 F.3d at 1353.

Remand would be especially required in the present situation, where VA has not "directly responded to the petition" for rulemaking, Pet. Br. 1, and argues that it has not issued a denial at all. In *Amerijet*, by contrast, the agency had expressly denied petitioner's requests. 753 F.3d at 1348 (describing denials). VA must have an opportunity to adequately address, in the first instance, petitioners' rulemaking request, which includes a claim that "[a] denial of [their rulemaking] petition . . . would . . . violate the Equal Protection component of the Fifth Amendment." Appx101-08; *see also Ventura*, 537 U.S. at 17; *cf. Coronado v. Holder*, 759 F.3d 977, 986-87 (9th Cir. 2014) (applying ordinary remand rule to permit agency to

address constitutional due-process claims in the first instance); *Montes-Lopez v. Gonzales*, 486 F.3d 1163, 1165 (9th Cir. 2007) (similar).

In these circumstances, it would be entirely improper to address the constitutional questions in this case "without affording the agency an opportunity to more fully address [petitioners'] request[]." *Amerijet*, 753 F.3d at 1353. On remand, "the possibility remains that [the agency] may reconsider its [purported] denial[] or offer adequate explanations for the agency's actions," which may moot or significantly reshape petitioners' equal-protection claim. *Id*.

Resolution of the constitutional questions also would run afoul of the long-settled "policy of the courts to decide cases on non-constitutional grounds when that is available, rather than reach out for the constitutional issue." *Stockton East Water Dist. v. United States*, 583 F.3d 1344, 1368 (Fed. Cir. 2009) (citing *Nw. Austin Mun. Util. Dist. No. One v. Holder*, 557 U.S. 193 (2009)). Because remand would be the proper course, it is unnecessary to reach the novel constitutional questions in this case. *See, e.g., Guilavogui v. Gonzales*, 228 F. App'x 33, 35 (2d Cir. 2007) (summary order) ("Because the agency's legal and factual errors require remand, we need not reach [petitioner's] constitutional claim."); *Nguyen v. Holder*, 315 F. App'x 617, 619 (9th Cir. 2009) (mem.) (remanding to allow for agency reconsideration in light of intervening case law and concluding that, "[i]n light of our disposition, we need not reach [petitioner's] equal protection claim.").

That policy has particular force here, where petitioners press this Court to adopt a significant expansion of the law in this Circuit. For example, petitioners assert (Pet. Br. 42-46) that VA's regulation constitutes sex discrimination, but there are strong arguments to the contrary. See Etsitty v. Utah Transit Auth., 502 F.3d 1215, 1221 (10th Cir. 1997) (rejecting argument that "discrimination against a transsexual based on the person's status as a transsexual" is sex discrimination under Title VII); Memorandum of the Attorney General, Oct. 4, 2017⁷ (providing several reasons as to why Title VII's prohibition on sex discrimination should not be construed to encompass discrimination based on transgender status). And petitioners assume (Pet. Br. 46) that the regulation is per se a discriminatory classification against transgender individuals simply because it excludes procedures that are disproportionately (if not exclusively) used by transgender individuals, but Supreme Court precedent strongly suggests to the contrary. See Geduldig v. Aiello, 417 U.S. 484, 494-96 & n.20 (1974) (exclusion of insurance benefits for pregnancy-related disabilities is not discrimination on the basis of sex under the Equal Protection Clause). Petitioners further argue (Pet Br. 46-49) that transgender status is a suspect classification that triggers heightened scrutiny, but the Supreme Court has not recognized transgender status as a suspect

⁷ Available at https://assets.documentcloud.org/documents/4067383/Attachment-2.pdf (last

visited November 27, 2017).

classification. Indeed, the Supreme Court has not recognized a new suspect classification in decades. Finally, petitioners contend (Pet. Br. 49-53) that VA could not assert any valid reason that would justify a denial of petitioners' request to include gender alteration surgery in the medical benefits package. But there are myriad rational reasons why VA could conclude that gender alteration surgery should remain excluded, such as budgetary constraints and medical uncertainty. Whatever the outcome on remand, VA's "informed discussion and analysis" would "help [this] [C]ourt later determine" the answers to these questions, Ventura, 537 U.S. at 17, if it needs to address them at all, see Amerijet, 753 F.3d at 1353. Even in petitioners' view, the quality of any explanation provided by VA in denying a rulemaking petition would be critical to determining the constitutionality of the agency's action. See, e.g., Pet. Br. 51 ("Nor is the explanation in the VA's letter sufficient."). Therefore, this Court need not—and should not—address the constitutional questions posed by petitioners' brief.

IV. VA Has Not Unreasonably Delayed Its Decision

Petitioners acknowledge that this Court may "conclude[] that the November 2016 letter did not finally deny the petition," and thus argue in the alternative that VA's "[y]ear-[l]ong" delay in addressing the petition is unreasonable. Pet. Br. 26 (citing 5 U.S.C. §§ 555(b), 706(1)). Petitioners fail to satisfy the high burden necessary to demonstrate that VA has unreasonably delayed in acting on their

petition. Even if they could, however, the proper remedy would be an order directing VA to respond to the petition, not to grant it.⁸

Whether brought as a petition for mandamus or as an APA claim, a petitioner bringing an unreasonable-delay claim faces a high burden. Relief will not be granted unless the agency's delay is "so egregious as to warrant" an order compelling the agency to act. *TRAC*, 750 F.2d at 79. That standard is "hardly ironclad," but the D.C. Circuit has set forth several factors that may provide useful guidance to this Court. *See id.* at 80.9 These factors include the passage of time, as

⁸ Although this Court's jurisdiction under 38 U.S.C. § 502 (providing that review is in accordance with the APA) is generally limited to review of final agency action, this Court may, in certain circumstances, have jurisdiction to review a claim that VA has failed to act, or has unreasonably delayed in acting, to protect its prospective jurisdiction under section 502. *See In re Paralyzed Veterans of Am.*, 392 F. App'x 858, 859-60 (Fed. Cir. 2010); *Military Order of Purple Heart v. Sec'y of Veterans Affairs*, No. 2010-7062, 2010 WL 1568485, *1 (Fed. Cir. Apr. 16, 2010) (*MOPH*); *see also Telecommunications Research Action Ctr. v. FCC*, 750 F.2d 70, 77-79 (D.C. Cir. 1984) (*TRAC*) (discussing jurisdiction of court of appeals to review unreasonable-delay claim).

⁹ In previously considering mandamus requests, this Court has affirmed the Veterans Court's application of an "arbitrary refusal to act" standard on numerous, albeit non-precedential, occasions. *See, e.g., Williams v. McDonald*, 614 F. App'x 499, 501 (Fed. Cir. 2015) (unpublished) (citing *Costanza v. West*, 12 Vet. App. 133, 134 (1999) ("The petitioner, who carries the burden in this matter, has not adequately demonstrated a clear and indisputable right to the writ. He has not demonstrated that the delay he complains of is so extraordinary, given the demands and resources of the Secretary, that the delay amounts to an arbitrary refusal to act, and not the product of a burdened system.")); *Bucholtz v. Snyder*, No. 2016-2485, 2017 WL 563158, at *2 (Fed. Cir. Feb. 13, 2017); *Adeyi v. McDonald*, 606 F. App'x 1002, 1005 (Fed. Cir. 2015); *Bryan v. McDonald*, 615 F. App'x 681, 684 (Fed. Cir. 2015). Given that Congress created the Veterans Court to fulfill one

evaluated under a "rule of reason"; any Congressional timetable for action; the agency's good faith; the agency's competing priorities; and the nature and extent of the interests prejudiced by delay, including the impact upon human health and welfare. *Id.* As applied in this case, these factors demonstrate that this Court's intervention is not required.

First, the passage of time is far from "egregious." *TRAC*, 750 F.2d at 79. Petitioners filed the present petition for review on January 9, 2017—a mere 9 months after filing their rulemaking request on May 9, 2016. To date, only 18 months have passed since the filing of the petition for rulemaking. In contrast, "[t]he cases in which courts have afforded relief have involved delays of years." *In re Cal. Power Exch. Corp.*, 245 F.3d 1110, 1125 (9th Cir. 2001); *see In re City of Va. Beach*, 42 F.3d 881, 885-86 (4th Cir. 1994) (denying writ where, although not "happy" about anticipated four and a half year delay in agency's action, the court found "rational explanation[]" for delay); *Liberty Fund, Inc. v. Chao*, 394 F. Supp. 2d 105, 114-15, 120 (D.D.C. 2005) (finding two to four year delay did not warrant a writ, and collecting similar cases); *Biodiversity Legal Foundation v. Norton*, 285

purpose—oversight of the veterans benefits system—the Veterans Court's mandamus standard is well suited to address the specific needs of veterans and the burdens on VA. *See Sanders v. Shinseki*, 556 U.S. 396, 412 (2009) (holding that the Veterans Court is better suited to exercise informed judgment on issues related to the veterans benefits system). For the reasons discussed above, any delay in this case is far from an arbitrary refusal to act.

F. Supp. 2d 1, 22 (D.D.C. 2003) (agency's four year delay was not unreasonable, even where species was in a "precarious position" and the parties agreed as to the "pressing need to revise critical habitat").

Second, there is no allegation here that VA has failed to comply with a statutory or regulatory deadline, and no such deadline to act on petitioners' rulemaking petition exists. *Compare MOPH*, 2010 WL 1568485 at *2 ("[W]e cannot order relief . . . because the final regulations are not required to be issued until 90 days after the issuance of the proposed regulations"), *with In re Paralyzed Veterans of Am.*, 392 F. App'x at 860 (granting mandamus where "Congress clearly imposed on the Secretary a date-certain deadline to issue a final regulation" and Secretary failed to issue regulation by that date).

Third, petitioners make no allegation calling into question the well-established presumption that Government officials act in good faith and "conscientiously in the discharge of their duties." *See, e.g., Croman Corp. v. United States*, 724 F.3d 1357, 1364 (Fed. Cir. 2013). Rather, as demonstrated in the record, VA has worked diligently and in good faith to consider issues relating to petitioners' rulemaking request. *See, e.g.*, Appx305-315; Appx320-330. Any perceived delay in resolving that request is largely attributable to VA's efforts to determine whether the Secretary will exercise his discretion to include gender alteration surgery in the medical benefits package and not due to inattention by

VA. Thus, VA's unchallenged good faith weighs in the agency's favor. *See W. Coal Traffic League v. Surface Transp. Bd.*, 216 F.3d 1168, 1176 (D.C. Cir. 2000); *Nat. Resources Def. Council, Inc. v. N.Y. Dep't of Envtl. Conservation*, 700 F. Supp. 173, 181-82 (S.D.N.Y. 1988).

Fourth, the agency has devoted substantial time and resources to consider issues relating to the rulemaking petition. As petitioners note, VA "draft[ed] a proposed rulemaking and conduct[ed] an impact analysis within a few months of receiving the petition." Pet. Br. 27. Petitioners argue that these significant steps weigh in favor of mandamus, but the opposite is true. These steps reflect the agency's serious consideration of these issues; there is no need for judicial intervention in that process, particularly at this early stage. As the D.C. Circuit has explained, an "agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way." In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991). Accordingly, it is the "exceptionally rare case[]" where a court will compel an agency to move forward on a specific project. Id. Particularly considering that only 18 months have elapsed since petitioners made their rulemaking request, during which time VA has worked to address the issues raised therein, this is not one of those rare cases.

Finally, petitioners note that the subject of their petition involves their health and welfare. Pet. Br. 28-29. The D.C. Circuit has held, however, that "this factor alone can hardly be considered dispositive when, as in this case, virtually the entire docket of the agency involves issues of this type." Sierra Club v. Thomas, 828 F.2d 783, 798 (D.C. Cir. 1987). Moreover, although VA does not dispute that obtaining medical care involves an individual's health and welfare, it is equally true that VA provides numerous medical benefits to transgender veterans suffering from gender dysphoria as part of the medical benefits package, including "hormone therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery." Appx53, Appx57. Veterans enrolled in the medical benefits package may also obtain gender alteration surgery outside of the VA health-care system. See Appx61. Thus, this is not the type of "extraordinary situation" where the "drastic remedy" of mandamus is warranted.

Even assuming, for the sake of argument, that petitioners had demonstrated unreasonable delay such that they are entitled to relief, they would not be entitled to an order that "direct[s] the VA to initiate rulemaking." Pet. Br. 29. As petitioners acknowledge, "[t]he ordinary remedy for an agency's unreasonable delay in responding to a petition for rulemaking is for the Court to direct a response"—not to grant the petition. Pet. Br. 29; *see also Norton v. S. Utah*

Wilderness All., 542 U.S. 55, 65 (2004) (reviewing APA claim under 5 U.S.C. § 706(1) and emphasizing that "when an agency is compelled by law to act within a certain time period, but the manner of its action is left to the agency's discretion, a court can compel the agency to act, but has no power to specify what the action must be."). That is true regardless of whether courts grant relief in the mandamus context or under the APA. See, e.g., 5 U.S.C. § 706(1) (authorizing a reviewing court to "compel agency action unlawfully withheld or unreasonably delayed"); In re Am. Rivers & Idaho Rivers United, 372 F.3d 413, 420 (D.C. Cir. 2004) (awarding mandamus and "direct[ing] [the agency] to issue a judicially reviewable response to the . . . petition").

Petitioners' efforts to craft an exception to this rule are misguided. They rely on the district court's decision in *Public Citizen*, but that case involved review of an agency's denial of a rulemaking petition, not an unreasonable-delay claim.

See 653 F. Supp. at 1235. In any event, as discussed above, the remedy the court directed in *Public Citizen* is reserved for "extremely rare circumstances" that do not exist in this case. See supra pp. 29-31.

CONCLUSION

For these reasons, this Court should dismiss for lack of jurisdiction petitioners' challenge to the purported denial of their rulemaking request or, in the alternative, remand to VA. This Court should likewise deny petitioners' request to compel VA to engage in rulemaking.

Respectfully submitted,

CHAD A. READLER

Principal Deputy Assistant Attorney General

ROBERT E. KIRSCHMAN, JR.

Director

Of Counsel: /s/Allison Kidd-Miller

ALLISON KIDD-MILLER

Assistant Director

Staff Attorney
Health Care Law Group /s/Eric P. Bruskin

DREW CORNACCHIO

Health Care Law Group

Department of Veterans Affairs

810 Vermont Avenue, NW

Senior Trial Counsel

Office of General Counsel Commercial Litigation Branch

Washington, DC 20420 Civil Division, Department of Justice

P.O. Box 480, Ben Franklin Station

Washington, DC 20044 Tel: (202) 307-5958

Fax: (202) 353-0461

November 28, 2017 Attorneys for Respondent

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on this 28th day of November, 2017, a copy of the foregoing "BRIEF FOR RESPONDENT" was filed electronically. The filing was served electronically to all parties by operation of the Court's electronic filing system.

/s/Eric P. Bruskin

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure, respondent's counsel certifies that this brief complies with the Court's type-volume limitation rules. According the word count calculated by the word processing system with which this brief was prepared, the brief contains a total of 10,198 words.

/s/Eric P. Bruskin
Eric P. Bruskin
Counsel for Respondent

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17-1460 Oral Argument Audio

Case: 24-108

Fulcher v. Secretary of Veterans Affairs, Federal Circuit, No. 17-1460, argued May 3, 2018

Panel

• Chief Judge Sharon Prost; Circuit Judges Richard G. Taranto and Todd M. Hughes

Presenting Argument

- Alan E. Schoenfeld (WilmerHale), for Petitioners
- · Catherine H. Dorsey (Department of Justice), for Respondent

00:00

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Federal Register/Vol. 83, No. 131/Monday, July 9, 2018/Proposed Rules

mine dust consist of interstitial and obstructive pulmonary diseases (79 FR 24819). Interstitial lung diseases, like coal workers' pneumoconiosis (CWP) and silicosis, have a significant latency period between exposure and disease. The health effects from exposure to respirable coal mine dust may not be realized for a decade or more until the disease becomes clinically apparent. In addition, the chronic effects of interstitial lung diseases, such as CWP and silicosis, may progress or worsen even after miners are no longer exposed to respirable coal mine dust. Thus, miners' exposure to respirable coal mine dust before final implementation of the Dust rule on August 1, 2016, may continue to contribute to the development of lung diseases in coal miners. New miners hired after August 1, 2016, are the only cohort of coal miners who are unaffected by exposures that occurred before full

implementation of the Dust rule. In the preamble to the Dust rule, MSHA stated its intent to take the lead in conducting a retrospective study beginning February 1, 2017 (79 FR 24867), with an unspecified completion date. Since the Dust rule went into effect, MSHA has analyzed more than 250,000 respirable dust samples taken by mine operators who use the CPDM and by MSHA inspectors who use the gravimetric sampler. MSHA's analysis shows that more than 99 percent of the samples were in compliance with the MSĤA respirable coal mine dust standards.

The sample data allow MSHA to evaluate the effectiveness of dust controls in mines and whether the rule results in reduced levels of respirable coal dust. However, due to the latency between exposure and disease, MSHA likely will not be able to evaluate fully the health effects of the rule for a decade or more.

While the Agency continues to evaluate the respirable dust samples, MSHA also is seeking comments, data, and information from stakeholders to assist the Agency in developing a framework to assess the health effects of the Dust rule and its impact on the health protections provided to coal miners going forward. With respect to suggested elements for a framework, commenters should be specific and include detailed rationales and supporting documentation, if any. Throughout the comment period, MSHA will continue to consult with interested parties and the Department of Health and Human Services' National Institute for Occupational Safety and Health (NIOSH), as it collects and evaluates all available information, comments in

response to this RFI, respirable coal mine dust sampling data, and compliance rates for controlling exposure to coal mine dust.

III. Engineering Controls and Best Practices

As mentioned, since the Dust rule's publication and implementation, MSHA has continually evaluated respirable dust controls and best practices for compliance with the rule's requirements. The Agency has met with mine operators and miners to provide mine-specific compliance and technical assistance. MSHA also held a MSHA/ NIOSH-sponsored meeting on engineering controls and best practices on December 6, 2016. Technical assistance materials and other materials from the meeting are available on MSHA's website at https:// www.msha.gov.

MSHA intends to continue its consultations and will continue to offer technical assistance on best practices for controlling coal mine dust and quartz exposures. MSHA is interested in the engineering controls and best practices that mine operators find most effective to achieve and maintain the required respirable coal mine dust and quartz levels—particularly those practices that can be replicated throughout coal mines nationwide to achieve similar results.

IV. Data Request

The purpose of this RFI is to solicit comments, data, and information from industry, labor, NIOSH, and other stakeholders to assist MSHA in developing the framework for a study to assess the health effects of the Dust rule. Commenters should be specific about any recommendations they offer, including detailed rationales and supporting documentation.

V. National Academy of Sciences Study

MSHA notes that in the Explanatory Statement to the 2016 Consolidated Appropriations Act (Pub. L. 114-113), Congress directed NIOSH to charter a National Academy of Sciences (NAS) study to examine and describe: Current monitoring and sampling protocols and requirements to understand miners' occupational exposure to respirable coal mine dust in the United States and other industrialized countries; coal mine dust composition and application procedures, including the impact of new rock dust mixtures and regulatory requirements; monitoring and sampling technologies, along with sampling protocols and frequency; and the efficacy of those technologies and protocols in aiding decisions regarding the control of respirable coal mine dust

and mine worker exposure. Congress directed MSHA to provide assistance and necessary data to NAS for its study, which the Agency has done and continues to do when requested. MSHA will evaluate the results of the NAS study after the report is final.

David G. Zatezalo,

Assistant Secretary of Labor for Mine Safety and Health.

[FR Doc. 2018–14536 Filed 7–6–18; 8:45 am]

BILLING CODE 4520-43-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

Exclusion of Gender Alterations From the Medical Benefits Package

AGENCY: Department of Veterans Affairs. **ACTION:** Petition for Rulemaking and request for comments.

SUMMARY: On May 9, 2016, the Department of Veterans Affairs (VA) received a Petition for Rulemaking petitioning VA to amend its medical regulations by removing a provision that excludes "gender alterations" from its medical benefits package. The effect of the amendment sought by the petitioners would be to authorize gender alteration surgery as part of VA care when medically necessary. VA seeks comments on the petition to assist in determining whether to amend the medical benefits package and eliminate the exclusion of gender alteration from VA's medical benefits package.

DATES: Comments must be received/submitted on or before September 7, 2018.

ADDRESSES: Written comments may be submitted through http:// www.regulations.gov; or by mail or hand delivery to Director, Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW, Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to "Notice of Petition for Rulemaking and request for comments— Exclusion of Gender Alterations from the Medical Benefits Package." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) During the comment period, comments may

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also be viewed online through the Federal Docket Management System (FDMS) at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Michael Shores, Director, Office of Regulation Policy and Management, Office of the Secretary, Department of Veterans Affairs, 810 Vermont Avenue

NW, Washington DC, 20420; (202) 461-

SUPPLEMENTARY INFORMATION: Section 1710 of title 38 United States Code (U.S.C.) requires VA to "furnish hospital care and medical services which the Secretary determines to be needed" for eligible veterans. In 1999, VA promulgated 38 CFR 17.38, establishing the Department's medical benefits package for veterans enrolled in VA's health care system. 64 FR 54207 (Oct. 6, 1999). The regulation describes the types of medical care and services available for such veterans. Care referred to in the medical benefits package is provided to individuals only if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice. 38 CFR 17.38(b). Paragraph (c) of that section provides a list of medical services the medical benefits package does not include. Paragraph (c)(4) explicitly excludes "gender alterations" from the medical benefits package.

On May 9, 2016, VA received a Petition for Rulemaking petitioning VA to amend its medical regulations by removing the exclusion of "gender alterations" from its medical benefits package. The petition asks VA to remove 38 CFR 17.38(c)(4), allowing VA to provide gender alteration surgeries.

As part of its ongoing consideration of the petition, VA now seeks public comment on the petition and on whether "gender alterations" should be included in the medical benefits package. On February 22, 2018, the Department of Defense issued a report that considered the efficacy of gender alteration surgery as treatment for gender dysphoria. That report noted considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments such as sex reassignment surgery remedy the multifaceted mental health problems associated with gender dysphoria.

Commenters are specifically invited to address the following questions:

What evidence is available about the safety and effectiveness of gender alterations for the treatment of gender

dysphoria and how reliable is that evidence?

Given the challenge of the high rates of Veteran suicide, what does the evidence, including peer-reviewed evidence, suggest about the impact of gender alterations on the rates of suicide and suicide ideation among those suffering from gender dysphoria?

Given that any addition to the medical benefits package will have an associated cost and burden on existing specialists, especially urological and vascular surgeons and other highly trained specialists who are already in shorty supply nationwide, what is the potential impact of adding "gender alterations" on Veterans' access to care, particularly for Veterans facing lifethreatening medical conditions waiting to see surgical specialists?

We are providing a 60-day period from the date of publication of this **Federal Register** Notice for the public to submit comments on this subject. VA will consider the comments received, and then determine whether to propose a regulatory change in response to the Petition for Rulemaking. VA will announce any action it takes in the **Federal Register**.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jacquelyn Hayes-Byrd, Acting Chief of Staff, Department of Veterans Affairs, approved this document on June 19, 2018, for publication.

Michael Shores,

Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2018–14629 Filed 7–6–18; 8:45 am]

BILLING CODE 8320-01-P

POSTAL SERVICE

39 CFR Part 111

New Mailing Standards for Mailpieces Containing Liquids

AGENCY: Postal ServiceTM. **ACTION:** Proposed rule.

SUMMARY: The Postal Service is proposing to revise *Mailing Standards* of the United States Postal Service, Domestic Mail Manual (DMM) section 601.3.4 to provide for more rigorous packaging requirements for mailpieces containing liquids.

DATES: Submit comments on or before August 8, 2018.

ADDRESSES: Mail or deliver written comments to the manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260-5015. If sending comments by email, include the name and address of the commenter and send to ProductClassification@usps.gov with a subject line of "New Standards for Liquids". Faxed comments are not accepted. You may inspect and photocopy all written comments, by appointment only, at USPS Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor North, Washington, DC 20260. These records are available for review Monday through Friday, 9 a.m.-4 p.m., by calling 202-268-2906.

FOR FURTHER INFORMATION CONTACT:

Direct questions to Wm. Kevin Gunther at wkgunther@uspis.gov or phone at (202) 268–7208, or Michelle Lassiter at michelle.d.lassiter@usps.gov or phone at (202) 268–2914.

SUPPLEMENTARY INFORMATION: The Postal Service and United States Postal Inspection Service (USPIS) have observed an increased frequency of incidents involving containers of liquids rupturing while in Postal Service networks. A typical result of these incidents is damage to surrounding mailpieces and to Postal Service equipment.

When responding to incidents involving liquid spills, Postal Service employees frequently note that mailpieces containing liquids are often not marked on the outer mailing container as required by DMM 601.3.4. Many of these leaking mailpieces contain plastic primary receptacles. Mailers often do not consider plastic primary receptacles to be breakable, and therefore do not cushion these primary receptacles with absorbent material or include secondary containers, as specified by DMM 601.3.4.

The Postal Service and USPIS have also observed that spills of non-hazardous materials in relatively small quantities can result in damage to surrounding mailpieces and cause temporary equipment shutdowns. This is especially true with viscous or oily substances, such as oils and lotions. These materials are often mailed by First-Class Package Service®. When ruptured, they will frequently leak onto other lightweight mailpieces containing photographs and documents.

This proposed revision would require mailers of all liquids in nonmetal containers, regardless of volume, to provide triple packaging, including

No.	2017-1	460

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DEE FULCHER, GIULIANO SILVA, AND THE TRANSGENDER AMERICAN VETERANS ASSOCIATION,

Petitioners,

v.

SECRETARY OF VETERANS AFFAIRS,

Respondent.

On Appeal from the United States Department of Veterans Affairs.

PETITIONERS' UNOPPOSED MOTION FOR VOLUNTARY DISMISSAL

Pursuant to Rule 42(b) of the Federal Rules of Appellate Procedure,

Petitioners hereby move to dismiss their appeal in Docket Number 2017-1460.

Each party shall bear its own costs. Counsel for Respondent has stated that he does not oppose this motion and will not file a response.

Case: 24-108 Document: 2-2 Page: 372 Filed: 01/25/2024

Dated: July 27, 2018

LYNLY S. EGYES

P.O. Box 70976

(510) 587-9696

Oakland, CA 94612

SASHA J. BUCHERT SHAWN THOMAS MEERKAMPER LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 1875 I Street NW Washington, DC 20006 (202) 999-8083

/s/ Alan Schoenfeld ALAN SCHOENFELD WILMER CUTLER PICKERING HALE AND DORR LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007 (212) 937-7294

Respectfully submitted,

TARA L. BORELLI M. Dru Levasseur LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 730 Peachtree St. NE, Ste. 640 Atlanta, GA 30308-1210 (404) 897-1880

TRANSGENDER LAW CENTER

PAUL R.Q. WOLFSON MICHAEL POSADA WILMER CUTLER PICKERING HALE AND DORR LLP 1875 Pennsylvania Ave. NW Washington, DC 20006 (202) 663-6390

Attorneys for Petitioners

CERTIFICATE OF INTEREST

Counsel for Petitioners Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association certifies the following:

1. The full name of every party or *amicus* represented by us is:

Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association

- 2. The names of the real party in interest represented by us is:

 Not applicable.
- 3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are (and who have not or will not enter an appearance in this case) are:

All counsel have filed appearances in this case.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

None.

July 27, 2018

/s/ Alan Schoenfeld
ALAN SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

CERTIFICATE OF SERVICE

I hereby certify that, on this 27th day of July, 2018, I filed the foregoing Unopposed Motion For Voluntary Dismissal with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Alan Schoenfeld

ALAN SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 27(d) and 32(g), the undersigned hereby certifies that this motion complies with the type-volume limitation of Circuit Rule 27(d).

- 1. Exclusive of the accompanying documents as authorized by Fed. R. App. P. 27(a)(2)(B) and the exempted portions of the response as provided by Fed. R. App. P. 27(d)(2) and 32(f), the motion contains 47 words.
- 2. The motion has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font as provided by Fed. R. App. P. 32(a)(5)-(6). As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Alan Schoenfeld
ALAN SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 937-7294

July 27, 2018

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

DEE FULCHER, GIULIANO SILVA, TRANSGENDER AMERICAN VETERANS ASSOCIATION,

Petitioners

v.

SECRETARY OF VETERANS AFFAIRS,

Respondent

Petition for review pursuant to 38 U.S.C. Section 502.

PER CURIAM.

ORDER

The parties having so agreed, it is

ORDERED that the proceeding is DISMISSED under Fed. R. App. P. 42 (b). Each party shall bear its own costs.

FOR THE COURT

2 Fulcher V. Secretary of Veterans Affairs

August 1, 2018 /s/ Peter R. Marksteiner

Peter R. Marksteiner

Clerk of Court

ISSUED AS A MANDATE: August 1, 2018

Pentagon & Congress

Case: 24-108

VA to offer gender surgery to transgender vets for the first time

By Leo Shane III

Sections

Military

News Pay & Benefits Flashpoints



Nick Rondoletto, left, and Doug Thorogood, wave a rainbow flag and a sign during a July 26, 2017, protest in San Francisco. (Olga R. Rodriguez/AP)

Veterans Affairs officials for the first time will offer surgeries for <u>transgender veterans</u> seeking to alter their physical attributes, Secretary Denis McDonough will announce on

Saturday.

Case: 24-108

The move follows repeated promises by VA officials to make the department "more welcoming" to all veterans and was accompanied by an announcement that the Veterans Health Administration will rename its LGBT health program to the LGBTQ+ program to "reflect new community standards of inclusiveness and anticipate future changes in terms."

"[This is] allowing transgender vets to go through the full gender confirmation process with VA by their side," McDonough said prepared remarks for an event at the Orlando VA Healthcare System in Florida. "We're making these changes not only because they are the right thing to do, but because they can save lives."

The National Center for Transgender Equality estimates there are more than 134,000 transgender veterans in America today, and another 15,000 transgender individuals serving in the armed forces.

RELATED



Reversing Trump, Pentagon releases new transgender policies

The new department regulations allow transgender people who meet military standards to enlist and serve openly in their self-identified gender, and they will be able to get medically...

By Lolita C. Baldor, The Associated Press

VA officials estimate that around 4,000 veterans nationwide will be interested in the surgeries. Total cost of the program is not yet known. The department also could not say when surgeries will be available, since officials must first go through a formal rule change process.

McDonough said making the change "will require changing VA's regulations and establishing policy that will ensure the equitable treatment and safety" of transgender veterans.

"There are several steps to take, which will take time. But we are moving ahead, methodically, because we want this important change in policy to be implemented in a manner that has been thoroughly considered to ensure that the services made available to veterans meet VA's rigorous standards for quality health care."

The announcement on gender confirmation surgeries, also known as gender reassignment surgeries, is a dramatic shift from the previous White House and President Donald Trump's moves to ban transgender individuals from joining the military and limit surgery options for those already in the ranks. Trump cited cost and morale concerns for that opposition.

McDonough, in his remarks, called it a matter of finding the best ways to serve veterans' needs.

"LGBTQ+ veterans experience mental illness and suicidal thoughts at far higher rates than those outside their community," he said. "But they are significantly less likely to seek routine care, largely because they fear discrimination.

"At VA, we're doing everything in our power to show veterans of all sexual orientations and gender identities that they can talk openly, honestly and comfortably with their health care providers about any issues they may be experiencing."

RELATED



Retired surgeons general say Trump's transgender ban damaged military readiness A Palm Center study found that the policy negative affected recruiting, retention and morale.

By Meghann Myers

Since 2016, all VA facilities have had a local LGBT Veteran Care Coordinator responsible for helping those veterans connect to available services.

In a statement, House Veterans' Affairs Committee Chairman Mark Takano, D-Calif. and the first openly gay minority individual elected to Congress, hailed the move.

"Veterans in need of gender confirmation surgery should not have to seek healthcare outside of the VA health system or navigate complicated processes to get the care they need," he said. "VA must be inclusive of all veterans who have served, regardless of their identity."

Senate Veterans' Affairs Committee Chairman Jon Tester, D-Mont., similarly praised the expansion of health care offerings for transgender veterans.

"Every service member and veteran deserves equal access to quality care from VA, and this includes our LGBTQ+ veterans," he said in a statement. "We must reaffirm our commitment to making VA a more welcoming place for everyone who fought to protect our freedoms."

But House Veterans' Affairs Committee ranking member Mike Bost, R-Ill., blasted the announcement as the White House trying to win "the culture wars."

"This announcement clearly has more to do with advancing a radical liberal agenda than serving veterans," he said. "It is a disgrace. This administration should rethink their priorities immediately."

In a statement, GLAAD President Sarah Kate Ellis praised the news as "not only an overdue victory for transgender veterans, but the latest move from Secretary McDonough and the VA in affirming LGBTQ veterans."

About Leo Shane III

Leo covers Congress, Veterans Affairs and the White House for Military Times. He has covered Washington, D.C. since 2004, focusing on military personnel and veterans policies. His work has earned numerous honors, including a 2009 Polk award, a 2010 National Headliner Award, the IAVA Leadership in Journalism award and the VFW News Media award.

Transgender Care CoordinationExternal Frequently Asked Questions (FAQs)

External FAQs: Removing "Gender Alterations" Exclusion from the VA Medical Benefits Package

1. What is VA's policy regarding health care for transgender Veterans?

VA is committed to ensuring that we, as an integrated service and benefits delivery system, are welcoming to all Veterans, including those with minority gender identities and expressions. As part of this commitment, VA provides all medically necessary gender affirming care to transgender Veterans with the exception of gender affirming surgical interventions due to an exclusion in the VA medical benefits package.

2. Is VA planning to remove this exclusion from its benefits package?

Yes. VA wants all eligible Veterans to have access to clinically appropriate, inclusive health care services. In 2016, VA received a Petition for Rulemaking (PFR) to remove this "gender alterations" exclusion that prevented and continues to prevent VA from performing medically necessary gender-affirming surgeries. This petition argued that the exclusion was discriminatory. Revising the medical benefits package would enable a safe, coordinated continuum of care that is Veteran-centric.

3. What is VA doing to ensure transgender Veterans are not facing discrimination?

VA is currently reviewing its policies to ensure that transgender Veterans do not face discrimination based on their gender identity and expression. This review includes an evaluation of statutory and regulatory requirements to build out a continuum of care that provides all medically necessary services for our transgender and gender diverse Veterans.

4. What are the steps involved to permanently remove the exclusion?

VA would formally grant the PFR and initiate rulemaking to remove the exclusion. The entire rulemaking process, itself, can take two years and includes a period of public comment.

Rulemaking is the term used when a federal government agency creates, modifies, or removes rules published in the Code of Federal Regulations (also known as the CFR). Rulemaking to remove this exclusion is recommended to align VA with current Administration priorities, best medical practice, research, and professional health organizations. Revising the medical benefits package would enable a safe, coordinated continuum of care that is Veteran-centric.

5. What about transgender Veteran care during the rulemaking process?

During the rulemaking process, VA will continue to provide or pay for the services it currently offers, including corrective procedures after gender affirming surgeries a Veteran obtains outside VA, hormone therapy, and other gender affirming care.

VA will also have the opportunity to develop processes to meet the surgical and care coordination needs so that Veterans have clear and consistent access nationwide. Delivery of the care will likely happen in a combination of venues including both within VA and through academic partners and other community-based experts in transition-related surgical care.

6. What are the benefits of removing this exclusion?

Removing this exclusion would enable VA to provide transgender and gender diverse Veterans with coordinated, medically necessary, transition-related surgical procedures. Gender affirming procedures have been proven effective at mitigating serious health conditions, including suicidality, substance abuse, and dysphoria.



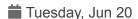


News Pay & Benefits Flashpoints

Veterans

After two years, still no timeline for transgender surgeries at VA

By Leo Shane III















Lindsay Church, executive director of Minority Veterans of America (center), speaks at a Capitol Hill rally on LGBTQ veterans rights on March 29. (Leo Shane III/Staff)

Two years after <u>Veterans Affairs leaders</u> announced they would make "life saving" <u>surgery</u> <u>options for transgender veterans</u> available through department medical centers for the first time, no such operations have been performed, and VA officials admit there is no timeline for when they might begin.

<u>The delay</u> comes as a national debate has erupted over both the <u>surgeries and transgender</u> <u>rights</u>. Instead of alleviating some of the stress associated with that, Veterans Affairs officials are adding to the anxiety by failing to follow through with its promise, advocates say.

"The frustration level is extremely high," said Cassandra Williamson, executive director of Transgender and Diverse Veterans of America. "This is impacting veterans' mental health and well-being, and postponing some medically necessary procedures. We're losing faith in VA in a big way."

On June 19, 2021, Veterans Affairs Secretary Denis McDonough <u>publicly vowed to start offering</u> gender confirmation procedures through department facilities for the first time. Officials at the time drew praise from LGBTQ activists for the move, even as department officials warned that the rulemaking process could drag on for months.

RELATED



VA to offer gender surgery to transgender vets for the first time

Officials do not know how long the rule making process will take or when surgeries will begin to be scheduled.

By Leo Shane III

Now, those months have turned into years. In the meantime, at least 20 states have placed limits on gender confirmation surgeries, largely aimed at minors. Florida Governor and Republican presidential candidate Ron DeSantis recently compared the operations to "mutilation."

In a statement, VA press secretary Terrence Hayes said department leaders are still committed to providing the surgery options to transgender veterans, and insisted that the larger political

debate over transgender rights has not slowed down the rulemaking work.

But he also said there is no timeline for when the first surgeries may be scheduled. Officials are "moving ahead methodically because we want this important change in policy to be implemented in a manner that has been thoroughly considered" and "meets VA's rigorous standards for quality health care."

Past estimates from the National Center for Transgender Equality and other advocacy groups put the number of transgender veterans in America today between 130,000 and 150,000. VA officials have estimated that around 4,000 veterans nationwide may be interested in gender confirmation surgeries, also known as gender reassignment surgeries.

Conservative groups have disputed both the estimates of transgender veterans and the need for VA to provide the surgery options, especially in states where it may run afoul of local laws.

Although gender confirmation surgeries are not yet available through VA, the department does offer hormone therapies and other transgender-specific medical options.

But advocates say that isn't enough, and question the reasons behind the delay.

RELATED



Transgender vets call for more protections from Congress, VA

Advocates want VA to move ahead with plans to provide gender-affirming surgery to transgender veterans, a policy change first promised in summer 2021.

By Leo Shane III

In late March, 157 outside groups — including Minority Veterans of America, Student Veterans of America and Iraq and Afghanistan Veterans of America — <u>sent a letter to McDonough</u> calling the continued delay over transgender surgery availability "not just an equity issue, but also a safety issue." They said that offering the operations could help cut down on depression and suicide rates among transgender veterans.

Lindsay Church, executive director and founder of Minority Veterans of America, called the lack of progress on the issue disheartening.

"When they announced this plan, they said it would save lives," Church said. "So where is the action now that trans people's lives are on the line?"

Church, who identifies as non-binary, was given breast implants years ago as part of reconstructive surgery from medical complications that arose during their time in the Navy. Earlier this year, during a medical appointment with VA, Church found out those implants had ruptured, causing a series of new health problems.

"I couldn't take them out earlier, because that falls under the transgender surgery options," Church said. "So the government can give you breast implants to affirm the gender they think you are, but they won't help you with other options unless it's a medical emergency."

Williamson, a Navy and Marine Corps veteran, said she has heard similar stories from other transgender veterans. "We're hearing that having these surgery options would have helped greatly, but for now, these veterans are still waiting."

House Veterans' Affairs Committee ranking member Mark Takano, D-Calif., said he is "concerned about the two-year delay" regarding the surgeries and hopes for resolution on the issue soon.

However, he said he still has faith that McDonough and his administration is committed to "providing much-needed healthcare to transgender veterans" in the near future.

<u>Veterans Affairs health care websites</u> promise that transgender veterans who reach out to the department will "receive affirming care and services to achieve optimal health and well-being." But for now, the list of services still excludes gender confirming surgeries.

"I just keep telling our folks to keep fighting, to stay on this," Williamson said. "We understand the regulatory process does take time. But we didn't expect it to be this long."

Filed: 01/25/2024 Case: 24-108 Document: 2-2 Page: 388

About Leo Shane III

Leo covers Congress, Veterans Affairs and the White House for Military Times. He has covered Washington, D.C. since 2004, focusing on military personnel and veterans policies. His work has earned numerous honors, including a 2009 Polk award, a 2010 National Headliner Award, the IAVA Leadership in Journalism award and the VFW News Media award.











In Other News >

Air Force expanding review of cancers in nuclear missile community

The expanded Air Force study will consider a broader range of career fields as well as an additional base.



Navy raises crashed P-8A Poseidon aircraft from Hawaii's Kaneohe Bay

The plane overshot a runway on Nov. 20 and landed in the environmentally sensitive bay. No injuries were reported.



Military-themed brewery sparks fight in Virginia military city

The controversy over Armed Forces Brewing mirrors increasingly divisive national battles about free speech.



Divers find sunken Osprey, remains of 5 airmen, Air Force says

American and Japanese crews continue to search for two people who are still missing.



SEAL to Storyteller: Remi Adeleke hosts new military podcast

The Down Range podcast features veterans' tales of combat.

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Town hall with VA Secretary Denis McDonough

November 8, 2023

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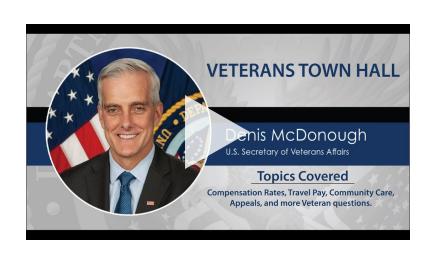
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from Veterans and their families, caregivers and survivors.

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The one-hour town hall was streamed live on YouTube. If you missed it, <u>you can watch</u> it online .

If you have questions, please go to <u>2023</u>

<u>Veterans Town Hall</u> on RallyPoint to submit a question where a VA expert will address your question by Nov. 17.

You can also <u>read the town hall Q&A</u> with answers to some of the most asked questions:

Why is it so difficult and take so long to increase a disability rating?

VA is determined to provide Veterans efficient, quality service and recognizes that timeliness is an important aspect of that service, which is why VA uses timeliness as an indicator to monitor the general effectiveness of the claims process. This past year, VA decided claims almost 20 days faster than the year before.

VA | News

800-698-2411). Veterans can also meet inperson with a public contact representative at a local VA regional office.

Why is it so hard for us to get community care referrals when care is not available at VA?

Community care is a force-multiplier for VA care — it's an essential part of our portfolio of care options for Veterans. That includes in-person, telehealth, or being seen at one of our clinical contact centers, such as VA Health Connect. In fiscal year 2023, over 2.4 million Veterans received community care, and over the past several years we've continued to make improvements to the overall community care experience. As of May 2023, our overall satisfaction score for community care was 85.3%, the highest ever.

To get a community care referral, of course, you have to be eligible based on your specific health care needs and circumstances. If you meet a least one of the six criteria, our staff are required to Appx 386

important because they have to meet our standards and requirements; this is how we make sure Veterans are getting high-quality care that's properly coordinated with VA.

I'm a Veteran who lives too far from a VA national cemetery. I want my family to be able to visit me if they choose. What options do I have?

In addition to VA's National Cemeteries, VA also works with State Cemetery partners who run their cemeteries in accordance with the very high standards the National Cemetery Administration (NCA) sets. We encourage you to look at the State and Tribal Cemeteries in your area that offer burials for Veterans and their spouse. Also, there are even smaller municipalities, such as counties, that have Veterans cemeteries as well.

bronze marker absolutely free (there may be an installation fee that a private cemetery charges). Finally, if you go with a private cemetery and a private headstone, you still can have a medallion from VA affixed to your headstone that annotates your branch of military service.

When will VA propose a rule to allow for gender confirmation surgery?

VA is committed to delivering timely access to world-class health care and earned benefits to all Veterans, family members, survivors and caregivers. VA is actively working on a gender affirming surgery regulatory action.

Why does it take so long to get an answer on a Veterans appeal? As a surviving spouse I need the help of that

VA News

with costs rising; it is very hard on one paycheck.

The Board of Veterans Appeals understands that many Veterans and appellants have been waiting a long time for a decision. We acknowledge that this wait can be very frustrating, and we want to explain why getting a Board decision can take a long time and what options are available to Veterans and appellants that may reduce the time they have to wait for a decision.

The Veterans Benefits Administration usually takes 12 to 18 months to review appeals and decide whether to grant some or all of the appeal. The good news is that the line is now moving faster because of increased resources and improved processes under the newer AMA system. I can report to you that in the last 5 years, the Board of Veterans' Appeals (Board) has issued a total of 496,012 appeals decisions, 103,245 during fiscal year 2023 alone, a new historical record. However, we are also aware that despite the high numbers of decisions each year, there are still over 200,000 pending appeals waiting in line for a decisAppx 389

VA News

significant considering the increasing number of Veterans who have filed an appeal at the Board in recent years. We have Congress to thank for providing enough resources for the Board to hire more Veterans Law Judges, supporting counsel and staff to help resolve and process these appeals.

Is it possible to have a rating increase posthumously? My husband passed in 2019. Why aren't benefits retroactive to 2012 when he first filed?

Accrued benefits may exist:

- if the decision was made within the past 12-months, which can still be appealed, or
- based on evidence in the file on the date of death, or
- if an eligible claimant continues a claim that was pending on the date of the Veteran's death.

Appx 390

VA News

death, including a claim in which the period to file an appeal has not yet expired.

Claimants who wish to apply for accrued benefits should use VAForm 21P-601,

"Application for Accrued Amounts Due a Deceased Beneficiary."

The retroactive amount due and date of entitlement is dependent on many factors. Generally, decisions are considered final one year after the date of a decision notice, unless an appeal was filed. Claims filed after the one-year period expires establish a new entitlement date. This includes claims for increased rating evaluation. The ability to provide retroactive benefits once a claim is closed is limited to either authorization from Congress to provide an earlier effective date or for cases in which it is determined that VA made a clear and unmistakable error.

Are you aware that travel benefits does not work for everyone?

One of VA's highest priorities is reducing barriers to VA health care and services. It is

VA News

VA travel pay reimburses eligible Veterans and VA caregivers for mileage and other travel expenses to and from approved health care appointments. The Beneficiary Travel program is predominantly a reimbursement mechanism for mileagebased transport in privately-owned vehicles for Veterans who are 30 percent or more service connected, traveling for a service-connected condition, in receipt of VA pension or fall below VA income guidelines. In addition, these Veterans may be aided with Special Mode Transportation (e.g., ambulance, ground, or air), or common carrier such as taxi, or rideshares such as Uber, Lyft, bus or airfare.

Additionally, all Veterans may be provided cost-free transportation assistance through Veterans Transportation Services, available at over 125 VA medical centers. VA does an extensive amount of collaboration to connect Veterans to services provided by local state Veterans service agencies such as Disabled American Veterans (DAV) and other Veterans Service Organizations.

For more information on these programs, see www.va.gov/healthbenefits/vtp.

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Printer-Friendly Version **Download RIN Data in XML**

RIN: 2900-AR34 Publication ID: Fall 2021

Title: •Gender Confirmation Surgery

Abstract:

VA

The Department of Veterans Affairs (VA) is proposing to revise its medical regulations by removing the exclusion on gender alterations from the medical benefits package. VA is proposing these changes so that transgender and gender diverse veterans may receive medically necessary health care, including surgical interventions for gender transition. This proposed change would be consistent with medical industry standards and would ensure that VA provides a full continuum of care to transgender and gender

Agency: Department of Veterans Affairs(VA)

RIN Status: First time published in the Unified Agenda

Major: No

CFR Citation: 38 CFR 17.38 Legal Authority: 38 U.S.C. 1710

Legal Deadline: None

Timetable:

Date FR Cite Action

NPRM 07/00/2022

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No Included in the Regulatory Plan: No RIN Information URL: www.regulations.gov

RIN Data Printed in the FR: No

Agency Contact: Jillian Shipherd

Director of the LGBT Program for Patient Care Services

Department of Veterans Affairs 810 Vermont Avenue NW, Washington, DC 20420 Phone:857 364-5821 Email: jillian.shipherd@va.gov

Priority: Substantive, Nonsignificant

Agenda Stage of Rulemaking: Proposed Rule Stage

Unfunded Mandates: No

Government Levels Affected: None

Federalism: No







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RIN: 2900-AR34

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Title: Removal of Exclusion of Gender Alterations From the Medical Benefits Package

Abstract:

VΑ

The Department of Veterans Affairs (VA) is proposing to revise its medical regulations by removing the exclusion on gender alterations from the medical benefits package. VA is proposing these changes so that transgender and gender diverse veterans may receive medically necessary health care, including surgical interventions for gender transition. This proposed change would be consistent with medical industry standards and would ensure that VA provides a full continuum of care to transgender and gender

Agency: Department of Veterans Affairs(VA)

RIN Status: Previously published in the Unified Agenda

Major: No

CFR Citation: 38 CFR 17.38 Legal Authority: 38 U.S.C. 1710

Legal Deadline: None

Timetable:

Date FR Cite Action

NPRM 07/00/2022

Regulatory Flexibility Analysis Required: No Small Entities Affected: No Included in the Regulatory Plan: No

RIN Information URL: www.regulations.gov

RIN Data Printed in the FR: No

Agency Contact: Jillian Shipherd

Director of the LGBT Program for Patient Care Services

Department of Veterans Affairs 810 Vermont Avenue NW, Washington, DC 20420 Phone:857 364-5821 Email: jillian.shipherd@va.gov

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule Stage

Unfunded Mandates: No

Government Levels Affected: None

Federalism: No









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Publication ID: Fall 2022

Title: Removal of Exclusion of Gender Alterations From the Medical Benefits Package

Abstract:

VA

The Department of Veterans Affairs (VA) is proposing to revise its medical regulations by removing the exclusion on gender alterations from the medical benefits package. VA is proposing these changes so that transgender and gender diverse veterans may receive medically necessary health care, including surgical interventions for gender transition. This proposed change would be consistent with medical industry standards and would ensure that VA provides a full continuum of care to transgender and gender

Agency: Department of Veterans Affairs(VA)

RIN Status: Previously published in the Unified Agenda

Major: Yes

CFR Citation: 38 CFR 17.38 Legal Authority: 38 U.S.C. 1710

Legal Deadline: None

Timetable:

Date FR Cite Action

NPRM 12/00/2022

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No Included in the Regulatory Plan: No RIN Information URL: www.regulations.gov

RIN Data Printed in the FR: No

Agency Contact:

Veterans Health Administration VHA Department of Veterans Affairs 810 Vermont Avenue NW. Washington, DC 20420 Phone:202 461-5049

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule Stage

Unfunded Mandates: No

Government Levels Affected: None

Federalism: No







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VΑ RIN: 2900-AR34 Publication ID: Spring 2023

Title: Removal of Exclusion of Gender Alterations From the Medical Benefits Package

Abstract:

The Department of Veterans Affairs (VA) is proposing to revise its medical regulations by removing the exclusion on gender alterations from the medical benefits package. VA is proposing these changes so that transgender and gender diverse veterans may receive medically necessary health care, including surgical interventions for gender transition. This proposed change would be consistent with medical industry standards and would ensure that VA provides a full continuum of care to transgender and gender diverse veterans. These amendments are in accordance with the President's priorities that advance equity and support underserved, vulnerable, and marginalized communities.

Agency: Department of Veterans Affairs(VA)

RIN Status: Previously published in the Unified Agenda

Major: No

CFR Citation: 38 CFR 17.38 Legal Authority: 38 U.S.C. 1710

Legal Deadline: None

Timetable:

FR Cite Action Date

NPRM 10/00/2023

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Included in the Regulatory Plan: No RIN Information URL: www.regulations.gov

RIN Data Printed in the FR: No

Agency Contact:

Veterans Health Administration VHA Department of Veterans Affairs 810 Vermont Avenue NW, Washington, DC 20420 Phone:202 461-5049

Agenda Stage of Rulemaking: Proposed Rule Stage

Unfunded Mandates: No.

Priority: Other Significant

Government Levels Affected: None

Federalism: No









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Title: Removal of Exclusion of Gender Alterations from the Medical Benefits Package

Agency/Subagency: VA

Concluded Action: Consistent with Change

Legal Deadline: None **Publication Date:** Major: Yes

Regulatory Flexibility Analysis Required: No

Federalism Implications: No International Impacts: No

Pandemic Response: No

Stage: Proposed Rule Concluded Date: 09/07/2022 Section 3(f)(1) Significant *: No Economically Significant **: No

Unfunded Mandates: No

Related To Homeland Security: No

Small Entities Affected: No

Affordable Care Act [Pub. L. 111-148 & 111-152]: No

Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]:

No

* Following the issuance of E.O. 14094 on April 6, 2023, which amended Section 3(f)(1) of E.O. 12866, OIRA has designated regulatory actions as "Section 3(f)(1) Significant" if under that newly amended section of E.O. 14366 they are likely to result in a rule that may have an annual effect on the economy, of \$200 million or more (adjusted every 3 years by the Administrator of ORA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities. Áfter April 6, 2023, OIRÁ no longer designated regulatory actions as "Economically Significant."

** Between September 30, 1993, when E.O. 12866 was issued, and April 6, 2023, when E.O. 14094 was issued, OIRA designated regulatory actions as "Economically Significant" if under Section 3(f)(1) of E.O. 12866 they were likely to result in a rule that may have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities









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RIN: 2900-AR34 Publication ID: Fall 2023 VA

Title: Removal of Exclusion of Gender Alterations From the Medical Benefits Package

Abstract:

The Department of Veterans Affairs (VA) is proposing to revise its medical regulations by removing the exclusion on gender alterations from the medical benefits package. VA is proposing these changes so that transgender and gender diverse veterans may receive medically necessary health care, including surgical interventions for gender transition. This proposed change would be consistent with medical industry standards and would ensure that VA provides a full continuum of care to transgender and gender

Agency: Department of Veterans Affairs(VA)

RIN Status: Previously published in the Unified Agenda

Major: No

CFR Citation: 38 CFR 17.38 Legal Authority: 38 U.S.C. 1710

Legal Deadline: None

Timetable:

Date **FR Cite** Action

NPRM 11/00/2023

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No Included in the Regulatory Plan: No RIN Information URL: www.regulations.gov

RIN Data Printed in the FR: No

Agency Contact:

Veterans Health Administration VHA Department of Veterans Affairs 810 Vermont Avenue NW. Washington, DC 20420 Phone:202 461-5049

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule Stage

Unfunded Mandates: No

Government Levels Affected: None

Federalism: No







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No. 24-___

In the United States Court of Appeals for the Federal Circuit

IN RE TRANSGENDER AMERICAN VETERANS ASSOCIATION, Petitioner.

APPENDIX VOLUME II (399-588)

Michael J. Wishnie

Counsel of Record

VETERANS LEGAL SERVICES

CLINIC

JEROME N. FRANK LEGAL

SERVICES ORGANIZATION

YALE LAW SCHOOL

P.O. Box 209090

New Haven, CT 06520-9090

(203) 436-4780

michael.wishnie@ylsclinics.org

Counsel for Petitioner

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- 91-95: Transgender Military Service in the United States, U.C.L.A. WILLIAMS INST. (May 2014), https://williamsinstitute.law.ucla.edu/publications/transmilitary-service-us.
- **96-104**: Matthew Rae et al., *Demographics, Insurance Coverage, and Access to Individuals Among Transgender Adults*, KFF (Oct. 21, 2020), https://www.kff.org/health-reform/issue-brief/demographics-insurance-coverage-and-access-to-care-among-transgender-adults.
- 105-107: Veterans with Transgender and Gender Diverse Identities, U.S. DEP'T VETERANS AFFS., https://www.mentalhealth.va.gov/communityproviders/veteranstransgender.asp.
- 108-115: Anthony N. Almazan & Alex S. Keuroghlian, *Association Between Gender-Affirming Surgeries and Mental Health Outcomes*, 156 J. Am. MED. ASS'N 611 (2021).
- 116-158: VA OFFICE OF MENTAL HEALTH AND SUICIDE PREVENTION, NATIONAL VETERAN SUICIDE PREVENTION ANNUAL REPORT (2022), https://www.mentalhealth.va.gov/docs/data-sheets/2022/2022-National-Veteran-Suicide-Prevention-Annual-Report-FINAL-508.pdf.
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- 176-177: Nicole Comstock, *California Veteran Shares Story of Gender Transition*, FOX40 (May 11, 2015), http://fox40.com/2015/05/11/california-veteran-shares-story-of-gender-transition.
- 178-183: VHA LGBTQ+ Health Program, U.S. DEP'T VETERANS AFFS., https://www.patientcare.va.gov/lgbt.

¹ Some items in the appendix are taken from the appendices in *Fulcher v. Sec'y of Veterans Affs.* (No. 2017-1460) (Fed. Cir.). The Bates numbers on these items have been struck through in red.

- **184-236**: Petition for Review, Fulcher v. Sec'y of Veterans Affs. (No. 2017-1460) (Fed. Cir. June 21, 2017).
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- **309-362**: Response Brief, Fulcher v. Sec'y of Veterans Affs. (No. 2017-1460) (Fed. Cir. Nov. 28, 2017).
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- **364-365**: 83 Fed. Reg. 31711 (July 9, 2018).
- 366-370: Motion to Voluntarily Dismiss, Fulcher v. Sec'y of Veterans Affs. (No. 2017-1460) (Fed. Cir. July 27, 2018).
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- **373-376**: Leo Shane III, *VA to Offer Gender Surgery to Transgender Veterans for the First Time*, MIL. TIMES (June 19, 2021), https://www.militarytimes.com/veterans/2021/06/19/va-to-offer-gender-surgery-to-transgender-vets-for-the-first-time.
- 377-378: External FAQs: Removing "Gender Alterations" Exclusion from the Medical Benefits Package, U.S. DEP'T VETERANS AFFS. (June 18, 2021), https://www.patientcare.va.gov/LGBT/docs/Transgender-Care-External-FAQs-18June21.pdf.
- **379-383**: Leo Shane III, *After Two Years, Still No Timeline for Transgender Surgeries at VA*, Mil. Times (June 20, 2023), https://www.militarytimes.com/veterans/2023/06/20/after-two-years-still-no-timeline-for-transgender-surgeries-at-va.
- **384-392**: *Town Hall with VA Secretary Denis McDonough*, VA NEWS (Nov. 8, 2023), https://news.va.gov/125963/town-hall-with-va-secretary-denismcdonough-2.
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- **396**: *RIN 2900-AR34*, OFF. INFO. & REGUL. AFFS. (Spring 2023), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN =2900-AR34.
- **397**: OIRA Conclusion of EO 12866 Regulatory Review RIN: 2900-AR34, OFF. INFO. & REGUL. AFFS. (Sept. 7, 2022), https://www.reginfo.gov/public/do/eoDetails?rrid=238661.
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- **440-474**: William Byne et al., *Report of the APA Task Force on Treatment of Gender Identity Disorder*, 169 Am. J. PSYCHIATRY 1 (2012).
- 475-509: Wylie C. Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102 J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869 (2017).
- 510-542: Am. Psych. Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (Dec. 2015).
- 543-547: Letter from Michael Wishnie, Counsel for TAVA, to U.S. Dep't of Veterans Affs. Acting General Counsel Richard J. Hipolit (November 20, 2023).
- **548**: Letter from U.S. Dep't of Veterans Affs. Acting General Counsel Richard J. Hipolit to Ilona Turner & Sasha Buchert, Former Counsel for TAVA (December 22, 2023).
- **549-552**: Frequently Asked Questions, REGULATIONS.GOV, https://www.regulations.gov/faq.
- **553-563**: Off. of the Sec'y, *Economic Impact Analysis for RIN 2900-AP69*, *Removing Gender Alterations Restriction from the Medical Benefits Package*, U.S. DEP'T VETERANS AFFS. (July 29, 2016).
- **564-575**: Am. Psychiatric Ass'n, *Gender Dysphoria*, *in* Diagnostic and Statistical Manual of Mental Disorders, Text Revisions 164.0 (5th ed. 2022).
- 576-579: Declaration of Natalie Rose Katner.

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580-583: Declaration of Ray Gibson.584-588: Declaration of Rebekka Eshler.

EXPERT DECLARATION OF DR. MARCI L. BOWERS

1. I, Marci L. Bowers, MD have been asked to provide my expert medical opinion regarding the efficacy and appropriateness of sex reassignment surgery ("SRS") as a medically necessary treatment for gender dysphoria. I have actual knowledge of the matters stated herein and could and would so testify if called as a witness.

QUALIFICATIONS AND BACKGROUND

- 2. I am a pelvic and gynecologic surgeon with over 25 years' experience. I was the former Department Chairperson at Swedish Medical Center (Providence) in Seattle, where I practiced as an Obstetrician/Gynecologist for 20 years, delivering more than 2,200 babies. I currently practice general gynecology and surgery and am the first North American gynecologic surgeon trained to functionally reverse female genital cutting.
 - 3. I am board certified by the American Board of Obstetrics & Gynecology.
 - 4. I am licensed to practice medicine in the states of Washington and California.
- 5. I have completed over 3,000 sex reassignment surgeries and perform approximately 220 other surgeries related to gender transition annually. Around 90% of the surgeries have been for people transitioning from male to female.
- 6. I received my bachelor's degree in Medical Microbiology (1980) from the University of Wisconsin, Madison, WI, and my medical degree (1986) from the University of Minnesota, Minneapolis, MN. I completed my residency (1986-1990) in Obstetrics/Gynecology at the University of Washington, Seattle, WA.
- 7. I am a current member of the European Academy of Sciences. I was honored as one of the Best Doctors in America (2002-2004), awarded the Chief Resident Award for Teaching Excellence (1986-1990), and was President of the University of Minnesota Medical Student Council (1985-1986).
- 8. I frequently speak at medical schools across the United States and with media on the subject of SRS. I have demonstrated SRS surgical techniques for plastic surgeons and urologists in Australia, Belgium, Brazil, China, Israel, Mexico, Serbia and other countries.
 - 9. I have published three chapters in books related to sex reassignment surgery:
- "Complications of Male-to-Female Vaginoplasty" in MANAGEMENT OF GENDER DYSPHORIA: A MULTIDISCIPLINARY APPROACH. Trombetta et al. (Eds.), 2015.
- "Transgender Surgery" in TRANS BODIES, TRANS SELVES: A RESOURCE FOR THE TRANSGENDER COMMUNITY. Erickson-Schroth (Ed.), 2014.
- "Male-to-female Vaginoplasty" in AESTHETIC GYNECOLOGY. Goodman, Alsinrod, et al. (Eds.), 2016.
- 10. I have not provided deposition or trial testimony as an expert witness in the past four years.

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- 11. I am providing my expert consulting services in this case pro bono.
- 12. A copy of my curriculum vitae is attached as Exhibit A.

OPINIONS

13. In forming my opinions, I have relied on my scientific education and training, my knowledge of the scientific literature in the pertinent fields, and my extensive clinical experience in treating patients with sex reassignment surgery. Based on my review of the foregoing, and for reasons set forth in more detail below, my opinions are the following:

I. Sex Reassignment Surgery

- 14. For transgender female patients, sex reassignment surgery commonly includes orchiectomy (removal of the testes) and vaginoplasty, and may also include breast augmentation, tracheal shaving (chondrolaryngoplasty), and facial feminization surgery.
- 15. Vaginoplasty is often seen as the definitive male-to-female sex reassignment surgery. It involves a variety of procedures including an orchiectomy, removal of the penis, creation of a vaginal cavity, a procedure to line the cavity, the shortening of the urethra, and the construction of the labia and a clitoris. The vagina should have a hairless epithelium (the tissue lining the inside of the vagina) and should have an adequate depth and diameter in order to function properly.
- 16. The procedure was first developed in 1933, and has evolved in the years since. In the 1950s, Dr. Georges Burou, a gynecologist, pioneered the modern vaginoplasty technique known as "penile inversion." Other leading surgeons performing the procedure included Dr. Stanley Biber, who provided over 4,000 sex reassignment surgeries from 1969 until the mid-2000s, and Drs. Yvan Menard and Pierre Brassard.
- 17. I worked closely with Drs. Biber and Brassard during 2003-2005. Under their tutelage, I developed a "one-stage procedure" for vaginoplasty with the basic principles of embryology in mind. As everyone has female genitalia early in gestation, the goal of the procedure is to reverse the current anatomy to its earlier configuration and to create a vagina as feminine in function and appearance as possible. The procedure is a version of the original "penile inversion technique," modified to include the use of scrotal skin grafting to line the vagina, and other advances. The two-stage procedure included one stage for function and a second stage designed to improve appearance and define the labia and clitoral hood. Utilizing the mucosa of the urethra, the one-stage procedure utilizes tissue that is sensory and secretory, pink and non-hair bearing to line the inner labia. The procedure is the most compatible with the normal developmental process the patient would have undergone had the patient been born with female genitals.
- 18. I typically see patients twice after a surgery: first to instruct them on dilation, and then again shortly before they return home. I also see patients at any other time, if needed. Patients usually return home within two weeks of surgery and are shifted to the care of a primary care physician. All patients are given detailed instructions on what to expect and a guide to

possible complications. I encourage patients to see their primary care physician one month following the surgery or sooner if needed. I also urge patients to implement a long-term follow up plan that will include a Pap smear at a frequency similar to that of a natal woman who has had a hysterectomy and a speculum examination once yearly at minimum.

- 19. For transgender male patients, sex reassignment surgeries may include chest reconstruction (mastectomy and reconstruction), metoidioplasty, phalloplasty, scrotoplasty, hysterectomy, and vaginectomy, among other surgical treatments. Of those, I regularly provide hysterectomies, vaginectomies, metoidioplasties, and scrotoplasties. I have performed over 2000 hysterectomies and over 350 metoidioplasties.
- 20. A hysterectomy usually includes removal of both ovaries and fallopian tubes (salingo-oophrectomy). The procedure can be performed from below (vaginal) or through the abdomen. The hysterectomy procedures I have performed on transgender men do not differ significantly from the hysterectomy procedures I have performed on women. When I have performed hysterectomy procedures on transgender men, the primary diagnosis is to treat gender dysphoria, rather than a gynecological diagnosis. When I have performed hysterectomy procedures on women, the medical necessity arises from pathology. Although many transgender men do not have a gynecological diagnosis, I have found in my practice that 15-20% will find incidental pathology at the time of the hysterectomy, meaning the post-surgical pathology report indicates pathology that was undetected prior to surgery, such as endometriosis, fibroids, precancerous conditions of the uterus or cervix such as dysplasia or ovarian cysts, tumors, or adhesive disease. The procedure for transgender men does not differ in price from hysterectomies performed on women. In fact, it may be cheaper since there is generally less pathology and therefore, the procedure is generally less complicated and less time-consuming.
- 21. The simple metoidioplasty ("SM") is a release of the testosterone-enlarged clitoris/phallus from the labia minora. The released hood is sewn along the midline undersurface to fashion a male penis. The penis is bulked by use of the labial subcutaneous tissue and levator musculature. A final length of 3-8 centimeters in length for the penis can be expected although without the ability to urinate through the phallus. The procedure is reasonably free of complications and inexpensive. It is performed as an outpatient procedure and can be combined with scrotoplasty in the same surgery.
- 22. Vaginectomy is the removal or obliteration of the vaginal walls, which allows full surgical closure of the vagina. It may be provided either alone or in combination with hysterectomy or metoidioplasty. One advantage of vaginal closure is to allow positioning of the testicles to a more masculine scrotal shape.
- 23. Scrotoplasty is the construction of a testicle implant laden scrotal sac, also known as testicle implants. The procedure can be combined with SM or done as a separate procedure. If done in combination with SM, the original incisions allow the implants to be placed through a single incision hidden in the midline between the testicles.
- 24. Most of the procedures that constitute SRS also are performed to treat conditions other than gender dysphoria, and most of these procedures are substantially similar when



performed as part of SRS and when performed for other medical reasons. For example, a vaginoplasty performed as part of SRS does not differ substantially from a vaginoplasty performed to address certain intersex conditions. Penectomies, orchiectomies, mastectomies, vaginectomies and hysterectomies performed as part of SRS do not differ substantially when these procedures are performed to address tissue pathology. Likewise, scrotoplasties and breast enlargement procedures performed as part of SRS are similar when performed for reconstructive purposes.

II. Requirements for Genital Sex Reassignment Surgery

- 25. Before performing SRS, I conduct an extensive consultation to review all of the inclusion criteria and to make certain that patients are aware of each aspect of the procedure. In making this assessment, I adhere to the guidelines established by the internationally recognized standards of care for transgender health care promulgated by the World Professional Association of Transgender Health ("WPATH").
- 26. For genital SRS, in accordance with the WPATH standards of care, I require that the patient have two referrals from qualified mental health professionals who have independently assessed the patient.
- 27. Certain medical concerns may delay surgery, such as serious cardiac issues, significant obesity, or a smoking habit. The risk of surgical complications for smokers is much higher, and tissue healing following surgery is much slower. I treat patients who have been diagnosed as HIV-positive or with Hepatitis C unless they are not receiving the appropriate treatment protocol for those co-existing conditions.
- 28. Psychiatric diagnoses generally do not preclude treatment and, in fact, those conditions generally improve after SRS.
- 29. The age of the patient by itself is not a determining factor, although the patient must be the legal age of majority in the jurisdiction.
- 30. Other requirements include that the patient demonstrate an understanding of the surgery, its potential complications and post-surgical complications and the required length of stay in the hospital.

III. Efficacy of Sex Reassignment Surgery

- 31. The vast majority of studies have shown that sex reassignment surgery is clinically effective. In my professional experience, the success rate of SRS is extremely high. A useful measure of the success rate of SRS is the rate of regret expressed by patients after receiving SRS. It is exceedingly rare for a patient to express regret following the treatment, and when they do it generally relates to issues of societal discrimination and relationship difficulties. Indeed, in my professional experience, patients who have had sex reassignment surgery have less regret than any other surgery of which I am aware.
- 32. Sex reassignment surgery has a very low rate of complications, and the complications that may result from sex reassignment surgery are mainly minor in nature.



33. My clinic contacts patients one year after their surgery to determine the impact on their life, and an overwhelming majority of patients report less self-loathing and significantly more confidence and well-being. Many patients report a dramatic improvement in mental health following surgery, and patients have been able to become productive members of society, no longer disabled with severe depression and gender dysphoria.

VI. Sex Reassignment Surgery Is Medically Necessary Treatment

- 34. Although some transgender people are able to treat their gender dysphoria effectively through other treatments, sex reassignment surgery for many is medically necessary to treat the individual's gender dysphoria and establish congruence between the individual's physical features and gender identity.
- 35. Sex reassignment surgery is not an "experimental" or "cosmetic" procedure. Many thousands of gender corrective surgeries have been performed worldwide for decades, and the treatment is in no way "experimental." Rather, sex reassignment surgery has been shown to be a life-saving procedure and is unequivocally medically necessary.
- 36. The American Medical Association ("AMA"), the preeminent health care organization in the United States, and the American Psychiatric Association and other health care organizations have issued resolutions supporting coverage of sex reassignment surgery as a medically necessary treatment for gender dysphoria.
- 37. It is vital that patients with severe gender dysphoria have access to sex-reassignment surgery in a timely manner. Gender dysphoria, if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death. As stated in the AMA resolution, "delays in access to appropriate medical care for gender identity disorder can result in significant psychological distress including debilitating depression, suicidality and death."
- 38. MediCal is California's version of the federal Medicaid program, which provides health coverage for low-income people and people with disabilities. MediCal covers sex reassignment surgery as a medically necessary treatment. I have a contract with the San Francisco Health Plan and also contract with other county MediCal administrators in California to provide SRS and other transition-related surgeries. We have performed operations on approximately two dozen MediCal contracted patients to date, all with relatively positive outcomes.

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I declare under penalty of perjury that the foregoing is true and correct.

Dated: 7, 2016 Marci L. Bowers, MD

EXHIBIT A

Marci L. Bowers, MD

345 Lorton Avenue, Suite 101 Burlingame, CA 94010 Phone: 650-570-2270 Fax: 650-570-2283

marcibdoc@gmail.com

EDUCATION

1980 Bachelor of Sciences in Medical Microbiology University of Wisconsin Madison, WI

1986 Medical Degree University of Minnesota, Minneapolis, MN

RESIDENCY

1986 – 1990 Obstetrics/Gynecology Residency University of Washington Seattle, WA

BOARD CERTIFICATION

Board Certified, American Board of Obstetrics & Gynecology 1992, 2004-present

LICENSURE

Washington, California

PROFESSIONAL EXPERIENCE

1990 – 2002 The Polyclinic Obstetrics and Gynecology 1145 Broadway Seattle, WA 98122-4299

2002 – Present Seattle Reproductive Healthcare Obstetrics and Gynecology 1229 Madison Street Suite #840 Seattle, WA 98104

2003 – 2010 Trinidad Reproductive Healthcare 328 Bonaventure Street, Suite #2 Trinidad, CO 81082

2010 – present Bay Area Reproductive Healthcare and Surgery 345 Lorton Ave Suite #101, Burlingame, CA 94010

HOSPITAL AFFILIATIONS

1990 – 2003 Swedish Hospital Medical Center/Seattle, WA

2003 – 2011 Mount San Rafael Hospital, Trinidad, CO

2010 – present Mills-Peninsula Medical Center (Sutter Health), Burlingame, CA

PROFESSIONAL MEMBERSHIPS

Fellow,

American College of Obstetrics & Gynecology

Member, San Mateo Medical Association

Member,

World Professional Association for Transgender Health

COMMITTEES

1983 - 1984

Representative, Medical School Educational Policy Committee University of Minnesota, MN

1993 - 1995

Chairperson, Quality Assurance Committee (CQI) Department of Obstetrics/Gynecology Swedish Medical Center (Providence), Seattle, WA

1996-1998 Chairperson, Department of OB/GYN Swedish (Providence) Medical Center

2002 – 2008 Advisory Board Midwives' Association of Washington State

2007 – 2009 Chief of Surgery Mt. San Rafael Hospital

2011 – present National Board of Directors GLAAD

2011 – present National Board of Directors Transgender Law Center (TLC)

HONORS AND AWARDS

1984 – 1985 President University of Minnesota Medical School Minneapolis, MN

1985 – 1986 President, Medical Student Council University of Minnesota Minneapolis, MN

1986 – 1990 Chief Resident Award for Teaching Excellence University of Washington, Obstetrics & Gynecology Seattle, WA

1990 – 1998 Family Practice Teaching Awards Providence Medical Center, Seattle, WA Swedish Medical Center, Seattle, WA

2002 – 2004 Best Doctors in America American Research Council

2003 – present Member-Elect European Academy of Sciences

PUBLICATIONS

Management of Gender Dysphoria: A Multidisciplinary Approach; "Complications of Male-to-Female Vaginoplasty", 2014.

Trans Bodies Trans Selves; "Transgender Surgery", 2014.

MEDIA APPEARANCES

2004 CSI: Las Vegas 100th episode

2007 The Oprah Winfrey Show

2008 CBS Sunday Morning

2009 CNN

2008-2011 The Tyra Banks Show (5 appearances)

2012 The Doctors Show

2014 BBC

EXPERT DECLARATION OF DR. RANDI C. ETTNER

1. I, Randi C. Ettner, have been retained by counsel for the Transgender American Veterans Association ("TAVA") in connection with its petition to the Secretary of the Department of Veterans Affairs for rulemaking to promulgate regulations governing provision of sex reassignment surgery to transgender veterans. TAVA's counsel have asked me to provide my expert opinion regarding whether there is any basis in medicine or science for the Veterans Health Administration's policy of excluding sex reassignment surgery from the medical benefits package offered to veterans. This exclusion is embodied in regulation 38 C.F.R. § 17.38(c) ("Section 17.38") and in the current implementing directive for that regulation, VHA Directive 2013-003 (Feb. 8, 2013). My conclusion is that this exclusion for sex reassignment surgery has no medical or scientific basis. I base this conclusion on: (i) scientific research on gender dysphoria and its impact on the health and well-being of individuals with that diagnosis; and (ii) information regarding best practices and the generally accepted standards of care for individuals with gender dysphoria, including the efficacy of sex reassignment surgery as a treatment for gender dysphoria. I have actual knowledge of the matters stated herein, except where otherwise stated, and could and would so testify if called as a witness.

I. QUALIFICATIONS

2. I received my doctorate in psychology from Northwestern University in 1979. I have been the chief psychologist at the Chicago Gender Center since 2005, which specializes in the treatment of individuals with gender dysphoria. I have been involved in treating patients

Section 17.38 reads, in relevant part, "In addition to the care specifically excluded from the "medical benefits package" under paragraphs (a) and (b) of this section, the "medical benefits package" does not include the following: ... (4) Gender alterations."

with gender dysphoria² since 1977, when I was an intern at the Cook County Hospital in Chicago, Illinois.

- 3. During the course of my career, I have evaluated and/or treated between 2,500 and 3,000 individuals with gender dysphoria and mental health issues related to gender variance.
- 4. I have published four books related to the treatment of individuals with gender dysphoria, including the medical text entitled *Principles of Transgender Medicine and Surgery*. (Ettner, Monstrey & Eyler, 2007) and the second edition (Ettner, Monstrey & Coleman, 2016). In addition, I have authored numerous articles in peer-reviewed journals regarding the provision of health care to this population. I have served as a member of the University of Chicago Gender Board, and am a member of the editorial boards for the *International Journal of Transgenderism* and *Transgender Health*.
- 5. I am a member of the Board of Directors of the World Professional Association for Transgender Health (WPATH) (formerly the Harry Benjamin International Gender Dysphoria Association) and an author of the WPATH Standards of Care for the Health of Transsexual, Transgender and Gender-nonconforming People, 7th version, published in 2012. The WPATH-promulgated Standards of Care ("Standards of Care") are the internationally recognized guidelines for the treatment of persons with gender dysphoria and serve to inform medical treatment in the United States and throughout the world.
- 6. I have lectured throughout North America, Europe and Asia on topics related to gender dysphoria. On numerous occasions, I have given grand rounds presentations on gender dysphoria at medical hospitals.

The American Psychiatric Association published a revised version of its Diagnostic and Statistical Manual of Mental Disorders in 2013, which replaced the "gender identity disorder" diagnosis with "gender dysphoria." For consistency, I will refer to the condition as "gender dysphoria" throughout my report, even when making reference to the condition prior to 2013.

7. I have been retained as an expert regarding gender dysphoria and the treatment of gender dysphoria in multiple court cases and administrative proceedings. I was deposed as an expert in three cases over the past ten years: *Fields v. Smith*, No. 06-C-112 (E.D. Wis. 2006), *Doe v. Clenchy*, No. CV-09-2011 (Me. Super. Ct. Nov. 20, 2012), and *Kothmann v. Rosario*, 558 F. App'x 907 (11th Cir. 2014).

- 8. My fees in this case are as follows: \$265 USD per hour for consulting; \$395 USD per hour for deposition and trial testimony; and \$900 USD per day for travel time spent out of the office. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.
- 9. A true and correct copy of my Curriculum Vitae, which provides a complete overview of my education, training, and work experience, and a full list of my publications, is attached hereto as Exhibit A.

II. MATERIALS CONSIDERED

10. I have considered information from various sources in forming my opinions expressed herein, in addition to drawing on my extensive experience and review of the literature related to gender dysphoria over the past three decades. A complete bibliography of the materials referenced in this report is attached hereto as Exhibit B. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject.

III. BACKGROUND INFORMATION ON GENDER DYSPHORIA

11. Scientific and clinical evidence of gender dysphoria and current medical standards of care for the treatment of gender dysphoria make clear that Section 17.38(c) and its 2013 implementing directive lack any basis in medicine or science. The concept of "gender identity"

is well-established in medicine and refers to every person's deeply held understanding of the person's own gender. Gender identity is an innate aspect of personality that is firmly established, generally by the age of four, although individuals vary in the age at which they come to understand and express that identity.

- 12. Typically, people who are designated female at birth based on the appearance of their genitalia identify as girls or women, and people who are designated male at birth identify as boys or men. For transgender individuals, however, the person's gender identity differs from the sex assigned to that person at birth, and this incongruence gives rise to a sense of being "wrongly embodied."
- 13. The medical diagnosis for this feeling of incongruence is Gender Dysphoria, formerly known as Gender Identity Disorder. Gender dysphoria is a serious medical condition codified in the International Classification of Diseases, 10th revision (World Health Organization, 2010) and the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, 5th edition (American Psychiatric Association, 2013) ("DSM-5"). The condition is manifested by symptoms such as preoccupation with ridding oneself of primary and secondary sex characteristics. Untreated gender dysphoria can result in significant clinical distress, debilitating depression, and often suicidality. Gender dysphoria is also the psychiatric term used to describe the severe and unremitting emotional pain associated with the condition.
- 14. The diagnostic criteria for establishing a diagnosis of Gender Dysphoria in adults are set forth in the DSM-V (302.85):
 - A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

- 1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics.
- 2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender.
- 3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
- 4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
- 5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
- 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
- B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.
- 15. Adults who manifest a severe degree of such dysphoria are commonly referred to as "transsexual individuals" or "transgender individuals." Without treatment, individuals with gender dysphoria experience anxiety, depression, suicidality and other attendant mental health issues. (*See, e.g.*, Fraser, 2009; Schaefer & Wheeler, 2004; Ettner, 1999; Brown, 2000, DSM-5 (2013).) Many such individuals carry a burden of shame and low self-esteem, attributable to a feeling of being inherently "defective," and as a result become socially isolated. This isolation in turn leads to the stigmatization of such individuals, which over time proves ravaging to healthy personality development and interpersonal relationships. As a result, without treatment, many such individuals are unable to function effectively in occupational, social, or other important

areas of daily living. A recent survey shows a 41% rate of suicide attempts among transgender people, far above the baseline rates for North America. (Haas *et al.*, 2014.)

- 16. Transsexuals without access to appropriate care are often desperate for relief, and in some instances resort to self-surgery, such as life-threatening attempts at auto-castration (*i.e.*, the removal of one's testicles). (Brown, 2010; Brown & McDuffie, 2009.)
- 17. Gender dysphoria intensifies with age. Middle-aged and elderly gender dysphoric adults experience an exacerbation of symptoms. (Ettner, 2013; Ettner & Wiley, 2013.)

IV. TREATMENT OF GENDER DYSPHORIA

A. WPATH Standards of Care

- 18. The World Professional Association for Transgender Health ("WPATH") has established internationally accepted Standards of Care for treating gender dysphoria. The WPATH Standards of Care are recognized as authoritative by the American Medical Association, the Endocrine Society, and the American Psychological Association. (*See* Br. of Amici Curiae Medical and Mental Health Professionals at 6, Nos. 10-2339 and 10-2446 (7th Cir. Nov. 29, 2010), *available at* www.lambdalegal.org/sites/default/files/fields_v_smith_-_brief_of_amici_curiae_medical_and_mental_health_professionals.pdf; American Psychological Association Policy Statement on Transgender, Gender Identity, and Gender Expression Non-discrimination (2009).)³
- 19. The Standards of Care identify the following treatment protocols for treating individuals with gender dysphoria:

See also Wylie C. Hembree, Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline, J. of Clinical Endocrinology & Metabolism, 94:9, 3132-3154 (2009), available at http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.ffOiZnIN.dpuf.

Changes in gender expression and role (which may involve living part-time or full-time in another gender role, consistent with one's gender identity);

- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia;
 enhancing social and peer support; improving body image; or promoting resilience;
- Hormone therapy to feminize or masculinize the body; and
- Surgery to change primary and/or secondary sex characteristics (*e.g.*, breasts/chest, external and/or internal genitalia, facial features, body contouring).
- 20. Once a diagnosis of gender dysphoria is made, a treatment plan should be developed based on an individualized assessment of the medical needs of the particular patient. Treatment short of sex reassignment surgery, such as psychotherapy or counseling, and hormone therapy, can provide support and help with many of the issues that arise in tandem with gender dysphoria. Counseling and hormone therapy alone are not substitutes for surgical intervention where surgical intervention is needed. By analogy, for breast cancer, counseling might provide psychoeducation about treatment and prognosis, and information about nutrition, but it does not obviate the need for medically necessary surgical treatment.

B. Sex Reassignment Surgery

- 21. For many individuals with severe gender dysphoria, relief from their dysphoria cannot be achieved without surgical intervention to modify primary and/or secondary sex characteristics.
- 22. Genital reconstructive surgery, for example, has two therapeutic purposes. *First*, removal of the gonads (*i.e.*, testes or ovaries, which are hormone-producing organs) eliminates

the major source of hormone production in the body. *Second*, the patient attains body congruence by gaining normal appearing and functioning uro-genital structures that conform to the patient's gender. Achieving both purposes is critical to alleviating or eliminating gender dysphoria in many patients.

- 23. Contrary to some outdated speculation, sex reassignment surgery is neither experimental nor cosmetic—no major medical association considers sex reassignment surgery to be either. Decades of careful and methodologically sound scientific research have demonstrated that sex reassignment surgery is a safe and effective treatment for severe gender dysphoria, and indeed, for many people, it is the only effective treatment. (*See, e.g.*, Pfafflin & Junge, 1998; Smith *et al.*, 2005; Jarolim *et al.*, 2009.)
- American Psychiatric Association, and the American Psychological Association all support surgery in accordance with the WPATH Standards of Care as medically necessary treatment for individuals with severe gender dysphoria. *See* American Medical Association (2008), Resolution 122 (A-08) ("public and private health insurance coverage for treatment of gender identity disorder as recommended by the patient's physician"); Endocrine Society (Hembree, W. *et al.*, 2009), Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline ("For many transsexual adults, genital sex reassignment surgery may be the necessary step towards achieving their ultimate goal of living successfully in their desired gender role."); American Psychiatric Association (2012), Position Statement on Access to Care for Transgender and Gender Variant Individuals (the American Psychiatric Association "[r]ecognizes that appropriately evaluated transgender and gender variant individuals can benefit greatly from medical and surgical gender transition treatments"); American Psychological

Association (2009), Policy Statement on Transgender, Gender Identity and Gender Expression Nondiscrimination (recognizing "the efficacy, benefit and medical necessity of gender transition treatments" and referencing studies demonstrating the effectiveness of sex-reassignment surgeries).

- 25. Surgeries are considered "effective" from a medical perspective if they "have a therapeutic effect." (Monstrey *et al.*, 2007.)
- 26. More than three decades of research confirms that sex reassignment surgery is therapeutic and therefore an effective treatment for gender dysphoria. In a 1998 meta-analysis, Pfafflin and Junge reviewed data from 80 studies, spanning 30 years, from 12 countries. They concluded that "reassignment procedures were effective in relieving gender dysphoria. There were few negative consequences and all aspects of the reassignment process contributed to overwhelmingly positive outcomes." *Id*.
- 27. Numerous subsequent studies confirm this conclusion. Researchers reporting on a large-scale prospective study of 325 individuals in the Netherlands concluded that after surgery there was "a virtual absence of gender dysphoria" in the cohort and "results substantiate previous conclusions that sex reassignment is effective." (Smith *et al.*, 2005.) Indeed, the authors of the study concluded that the surgery "appeared therapeutic and beneficial" across a wide spectrum of factors, and "[t]he main symptom for which the patients had requested treatment, gender dysphoria, had decreased to such a degree that it had disappeared." (*Id.*)
- 28. In 2007, Gijs and Brewayes analyzed 18 studies published between 1990 and 2007, encompassing 807 patients. The researchers concluded: "Summarizing the results from the 18 outcome studies of the last two decades, the conclusion that [sex reassignment surgery] is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric

individuals still stands: Ninety-six percent of the persons who underwent [surgery] were satisfied and regret was rare." (*Id.*)

- 29. Studies conducted in countries throughout the world conclude that surgery is an extremely effective treatment for gender dysphoria. For example, a 2001 study published in Sweden states: "The vast majority of studies addressing outcome have provided convincing evidence for the benefit of sex reassignment surgery in carefully selected cases." (Landen, 2001.) Similarly, urologists at the University Hospital in Prague, Czech Republic, in a Journal of Sexual Medicine article concluded, "Surgical conversion of the genitalia is a safe and important phase of the treatment of male-to-female transsexuals." (Jarolim, 2009.)
- 30. Patient satisfaction is an important measure of effective treatment. Achieving functional and normal physical appearance consistent with gender identity alleviates the suffering of gender dysphoria and enables the patient to function in everyday life. Studies have shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, sex reassignment surgery improves virtually every facet of a patient's life. This includes satisfaction with interpersonal relationships and improved social functioning (Rehman *et al.*, 1999; Johansson *et al.*, 2010; Hepp *et al.*, 2002; Ainsworth & Spiegel, 2010; Smith *et al.*, 2005); improvement in self-image and satisfaction with body and physical appearance (Lawrence, 2003; Smith *et al.*, 2005; Weyers *et al.*, 2009); and greater acceptance and integration into the family (Lobato *et al.*, 2006).
- 31. Studies have also shown that surgery improves patients' abilities to initiate and maintain intimate relationships (Lobato *et al.*, 2006; Lawrence, 2005; Lawrence, 2006; Imbimbo *et al.*, 2009; Klein & Gorzalka, 2009; Jarolim *et al.*, 2009; Smith *et al.*, 2005; Rehman *et al.*, 1999; DeCuypere *et al.*, 2005).

32. Multiple long-term studies have confirmed these results. *See, e.g.*, "Transsexualism in Serbia: A Twenty-Year Follow-up Study" (Vujovic *et al.*, 2009); "Long-term Assessment of the Physical, Mental, and Sexual Health Among Transsexual Women" (Weyers, 2009); "Treatment Follow-up of Transsexual Patients" (Hepp *et al.*, 2002); "A Five-year Follow-up Study of Swedish Adults with Gender Identity Disorder" (Johansson *et al.*, 2010); "A Report from a Single Institute's 14-Year Experience in Treatment of Male-to-Female Transsexuals" (Imbimbo *et al.*, 2009); 'Followup of Sex Reassignment Surgery in Transsexuals: A Brazilian Cohort" (Lobato *et al.*, 2006).

- 33. Recognizing this consensus in the literature, in 2008, WPATH issued a "Medical Necessity Statement" stating: "These medical procedures and treatment protocols are not experimental: decades of both clinical and medical research show they are essential to achieving well-being for the transsexual patient." (World Professional Association for Transgender Health, 2008).
- 34. On May 30, 2014, the Appellate Division of the Departmental Appeals Board of the United States Department of Health and Human Services issued decision number 2576, in which the Board determined that a Medicare regulation denying coverage of "all transsexual surgery as a treatment for transsexualism" was not valid under the "reasonableness standard." (U.S. Dept. of Health and Human Services, 2014). The Board specifically concluded that "transsexual surgery is an effective treatment option for transsexualism in appropriate cases." *Id.*
- 35. Because of the overwhelming scientific evidence that transition-related care, including sex reassignment surgery, is medically necessary for the treatment of gender dysphoria in some patients, many of the leading medical and professional organizations have stated their opposition to exclusions of insurance coverage for that care, including the American Medical

Association, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, the American Psychiatric Association, and WPATH.⁴

36. Moreover, I understand that the Department of Veterans Affairs provides non-surgical medical care in connection with gender transition, including hormone therapy, and pre-and post-surgical care. In light of that, the surgical exclusion is particularly arbitrary. As described above, hormone therapy and other forms of non-surgical treatments are not substitutes for surgical intervention where such intervention is needed. I am aware of no support in the medical or scientific literature for policies that provide access to non-surgical care, while simultaneously maintaining a blanket exclusion of surgical care regardless of an individual's medical needs.

See (a) The American Medical Association, Resolution 122 (2008), attached as Exhibit C at 489 ("RESOLVED, That our American Medical Association support public and private health insurance coverage for treatment of gender identity disorder as recommended by the patient's physician."); (b) The American Academy of Family Physicians ("AAFP"), Summary of Actions: 2012 National Conference of Special Constituencies, Action on Resolution No. 1004, attached hereto in excerpted form as Exhibit D ("RESOLVED, [AAFP] supports efforts to require insurers to provide coverage for comprehensive care of transgendered individuals including ... when medically necessary, gender reassignment surgery."); (c) The American College of Obstetricians and Gynecologists, Committee Opinion of the Committee on Healthcare for Underserved Women, No. 512 (Dec. 2011), attached hereto as Exhibit E at 1 ("The American College of Obstetricians and Gynecologists opposes discrimination on the basis of gender identity and urges public and private health insurance plans to cover the treatment of gender identity disorder."); (d) The American Psychiatric Association, "Position Statement on Access to Care for Transgender and Gender Variant Individuals" (2012), attached hereto as Exhibit F (stating that the American Psychiatric Association "[a]dvocates for removal of barriers to care and supports both public and private health insurance coverage for gender transition treatment" and "[o]pposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician"); (e) The American Psychological Association, "Transgender, Gender Identity & Gender Expression Non-Discrimination" Policy Statement (Aug. 2008), attached hereto as Exhibit G at 26 ("BE IT FURTHER RESOLVED that APA recognizes the efficacy, benefit, and necessity of gender transition treatments for appropriately evaluated individuals and calls upon public and private insurers to cover these medically necessary treatments"); and (f) WPATH SOC, attached hereto as Exhibit H at 186 ("WPATH urges health insurance companies and other third-party payers to cover the medically necessary treatments to alleviate gender dysphoria").

V. CONCLUSION

37. Given the extensive scientific research, spanning decades, that supports the efficacy and necessity of sex reassignment surgery, it is clear that sex reassignment surgery is neither experimental nor cosmetic, but rather is a medically necessary treatment for gender dysphoria in patients prescribed this treatment. Accordingly, I am aware of no medical or scientific basis for the Department of Veterans Affairs' policy of excluding sex reassignment surgery from the medical benefits package offered to veterans. The exclusion embodied in Section 17.38 and its 2013 implementing directive has no basis in the scientific literature and is contrary to the medical consensus recognizing the efficacy and necessity of access to sex reassignment surgery.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: ________, 2016

Randi C. Ettner, Ph.D.

EXHIBIT A

RANDI ETTNER, PHD

1214 Lake Street Evanston, Illinois 60201 Tel 847-328-3433 Fax 847-328-5890 rettner@aol.com

POSITIONS HELD

Clinical Psychologist

Forensic Psychologist

Fellow and Diplomate in Clinical Evaluation, American Board of Psychological Specialties

Fellow and Diplomate in Trauma/PTSD

President, New Health Foundation Worldwide

Board of Directors, World Professional Association of Transgender Health (WPATH)

Chair, Committee for Incarcerated Persons, WPATH

University of Minnesota Medical Foundation: Leadership Council

Psychologist, Chicago Gender Center

Adjunct Faculty, Prescott College

Editorial Board, International Journal of Transgenderism

Editorial Board, *Transgender Health*

Television and radio guest (more than 100 national and international appearances)

Internationally syndicated columnist

Private practitioner

Medical staff privileges attending psychologist; Advocate Lutheran General Hospital

EDUCATION

PhD, 1979 Northwestern University (with honors)

Evanston, Illinois

MA, 1976 Roosevelt University (with honors)

Chicago, Illinois

Major: Clinical Psychology

BA, 1969-72 Indiana University (cum laude)

Bloomington, Indiana

Major: psychology, Minor: sociology

1972 Moray College of Education

Edinburgh, Scotland

International Education Program

1970 Harvard University

Cambridge, Massachusetts

Social relation undergraduate summer program in

group dynamics and processes

CLINICAL AND PROFESSIONAL EXPERIENCE

2016 Psychologist: Chicago Gender Center

Consultant: Walgreens; Tawani Enterprises

Private practitioner

2011 Instructor, Prescott College: Gender - A multidimensional

approach

2000 Instructor, Illinois Professional School of Psychology

1995-present Supervision of clinicians in counseling gender non-conforming

clients

1993 Post-doctoral continuing education with Dr. James Butcher in

MMPI-2 interpretation University of Minnesota

1992 Continuing advanced tutorial with Dr. Leah Schaefer in

psychotherapy

1983-1984 Staff psychologist, Women's Health Center, St. Francis

Hospital, Evanston, Illinois

1981-1984 Instructor, Roosevelt University, Department of Psychology:

Psychology of Women, Tests and Measurements, Clinical

Psychology, Personal Growth, Personality Theories,

Abnormal Psychology

1976-1978 Research Associate, Cook County Hospital, Chicago, Illinois

Department of Psychiatry

1975-1977 Clinical Internship, Cook County Hospital, Chicago, Illinois,

Department of Psychiatry

1971 Research Associate, Department of Psychology, Indiana

University

1970-1972 Teaching Assistant in Experimental and Introductory

Psychology Department of Psychology, Indiana University

1969-1971 Experimental Psychology Laboratory Assistant, Department of



Psychology, Indiana University

LECTURES AND HOSPITAL GRAND ROUNDS PRESENTATIONS

Foundations in mental health; role of the mental health professional in legal and policy issues, WPATH global education initiative, Chicago, 2015; Atlanta, 2016; The transitioning client, Springfield, MO, 2016

*Pre-operative evaluation in gender-affirming surgery-*American Society of Plastic Surgeons, 2015

Gender affirming psychotherapy; Assessment and referrals for surgery-Standards of Care- Fenway Health Clinic, Boston, 2015

Gender reassignment surgery- Midwestern Association of Plastic Surgeons, 2015

Adult development and quality of life in transgender healthcare- Eunice Kennedy Shriver National Institute of Child Health and Human Development, 2015

Healthcare for transgender inmates- American Academy of Psychiatry and the Law, 2014

Supporting transgender students: best school practices for success- American Civil Liberties Union of Illinois and Illinois Safe School Alliance, 2014

Addressing the needs of transgender students on campus- Prescott College, 2014

The role of the behavioral psychologist in transgender healthcare – Gay and Lesbian Medical Association, 2013

Understanding transgender- Nielsen Corporation, Chicago, Illinois, 2013;

Role of the forensic psychologist in transgender care; Care of the aging transgender patient- University of California San Francisco, Center for Excellence, 2013

Evidence-based care of transgendered patients- North Shore University Health Systems, University of Chicago, Illinois, 2011; Roosevelt-St. Vincent Hospital, New York; Columbia Presbyterian Hospital, Columbia University, New York, 2011

Children of Transsexuals-International Association of Sex Researchers, Ottawa, Canada, 2005; Chicago School of Professional Psychology, 2005

Gender and the Law- DePaul University College of Law, Chicago, Illinois, 2003; American Bar Association annual meeting, New York, 2000



Gender Identity and Clinical Issues – WPATH Symposium, Bangkok, Thailand, 2014; Argosy College, Chicago, Illinois, 2010; Cultural Impact Conference, Chicago, Illinois, 2005; Weiss Hospital, Department of Surgery, Chicago, Illinois, 2005; Resurrection Hospital Ethics Committee, Evanston, Illinois, 2005; Wisconsin Public Schools, Sheboygan, Wisconsin, 2004, 2006, 2009; Rush North Shore Hospital, Skokie, Illinois, 2004; Nine Circles Community Health Centre, University of Winnipeg, Winnipeg, Canada, 2003; James H. Quillen VA Medical Center, East Tennessee State University, Johnson City, Tennessee, 2002; Sixth European Federation of Sexology, Cyprus, 2002; Fifteenth World Congress of Sexology, Paris, France, 2001; Illinois School of Professional Psychology, Chicago, Illinois 2001; Lesbian Community Cancer Project, Chicago, Illinois 2000; Emory University Student Residence Hall, Atlanta, Georgia, 1999; Parents, Families and Friends of Lesbians and Gays National Convention, Chicago, Illinois, 1998; In the Family Psychotherapy Network National Convention, San Francisco, California, 1998; Evanston City Council, Evanston, Illinois 1997; Howard Brown Community Center, Chicago, Illinois, 1995; YWCA Women's Shelter, Evanston, Illinois, 1995; Center for Addictive Problems, Chicago, 1994

Psychosocial Assessment of Risk and Intervention Strategies in Prenatal Patients- St. Francis Hospital, Center for Women's Health, Evanston, Illinois, 1984; Purdue University School of Nursing, West Layette, Indiana, 1980

Psychonueroimmunology and Cancer Treatment- St. Francis Hospital, Evanston, Illinois, 1984

Psychosexual Factors in Women's Health- St. Francis Hospital, Center for Women's Health, Evanston, Illinois, 1984

Sexual Dysfunction in Medical Practice- St. Francis Hospital, Dept. of OB/GYN, Evanston, Illinois, 1980

Sleep Apnea - St. Francis Hospital, Evanston, Illinois, 1996; Lincolnwood Public Library, Lincolnwood, Illinois, 1996

The Role of Denial in Dialysis Patients - Cook County Hospital, Department of Psychiatry, Chicago, Illinois, 1977

PUBLICATIONS

Ettner, R. & Guillamon, A. Theories of the etiology of transgenderism. In <u>Principles of Transgender Medicine and Surgery</u>. Ettner, Monstrey & Coleman (Eds.), 2nd edition; Routledge, June, 2016.

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PROFESSIONAL AFFILIATIONS

University of Minnesota Medical School –Leadership Council
American College of Forensic Psychologists
World Professional Association for Transgender Health
World Health Organization (WHO) Global Access Practice Network
TransNet national network for transgender research
American Psychological Association
American College of Forensic Examiners
Society for the Scientific Study of Sexuality
Screenwriters and Actors Guild
Phi Beta Kappa

AWARDS AND HONORS

The Randi and Fred Ettner Transgender Health Fellowship-Program in Human Sexuality, University of Minnesota, 2016

Phi Beta Kappa, 1971
Indiana University Women's Honor Society, 1969-1972
Indiana University Honors Program, 9-1972
Merit Scholarship Recipient, 1970-1972
Indiana University Department of Psychology Outstanding Undergraduate Award Recipient, 1970-1972
Representative, Student Governing Commission, Indiana University, 1970

LICENSE

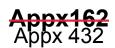
Clinical Psychologist, State of Illinois, 1980



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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 122

(A-08)

Introduced by: Resident and Fellow Section, Massachusettes Medical Society, California

Medical Association, Medical Society of the State of New York

Subject: Removing Financial Barriers to Care for Transgender Patients

Referred to: Reference Committee A

Whereas, The American Medical Association opposes discrimination on the basis of gender identity¹ and

Whereas, Gender Identity Disorder (GID) is a serious medical condition recognized as such in both the Diagnostic and Statistical Manual of Mental Disorders (4th Ed., Text Revision) (DSM-IV-TR) and the International Classification of Diseases (10th Revision),² and is characterized in the DSM-IV-TR as a persistent discomfort with one's assigned sex and with one's primary and secondary sex characteristics, which causes intense emotional pain and suffering;³ and

Whereas, GID, if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death;⁴ and

Whereas, The World Professional Association For Transgender Health, Inc. ("WPATH") is the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders, and has established internationally accepted Standards of Care for providing medical treatment for people with GID, including mental health care, hormone therapy and sex reassignment surgery, which are designed to promote the health and welfare of persons with GID and are recognized within the medical community to be the standard of care for treating people with GID; and

Whereas, An established body of medical research demonstrates the effectiveness and medical necessity of mental health care, hormone therapy and sex reassignment surgery as forms of therapeutic treatment for many people diagnosed with GID; ⁷ and

Whereas, Health experts in GID, including WPATH, have rejected the myth that such treatments are "cosmetic" or "experimental" and have recognized that these treatments can provide safe and effective treatment for a serious health condition;⁷ and

Whereas, Physicians treating persons with GID must be able to provide the correct treatment necessary for a patient in order to achieve genuine and lasting comfort with his or her gender, based on the person's individual needs and medical history;⁸ and

Whereas, The AMA opposes limitations placed on patient care by third-party payers when such care is based upon sound scientific evidence and sound medical opinion;^{9, 10} and



Resolution: 122 (A-08)

Page 2

Whereas, Many health insurance plans categorically exclude coverage of mental health, medical, and surgical treatments for GID, even though many of these same treatments, such as psychotherapy, hormone therapy, breast augmentation and removal, hysterectomy, oophorectomy, orchiectomy, and salpingectomy, are often covered for other medical conditions; and

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Whereas, The denial of these otherwise covered benefits for patients suffering from GID represents discrimination based solely on a patient's gender identity; and

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Whereas, Delaying treatment for GID can cause and/or aggravate additional serious and expensive health problems, such as stress-related physical illnesses, depression, and substance abuse problems, which further endanger patients' health and strain the health care system; therefore be it

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RESOLVED, That the AMA support public and private health insurance coverage for treatment of gender identity disorder (Directive to Take Action); and be it further

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RESOLVED, That the AMA oppose categorical exclusions of coverage for treatment of gender identity disorder when prescribed by a physician (Directive to Take Action).

Fiscal Note: No significant fiscal impact.

References

- 1. AMA Policy H-65.983, H-65.992, and H-180.980
- 2. Diagnostic and Statistical Manual of Mental Disorders (4th ed.. Text revision) (2000) ("DSM-IV-TR"), 576-82, American Psychiatric Association; International Classification of Diseases (10th Revision) ("ICD-10"), F64, World Health Organization. The ICD further defines transsexualism as "[a] desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with, or inappropriateness of, one's anatomic sex, and a wish to have surgery and hormonal treatment to make one's body as congruent as possible with one's preferred sex." ICD-10, F64.0.
- 3. DSM-IV-TR, 575-79
- 4. <u>Id.</u> at 578-79.
- 5. World Professional Association for Transgender Health: http://www.wpath.org. Formerly known as The Harry Benjamin International Gender Dysphoria Association.
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- 8. The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders, at 18.
- 9. ld.
- 10. AMA Policy H-120.988

Relevant AMA policy

H-65.983 Nondiscrimination Policy

The AMA opposes the use of the practice of medicine to suppress political dissent wherever it may occur. (Res. 127, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CEJA Rep. 2, A-05)

H-65.992 Continued Support of Human Rights and Freedom

Our AMA continues (1) to support the dignity of the individual, human rights and the sanctity of human life, and (2) to oppose any discrimination based on an individual's sex, sexual orientation, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies. (Sub. Res. 107, A-85; Modified by CLRPD Rep. 2, I-95; Reaffirmation A-00; Reaffirmation A-05)

H-180.980 Sexual Orientation as Health Insurance Criteria

The AMA opposes the denial of health insurance on the basis of sexual orientation. (Res. 178, A-88; Reaffirmed: Sub. Res. 101, I-97)

H-120.988 Patient Access to Treatments Prescribed by Their Physicians

The AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon



Resolution: 122 (A-08)

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sound scientific evidence and sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as reasonable and necessary medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses of drugs on their formulary. (Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified by CSA Rep. 3, A-97; Reaffirmed and Modified by Res. 528, A-99; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: CMS Rep. 6, A-03; Modified: Res. 517, A-04)

APA Official Actions

Report of the APA Task Force on Treatment of Gender Identity Disorder

Approved by the Joint Reference Committee, July 2011 Approved by the Board of Trustees, September 2011

The findings, opinions, and conclusions of this report do not necessarily represent the views of the officers, trustees, or all members of the American Psychiatric Association. Views expressed are those of the authors." -- APA Operations Manual.

William Byne M.D., Ph.D. (Chair)*	Table of Contents	
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Preface

After the announcement of the DSM-5 Work Group membership in May 2008, the American Psychiatric Association (APA) received many inquiries regarding the workgroup named to address the entities included under Gender Identity Disorder (GID) in versions III through IV-TR of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM). These inquiries most often dealt with treatment controversies regarding GID, especially in children, rather than issues related specifically to the *DSM* text and diagnostic criteria. In addition, the APA Committee on Gay, Lesbian, and Bisexual Issues had previously raised concerns about the lack of evidence-based guidelines for GID, and questions about whether such guidelines could and should be developed.

While the diagnosis and treatment of mental disorders are inextricably linked, they are separate issues and the evaluation of treatments is not addressed by the DSM Work Groups. The APA Board of Trustees, therefore, formed a task force on the treatment of GID under the oversight of the Council on Research. Members of the GID Task Force were appointed by the APA President, Dr. Nada Stotland,

and charged by the Board of Trustees "to perform a critical review of the literature on the treatment of Gender Identity Disorder at different ages and to present a report to the Board of Trustees." The report "would include an opinion as to whether or not there is sufficient credible literature to take the next step and develop treatment recommendations."

(Am J Psychiatry 2012; Suppl.,

The Task Force commenced its work as the DSM- $5^{\rm TM}$ workgroups were deliberating. Questions, therefore, arose regarding the impact of potential differences between the forthcoming DSM-5 and previous iterations of the DSM on the utility of the Task Force Report. Of particular concern was the question of whether or not the diagnostic entity designated as GID would be carried forward into the DSM-5. The Task Force concluded that most of the issues pertaining to gender variance (GV) that lead individuals (or their parents in the case of minors) to seek mental health services would remain the same regardless of any changes in DSM nomenclature or diagnostic criteria. Any such changes to the DSM should, therefore, have minimal impact on the utility of the Task Force Report. Since the DSM-5 would be published only after completion of work

^{*} The authors comprise the Task Force on Treatment of Gender Identity Disorder, APA Council on Research. We would like to thank the following for reading and providing comments on the initial draft of the report: Peggy T. Cohen-Kettenis, Ph.D., Jack Drescher, M.D., Sharon Preves, Ph.D., and Nada Stotland, M.D., as well as William Narrow, M.D., M.P.H., and Erin Dalder for APA staff support. DISCLOSURES: Dr. Coleman chairs the Sexual Health Advisory Committees for Church & Dwight and the Sinclair Institute. The other authors report no financial relationships with commercial interests. [Note added in print: Since the completion of this report, Version 7 of the WPATH SOC has been published and is available at www.wpath.org.]

GENDER IDENTITY DISORDER

by the Task Force, the evidence base available for consideration by the Task Force was necessarily based on prior diagnostic formulations. The Task Force chose to conduct its deliberations primarily in terms of the $DSM-IV-TR^{TM}$ formulations with reference to other formulations as necessary.

Although the charge to the Task Force was to comment on the feasibility of making treatment recommendations, questions arose in the initial conference calls regarding the nature of the evidence base required by the APA for development of recommendations in the specific form of APA practice guidelines. APA practice guidelines are defined as systematically developed documents in a standardized format that present patient care strategies to assist psychiatrists in clinical decision making. The APA's Steering Committee on Practice Guidelines (SCPG) both selects topics for guideline development and oversees their development. According to the (http://www.psychiatryonline.com/content.aspx?aID=58560) at the time the Task Force commenced it work in 2008 and concluded it in May 2011, two of the criteria for topic selection by the SCPG are quality of the relevant data base and prevalence of the disorder. The randomized double blind control trial is the study design that affords the highest quality evidence regarding the comparative efficacy of various treatment modalities; however, no such trials have been conducted to address any aspect of the treatment of GID. Given the very nature of GID, such trials, or even unblinded trials with random assignment to treatment groups, are not likely to be forthcoming due to a lack of feasibility and/or ethical concerns. In addition to the lack of evidence of the highest quality relevant to the treatment of GID, GID is widely believed to be a rare phenolmenon (1)1 and likely to fall short of the SCPG's criterion for prevalence. The Task Force, therefore, decided to consider whether available evidence, together with clinical consensus, constitutes a sufficient basis to support the development of treatment recommendations, broadly defined, in addition to assessing the quality of evidence relevant to the potential development of APA practice guidelines, as defined above.

In order to address its charge, the Task Force divided itself into subgroups to address GID and related issues in four populations. Three of these populations are defined by age: children, adolescents and adults. The fourth population comprises individuals with the desire to change their assigned gender who have a somatic disorder of sex development (DSD). The makeup of the subgroups was as follows: **child** (Drs. Pleak and Menvielle); **adolescent** (Drs. Bradley and Green); **adult** (Drs. Eyler, Coleman and Tompkins), and **DSD** (Drs. Meyer-Bahlburg and Byne).

Each subgroup conducted database searches and produced a document addressing the Task Force's charge pertaining to its assigned subpopulation. These documents were circulated to all members of the Task Force, discussed

during conference calls and revised until approved by group consensus. Because the consensus process involves compromise, all members of the Task Force do not necessarily agree with all views expressed within the report. The Task Force could not reach a consensus regarding the question of whether or not persistent cross-gender identification sufficient to motivate an individual to seek sex reassignment, per se, is a form of psychopathology in the absence of clinically significant distress or impairment due to a self-perceived discrepancy between anatomical signifiers of sex and gender identity. Since this question falls within the purview of the DSM Committee and is not central to the Task Force's charge of evaluating treatment, text suggesting a stand on this issue was deleted from the report. Similarly, a consensus could not be reached regarding the legitimacy of particular goals of therapy with children diagnosed with GID (e.g., prevention of transgenderism or homosexuality) even when consistent with the religious beliefs or sociocultural values of the parents or primary caregivers.

EXECUTIVE SUMMARY AND RECOMMENDATIONS

This Task Force report assesses the current status of evidence bearing on treatment, by mental health professionals, of the entities included under GID in the DSM (versions III through IV-TR) as well as gender dysphoria in individuals with somatic DSDs (designated as GID Not Otherwise Specified (GID NOS)) in DSM-IV-TR. The primary aim of the report is to answer the question posed by the APA Board of Trustees as to whether or not there is sufficient credible literature to support development by the APA of treatment recommendations for GID. Separate sections of the report are addressed to GID in children, adolescents, and adults as well as to GID NOS in individuals with somatic DSDs. The Executive Summary provides a synopsis of each of those sections (readers are referred to each primary section for full citations), together with an opinion from the Task Force regarding support for treatment recommendations in the literature. The Task Force concludes that the current credible literature is adequate for the development of consensus-based treatment recommendations for all subgroups reviewed. Moreover, with subjective improvement as the primary outcome measure, it is concluded that for adults sufficient evidence exists for the development of recommendations in the form of an APA practice guideline, with gaps in the research database filled in by clinical consensus.

The case is also made that treatment recommendations from the APA are needed, even in areas where criteria are not met for selection by the SCPG for APA practice guideline development, and that the APA should proceed with their preparation. The Task Force recommends that additional steps be taken by the APA pertaining to issues relating to GV (Appendix I) and to DSDs, whether or not GV is an issue (Appendix II). These include issuing a position

¹ Epidemiological studies are lacking so that no strong conclusions about the prevalence of GID can be drawn (1). The prevalence estimates cited in DSM-IV for adults of 1:30,000 for natal males and 1:100,000 in natal females are likely to be under estimates (1).

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statement to clarify the APA's position regarding the medical necessity of treatments for GID, the ethical bounds of treatments for minors with GID, and the rights of persons of any age who are gender variant or transgender.

Evaluation of Levels of Evidence

Where possible, the Task Force Report comments on the level of evidence from research studies bearing on treatment issues. Unless otherwise specified, the levels of evidence refer to the APA evidence coding system which was in use at the time the Task Force was commissioned (http://www.psychiatryonline.com/content.aspx?aID=58560) and is specified below:

- Randomized, double-blind clinical trial. A study of an intervention in which [A] subjects are prospectively followed over time; there are treatment and control groups; subjects are randomly assigned to the two groups; and both the subjects and the investigators are "blind" to the assignments.
- [A-] Randomized clinical trial. Same as above but not double blind.
- [B] Clinical trial. A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally. Does not meet standards for a randomized clinical trial.
- Cohort or longitudinal study. A study in which subjects are prospectively [C] followed over time without any specific intervention.
- [D] Control study. A study in which a group of patients and a group of control subjects are identified in the present and information about them is pursued retrospectively or backward in time.
- [E] Review with secondary data analysis. A structured analytic review of existing data, e.g., a meta-analysis or a decision analysis.
- Review. A qualitative review and discussion of previously published literature [F] without a quantitative synthesis of the data.
- [G] Other. Opinion-like essays, case reports, and other reports not categorized

Terminology

The diagnostic category, GID, was introduced by DSM-III and included the diagnoses of GID of Childhood and Transsexualism. In DSM-III-R, GID of Childhood, and Transsexualism were retained; GID of Adolescence and Adulthood, Nontranssexual Type (GIDAANT), was added; and "disorders in gender identity" not otherwise classified, were designated as GID, Not Otherwise Specified (GID NOS). Note that under GID of Childhood, physical disorders of the sex organs, when present, were noted under Axis III. This stipulation was not made explicit for transsexualism and GIDAANT, but intersex is not noted under GID NOS in DSM-III-R. Thus, if a person with a DSD met GID criteria, s/he would be given the GID diagnosis, with the intersex syndrome listed on Axis III. In DSM-IV and IV-TR, GID of Childhood and GID NOS (in addition to some other conditions) were retained; however, the designation GID of Adolescence and Adulthood subsumed both Transsexualism and the Nontranssexual Types.

DSM-IV-TR excludes individuals with a disorder of sex development (DSD) from the diagnosis of GID. Individuals with gender dysphoria and a DSD are placed under the category GID NOS, rather than under the more specifically defined term, GID. GID NOS is commonly used also for individuals without a DSD who meet some but not all required GID criteria (often referred to as "subthreshold cases"). Thus, the DSM-IV-TR applies the term, GID NOS (apart from other examples), to three groups of individuals with gender dysphoria: 1) those without a DSD who do not meet full criteria for GID, 2) those who would meet full criteria for GID if not for the DSD exclusion, and 3) those with a DSD who do not meet the full inclusion criteria.

The criteria for the GID diagnoses, as well as the nomenclature itself, are under revision at the time of this writing. Documentation regarding the development of the DSM-5, and potential changes in nomenclature and diagnostic criteria are available through the American Psychiatric Association's website (http://www.psych.org) and are not addressed here.

Abbreviations

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AACAP	American Academy of Child and Adolescent Psychiatry
APA	American Psychiatric Association
CAH	congenital adrenal hyperplasia
DSD	disorder of sex development
DSM	Diagnostic and Statistical Manual
FTM	female to male
GID	Gender Identity Disorder
GIDAANT	Gender Identity Disorder of Adolescence and Adulthood, Nontranssexual Type
GID NOS	Gender Identity Disorder, Not Otherwise Specified
GLBT	gay, lesbian, bisexual transgender/transsexual
GnRH	gonadotropin releasing hormone
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
GV	gender variance
HBIDGA	Harry Benjamin International Gender Dysphoria Association
ICTLEP	International Conference on Transgender Law and Employment Policy, Inc.
MTF	male to female
WPATH	World Professional Association for Transgender Health (formerly the Harry Benjamin International Gender Dysphoria Association [HBIDGA])
RCT	randomized controlled trial
SCPG	Steering Committee on Practice Guidelines
SOC	Standards of Care
SRS	sex reassignment surgery

In the present report, the abbreviations, GID and GID NOS, are used to refer to Gender Identity Disorders as defined in the DSM-IV-TR. The entities designated as Gender Identity Disorders by the DSM-IV-TR include only a subset of individuals for whom clinical concerns related to GV may be raised (whether by the individual or the individual's primary caregivers, educators, or healthcare providers). Gender Variance (GV) is used to refer to any degree of cross-gender identification or nonconformity in gender role behavior regardless of whether or not criteria are met for either GID or GID NOS. The terms, transsexual and transsexualism, are used to refer to adults who meet diagnostic criteria for GID and have employed hormonal and/or surgical treatments in the process of transitioning gender or who plan to do so. Transgender denotes individuals with cross-gender identification whether or not hormonal or surgical treatments have been, or are planned to be, employed in transitioning gender. Natal sex is used to refer to the sex at birth of individuals who subsequently desire or undergo any degree of sex reassignment or Case: 24-108 Document: 2-3 Page: 50 Filed: 01/25/2024

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gender transition, provided that they do not have a disorder of sex development (DSD). DSD as employed here, refers to congenital conditions (formerly referred to as intersex disorders, hermaphroditism, and pseudohermaphroditism) which entail atypical development of chromosomal, gonadal and/or genital sex.

Synopses of Literature Reviews and Opinions with Respect to Recommendations

Synopsis: Children have limited capacity to participate in decision making regarding their own treatment, and no legal ability to provide informed consent. They must rely on caregivers to make treatment decisions on their behalf, including those that will influence the course of their lives in the long term. The optimal approach to treating prepubertal children with GV including DSM-defined GID, is, therefore, more controversial than treating these phenomena in adults and adolescents. An additional obstacle to consensus regarding treatment is the lack of randomized controlled treatment outcome studies of children with GID or with any presentation of GV (2). In the absence of such studies, the highest level of evidence available for treatment recommendations for these children can best be characterized as expert opinion. Opinions vary widely among experts, and are influenced by theoretical orientation, as well as assumptions and beliefs (including religious) regarding the origins, meanings and perceived fixity or malleability of gender identity. Primary caregivers may, therefore, seek out providers for their children who mirror their own world views, believing that goals consistent with their views are in the best interest of their children.

The outcome of childhood GID without treatment is that only a minority will identify as transsexual or transgender in adulthood (a phenomenon termed persistence), while the majority will become comfortable with their natal gender over time (a phenomenon termed desistence) (3-6). GID that persists into adolescence is more likely to persist into adulthood (2). Compared to the general population, the rate of homosexual orientation is increased in adulthood whether or not GID was treated (2, 4). It is currently not possible to differentiate between preadolescent children in whom GID will persist and those in whom it will not. To date, no long-term follow-up data have demonstrated that any modality of treatment has a statistically significant effect on later gender identity.

The overarching goal of psychotherapeutic treatment for childhood GID is to optimize the psychological adjustment and wellbeing of the child. What is viewed as essential for promoting the wellbeing of the child, however, differs among clinicians, as does the selection and prioritization of goals of treatment. In particular, opinions differ regarding the questions of whether or not minimization of gender atypical behaviors, and prevention of adult transsexualism, are acceptable goals of therapy.

Several approaches to working with children with GID were identified in the professional literature. The first of these focuses on working with the child and caregivers to lessen gender dysphoria and to decrease cross-gender behaviors and identification. The assumption is that this approach decreases the likelihood that GID will persist into adolescence and culminate in adult transsexualism (7). For various reasons (e.g., social stigma, likelihood of hormonal and surgical procedures with their associated risks and costs), persistence is considered to be an undesirable outcome by some (4, 7, 8) but not all (9-11) clinicians who work in this area of practice.

A second approach makes no direct effort to lessen gender dysphoria or gender atypical behaviors. This approach is premised on the evidence that GID diagnosed in childhood usually does not persist into adolescence and beyond (4, 5), and on the lack of reliable markers to predict in whom it will or will not persist. A variation of this second approach is to remain neutral with respect to gender identity and to have no therapeutic target with respect to gender identity outcome. The goal is to allow the developmental trajectory of gender identity to unfold naturally without pursuing or encouraging a specific outcome (12-14). Such an approach entails combined child, parent and community-based interventions to support the child in navigating the potential social risks (12, 13, 15, 16). Support for this approach is centered on the assumption that self-esteem may be damaged by conveying to the child that his or her likes and dislikes, behaviors and mannerisms, are somehow intrinsically wrong (17). A counter argument proposes that self-esteem can be best served by improved social integration including positive relationships with same-sex peers (18). Alternatively, proponents of this second approach suggest that the child's self-recognition of a gender variant and stigmatized status may be actively encouraged, with the goal of mastery, e.g., developing cognitive, emotional and behavioral coping tools for living as a gender variant person (12, 19). A third approach may entail affirmation of the child's cross-gender identification by mental health professionals and family members (7). Thus, the child is supported in transitioning to a cross-gendered role, with the option of endocrine treatment to suspend puberty in order to suppress the development of unwanted secondary sex characteristics if the cross-gendered identification persists into puberty (12). The rationale for supporting transition before puberty is the belief that a transgender outcome is to be expected in some children, and that these children can be identified so that primary caregivers and clinicians may opt to support early social transition. A supporting argument is that children who transition this way can revert to their originally assigned gender if necessary since the transition is done solely at a social level and without medical intervention (9). The primary counterargument to this approach is based on the evidence that GID in children usually does not persist into adolescence and adulthood. Thus, supporting gender transition in childhood might increase the likelihood of persistence (20). Furthermore, the peer-reviewed literature does not support the view that desisters and persisters can currently be reliably distinguished as children (5, 21-23).

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Moreover, after transitioning gender in childhood, reverting to the natal gender may entail complications (24).

Primary modes of therapy utilized in working with children with GID include individual insight-oriented psychoanalytic or psychodynamic psychotherapy (25); protocol-driven psychotherapy such as behavior modification (26); parent and peer relations focused therapy (18); and parent and child therapeutic groups (12, 13, 15). Additional interventions include support groups for primary caregivers, community education through websites and conferences, school-based curricula, and specialized youth summer camps. The primary focus of intervention is sometimes the primary caregivers. Depending on the treatment approach chosen, work may include parenting support and psychoeducation, guidance in reinforcing behavior modification, and instruction in techniques for building self-acceptance and resilience in the child. Some interventions are multifaceted and involve the school and community as well as the child and family. These include diversity education and steps to prevent bullying.

The Task Force identified the following as the major tasks for mental health professionals working with children referred for gender concerns: 1) to accurately evaluate the gender concerns that precipitated the referral; 2) to accurately diagnose any gender identity related disorder in the child according to the criteria of the most current *DSM*; 3) to accurately diagnose any coexisting psychiatric conditions in the child, as well as problems in the parent-child relationship, and to recommend their appropriate treatment; 4) to provide psychoeducation and counseling to the caregivers about the range of treatment options and their implications; 5) to provide psychoeducation and counseling to the child appropriate to his or her level of cognitive development; 6) when indicated, to engage in psychotherapy with the appropriate persons, such as the child and/or primary caregivers, or to make appropriate referrals for these services; 7) to educate family members and institutions (e.g., day care and preschools, kindergartens, schools, churches) about GV and GID; and 8) to assess the safety of the family, school and community environments in terms of bullying and stigmatization related to gender atypicality, and to address suitable protective measures.

With respect to comparing alternative approaches to accomplishing the above tasks, the Task Force found no randomized (APA level A) or adequately controlled nonrandomized longitudinal (APA level A-) studies, and very few follow-up studies without a control group either with (APA level B) or without (APA level C) an intervention. The majority of available evidence is derived from qualitative reviews (APA level F) and experimental systematic single case studies that do not fit into the APA evidence grading system.

Opinion Regarding Treatment Recommendations for Children: Despite deficiencies in the evidence base and the lack of consensus regarding treatment goals, the present literature review suggests consensus on a number of points. Areas where existing literature supports development of consensus recommendations include, but are not limited to, the following: 1) assessment, and accurate DSM diagnosis of the child referred for gender concerns, including the use of validated questionnaires and other validated assessment instruments to assess gender identity, gender role behavior and gender dysphoria; 2) diagnosis of any coexisting psychiatric conditions in the child and seeing to their appropriate treatment or referral; 3) identification of mental health concerns in the caregivers, and difficulties in their relationship with the child; ensuring that these are adequately addressed, 4) provision of adequate psychoeducation and counseling to caregivers to allow them to choose a course of action and to give fully informed consent to any treatment chosen. This entails disclosing the full range of treatment options available (including those that might conflict with the clinician's beliefs and values), the limitations of the evidence base that informs treatment decisions, the range of possible outcomes, and the currently incomplete knowledge regarding the influence of childhood treatment on outcome; 5) provision of age appropriate information to the child; and 6) assessment of the safety of the family, school and community environments in terms of bullying and stigmatization related to gender atypicality, and addressing suitable protective measures.

Adolescents

Synopsis: For purposes of this Task Force report, adolescence is defined as the developmental period from 12 to 18 years of age. Adolescents with GID comprise two groups, those in whom GID began in childhood and has persisted, and those with the onset of GID in adolescence. Only two clinics (one in Canada and one in The Netherlands) have systematically gathered data on sufficient numbers of subjects to provide an empirical "experience base" on the main issues in adolescence. Both of these teams concur that management of those in whom GID has persisted from childhood is more straightforward than management of those in whom GID is of more recent onset. In particular, the latter group is more likely to manifest significant psychopathology in addition to GID. This group should be screened carefully to detect the emergence of the desire for sex reassignment in the context of trauma as well as for any disorders such as schizophrenia, mania or psychotic depression that may produce gender confusion. When present, such psychopathology must be addressed and taken into account prior to assisting the adolescent's decision as to whether or not to pursue sex reassignment or actually assisting the adolescent with the gender transition. Both the Canadian and Dutch groups are guided by the World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) which endorse a program of staged gender transition including a period of living as the other gender prior to any somatic treatment.

With the beginning of puberty, development of the secondary sex characteristics of the natal gender often triggers or exacerbates the anatomical dysphoria of adolescents with GID (11, 27). Recently, the option has become available for pubertal patients with severe gender dysphoria and minimal, if any, additional psychopathology Case: 24-108 Document: 2-3 Page: 52 Filed: 01/25/2024

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to have puberty suspended medically in order to prevent or to minimize development of unwanted secondary sex characteristics, some of which are not fully reversible with subsequent hormonal or surgical sex reassignment therapies (28). A practice guideline developed by the Endocrine Society (29) suggests that pubertal suspension can be done for a period of up to several years during which time the patient, with the clinicians, can decide whether it is preferable for the adolescent to revert to living in the birth sex or to continue gender transition with crosssex hormone therapy. There are currently little data regarding the timing of cross-sex hormone treatment in adolescents and no studies comparing outcomes when such treatment is initiated in adolescence as opposed to adulthood, with or without prior suspension of puberty. We know, however, that many adult transsexuals express regret over the body changes that occurred during puberty, some of which are irreversible. In the absence of a DSD (addressed in a separate section), at present, sex reassignment surgery (SRS) is not performed prior to the age of 18 in the United States. It is noted, however, that one study on carefully selected individuals in the Netherlands suggests that, as assessed by satisfaction with surgery and lack of regrets, outcome was generally better in individuals who initiated sex reassignment as adolescents compared to those who initiated reassignment as adults (30, 31). Even in these studies, however, SRS was not initiated prior to the age of 18.

The major tasks identified by the Task Force to be germane to provision of mental health services to adolescents with the desire to transition in gender, or who are in the process of transitioning, are: 1) psychiatric and psychological assessment to both assure that any psychopathology is adequately diagnosed and addressed, and to determine whether the clinicians' approach will be neutral or supportive with respect to the desire to transition in gender; 2) provision of psychotherapy as indicated by the initial assessment and as indicated by changes over time. This includes providing psychological support during the real-life experience and suspension of puberty and/or the administration of cross-sex hormones; and 3) assessment of eligibility and readiness for each step of treatment.

Database searches failed to reveal any RCTs related to any of these issues. The quality of the evidence is primarily individual case reports (APA level G); follow-up studies with control groups of limited utility and without random assignment, or longitudinal follow-up studies after an intervention without control groups (APA level B); and reviews of the above (APA level F). Between 2001 and 2009, over 80 adolescents selected based on conservative criteria have been treated with pubertal suspension with overall positive results in the most detailed follow-up study published to date (APA evidence level B) (28, 32). In a consecutive series of 109 adolescents (55 females, 54 males) with GID, the Toronto group identified demographic variables correlated with clinical decisions to recommend, or not recommend, gonadal hormone blocking therapy (33). Follow-up data, to date, however, are not adequate for statistical analyses of outcome variables.

Opinion Regarding Treatment Recommendations for Adolescents: Existing literature is insufficient to support development of an APA practice guideline for treatment of GID in adolescence but is sufficient for consensus recommendations in the following areas: 1) psychological and psychiatric assessment and diagnosis of adolescents presenting with a wish for sex reassignment, including assessment and diagnosis of co-occurring conditions and facilitation of appropriate management; 2) psychotherapy (including counseling and supportive therapy as indicated) with these adolescents, including enumeration of the issues that psychotherapy should address. These would include issues that arise with adolescents who are transitioning gender, including the real life experience; 3) assessment of indications and readiness for suspension of puberty and/or cross-sex hormones as well as provision of documentation to specialists in other disciplines involved in caring for the adolescent; 4) psychoeducation of family members and institutions regarding GV and GID; and 5) assessment of the safety of the family/school/community environment in terms of gender-atypicality-related bullying and stigmatization, and to address suitable protective measures.

Adults

Synopsis: The adult section addresses individuals 18 years of age and older, and thus picks up where the adolescent section leaves off in considering individuals who seek mental health services for reasons related to GV, some of whom meet diagnostic criteria for GID. For some adults, GID/GV has clearly persisted from childhood and adolescence, but for others it has arisen (or at least come to clinical attention) for the first time in adulthood. Among natal males, there tend to be a number of differences between those with an early (childhood) as opposed to late (adulthood) onset. In particular, those with late onset are more likely to have had unremarkable histories of gender nonconformity as children, and are less likely to be primarily sexually attracted to individuals of their natal gender, at least prior to gender transition (34). Age of onset may have some, albeit limited, value in predicting satisfaction versus regret following sex reassignment surgery (35-

The WPATH SOC and the recent Endocrine Society guideline (29) endorse psychological evaluation and a staged transition in which fully reversible steps (e.g., presenting as the desired gender) precede partially reversible procedures (administration of gonadal hormones to bring about the desired secondary sex characteristics), which precede the irreversible procedures (e.g., gonadectomy, vaginoplasty in natal males, mastectomy and surgical construction of male-typical chest and phalloplasty in natal females). Adults who have capacity to give informed consent may receive the gender transition treatments for which they satisfy the qualifying criteria of the providers. These criteria vary among providers and clinics. A recent review graded the quality of evidence relating particular components of the WPATH SOC to outcomes and concluded that psychotherapy prior to initiating hormonal or surgical treatments, and staged

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transition (including a period of real-life experience) were associated with good outcome (39). Most of the studies reviewed were case series and case reports or reviews (APA level D or lower), although some included sufficient longitudinal follow-up and standardization to meet APA level B

Prior to adulthood, some individuals will have already transitioned without medical intervention, while others may have had puberty medically suspended in order to prevent the emergence of undesired secondary sex characteristics, and others may have initiated cross-sex hormone treatments. Some of these individuals may have previously formulated a plan, together with their healthcare providers, to move to the next stage of medical/ surgical gender transition as soon as they reach the legal age of majority and can legally assume responsibility for themselves and give informed consent. Such individuals may seek the services of mental health professionals at this point only for the assessment of their eligibility and readiness for the desired procedures as required by the WPATH SOC or their particular provider's policy.

As is the case with GID in childhood and adolescence, and for similar reasons, there are no RCTs pertaining to any treatment intervention in adults. Nor is there universal agreement regarding treatment goals other than improving the sense of wellbeing and overall functioning of the individual. Recently, the greatest emphasis has been placed on subjective patient reports, particularly those of satisfaction, and self-perceived improvement or regrets. Several correlates of regret have been identified including major co-existing psychiatric issues such as psychosis or alcohol dependency; an absence of, or a disappointing, real-life experience; and disappointing cosmetic or functional surgical results (39-48). Regrets are somewhat more frequent for patients with late as opposed to early onset of GID. For both early and late onset groups, a favorable outcome is more likely among individuals who were high functioning prior to transition, and who received care, including surgeries, from experienced providers, and who were satisfied with the quality of their surgical results.

As was the case for GID in children and adolescents, database searches failed to reveal any RCTs related to addressing the mental health issues raised by GID in adults. Most of the literature addressing psychotherapy with gender variant adults would be categorized as APA level G and consists of case reports and review articles without additional data analysis. This body of work nevertheless, identifies the major issues that should be addressed in psychotherapy with these individuals. There are some level B studies examining satisfaction/regret following sex reassignment (longitudinal follow up after an intervention, without a control group); however, many of these studies obtained data retrospectively and without a control group (APA level G). Overall, the evidence suggests that sex reassignment is associated with an improved sense of wellbeing in the majority of cases, and also indicates correlates of satisfaction and regret. No studies have directly compared various levels of mental health screening prior to hormonal and surgical treatments on outcome variables; however, existing studies suggest that comprehensive mental health screening may be successful in identifying those individuals most likely to experience regrets (39-48).

Opinion Regarding Treatment Recommendations for Adults: The Task Force concludes that, with subjective improvement as the primary outcome measure, the existing evidence base combined with clinical consensus is sufficient for developing recommendations in the form of an APA practice guideline. Areas where recommendations can be made include the following: 1) assessing and diagnosing patients' gender concerns according to DSM criteria and assuring that these are appropriately addressed; 2) assessing and correctly diagnosing any coexisting psychopathology and assuring that it is addressed adequately. This may entail modification of the plans/ schedule for gender transitioning; 3) distinguishing between GID with concurrent psychiatric illness and gender manifestations that are not part of GID but epiphenomena of psychopathology; 4) engaging in psychotherapy with gender variant individuals as indicated. This includes identifying the elements that should be addressed in therapy including the impact of discrimination and stereotyping; 5) ensuring that individuals who are in the process of transitioning, or who are considering or planning to do so, receive counseling from a qualified professional about the full range of treatment options and their physical, psychological and social implications including both their potential benefits and the full range of potential limitations (e.g., loss of reproductive potential), risks and complications; 6) ascertaining eligibility and readiness for hormone and surgical therapy, or locating professionals capable of making these ascertainments to whom the patient may be referred; 7) educating family members, employers and institutions about GV including GID; and 8) ensuring that documentation, including preparation of letters to endocrineologists and surgeons, employs terminology that facilitates accurate communication, minimizes pejorative or potentially stigmatizing language, and conforms (when applicable) to standards for third party reimbursement and tax deductible medical expense.

Individuals with Disorders of Sex Development

Overview and Synopsis: As employed here, the term, disorders of sex development (DSD) refers to congenital conditions (formerly referred to as intersex disorders, hermaphroditism and pseudohermaphroditism) which entail atypical development of chromosomal, gonadal and/or genital sex. The gender that should be assigned may not be obvious at birth, and in many cases the process of decision making with respect to gender assignment is complex and fraught with uncertainties. Genitoplasty is often employed to bring the appearance of the external genitalia in line with the gender assigned. Additionally, gonadectomy must be considered in a variety of DSD syndromes due to increased risk of malignancy. The multiple medical (e.g., malignancy risk) and psychological (cross-gender puberty) factors that bear on such decisions were acknowledged by the Task Force as were the current debates regarding the timing of gonadectomy and the lack of consensus regarding the multiple issues relating to genital surgeries

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performed on minors. Readers are referred elsewhere for various viewpoints on these controversial interdisciplinary issues, e.g., (49-55).

Some individuals with DSDs, in a proportion that varies greatly with syndrome and assigned gender, become dysphoric in the assigned gender and may reject it. A variety of issues in the clinical care of individuals with DSDs require the expertise of mental health professionals (49, 56). This Task Force report addresses only those issues related to gender dysphoria and gender transition in these individuals. The clinical options and decision-making processes that bear on gender transition and reassignment overlap to some extent regardless of the presence or absence of a DSD. When a DSD is present, however, there are fewer barriers to legal gender reassignment, and the barriers to hormonal and surgical treatments in conjuncttion with gender reassignment are lower.

Major areas of involvement of mental health professsionals in the care of individuals with DSDs and gender dysphoria include: 1) the evaluation of gender identity and the assessment of incongruences, if present, between gender identity and assigned gender; 2) decision making regarding gender reassignment; 3) psychotherapy to address significant gender dysphoria in individuals with a DSD who do not transition gender; 4) selected psychological/psychiatric aspects of the endocrine management of puberty in the context of gender reassignment; and 5) selected psychological/psychiatric aspects of genital surgery in the context of gender reassignment.

The literature bearing on the above issues includes numerous long-term follow-up studies (APA levels B and C) of gender outcome in individuals with DSDs, including some with gender dysphoria and reassignment. These often have significant methodological weaknesses related to sample size and heterogeneity as well as inadequate control groups. There are also multiple reviews (APA level F), some of which integrate data from accessible case reports and small group studies [e.g., (57-61)].

Opinion Regarding Treatment Recommendations for Individuals with DSDs: The general absence of systematic studies linking particular interventions within the purview of psychiatry to mental health outcome variables largely limits the development of practice recommendations for DSDs to their derivation from clinical consensus. For individuals with gender dysphoria and a DSD, consensus recommendations could be developed for: 1) the evaluation of gender identity and assessment of incongruences between gender identity and assigned gender; 2) decisions/recommendations regarding gender reassignment based on assessment; and 3) psychotherapy to address dysphoria in the context of incongruences between gender identity and assigned gender in the absence of desire for gender transition. Although recent medical guidelines emphasize the desirability of, and need for, mental health service providers with expertise in this area of care [e.g., (29, 49, 51, 54)] it is premature to recommend detailed guidelines on their required qualifycations. To do so might jeopardize existing providers rather than contribute to closing the gap in the availability of mental health service providers. Recommendations regarding the mental health needs of individuals with DSDs and their caregivers, whether or not gender dysphoria is present, are found in Appendix II and are not summarized

Why APA Recommendations Are Needed for the Treatment of GID

APA recommendations are needed for the treatment of GID for a variety of reasons. First, the existing guidelines, standards of care and policy statements of other professional organizations, including the WPATH SOC, and recent reviews highlight the role of mental health professionals in a multidisciplinary team approach to providing medical services to individuals with GID (29, 49, 62-66); however, to date no professional organization of mental health practitioners provides such recommenddations. Recognizing the current absence of guidelines by any professional organization of mental health professionals, the clinical practice guideline of the Endocrine Society (29) states that mental health professionals usually follow the guidelines set forth by WPATH. Although WPATH is not a professional organization of mental health professionals, it counts many mental health professionals among its members, including psychologists, psychiatrists and psychiatric social workers. A limitation of the Current WPATH SOC (version 6), which will be remedied in the forthcoming version 7, is that it does not cite its underlying evidence base, nor indicate the level of evidence upon which its standards are based. An appreciation of the quality of evidence upon which recommendations are based is critical for the practitioner who must judge whether or not implementation of a particular recommendation is likely to be in the patient's best interest. Version 7 of the WPATH SOC is now in preparation, and in that context numerous reviews of the supporting evidence have recently been published. In fact, all four issues of the 2009 volume of International Journal of Transgenderism are devoted to this topic. Additionally, the Task Force on Gender Identity and Gender Variance of the American Psychological Association has recently called for guideline development by its parent organization. Exactly when such guidelines will be available remains to be determined, however, their preparation is expected to get underway shortly. A call for nominations to a "Task Force on Guidelines for Psychological Practice with Transgender and Gender Nonconforming Clients" was issued by the American Psychological Association on April 8, 2011.

Second, although the practice of psychiatry overlaps with that of other medical specialties as well as with other mental health fields, including psychology, it is distinct in many respects. In particular, the diagnosis and treatment of major mental illnesses (e.g., psychotic disorders) in which gender identity concerns may arise as epiphenomena are primarily within the purview of psychiatrists, as are the pharmacological management of psychiatric disorders that may coexist with GID (e.g., mood and anxiety disorders and the assessment of undesired psychiatric manifestations of hormonal manipulations). It is, therefore, important that the available clinical evidence be Case: 24-108 Document: 2-3 Page: 55 Filed: 01/25/2024

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evaluated from a psychiatric perspective for the benefit of practicing psychiatrists and their patients.

Third, it is likely that APA recommendations for the treatment of GID would positively impact the number of psychiatrists willing to provide services to individuals with GID as well as the development of opportunities to receive training in providing such care. Such opportunities could include continuing medical education activities as well as workshops and similar venues at national meetings such as the APA and AACAP.

Finally, recommendations from the APA would frame its position on what constitutes realistic and ethical treatment goals as well as what constitutes ethical and humane approaches to treatment. In addition to providing guidance to psychiatrists and other healthcare professionals, such a document would provide guidance to consumers of mental healthcare services, including the primary caregivers of minors with GID, in selecting among the various available approaches to treatment.

Recommendations for the APA

1) The opinion of the Task Force is that the current credible literature is sufficient to support treatment recommendations, and that such recommendations are needed. The Task Force, therefore, recommends that the APA proceed with developing treatment recommendations. These recommendations should address, but not be limited to, those areas identified in this report for which recommendations are needed and substantial support is available from either research data or clinical consensus within the literature. With the possible exception of GID in adults, it is unlikely that GID/GID NOS will meet the criteria to be prioritized by the SCPG for APA practice guideline development. If not, the Task Force suggests that recommendations for each of the groups discussed in this report (children, adolescents, adults and individuals with DSDs) be prepared as APA resource documents.

2) There is a critical need for an APA position statement on the treatment of GID, and given the time it will take to develop treatment recommendations, a position statement should precede the development of recommendations. In recent years, the APA has received many requests from advocacy groups and the media inquiring about APA's position on the treatment of individuals with GID. As the APA has never had any specific component charged with directly addressing such inquiries, such questions were usually referred by default to the Committee on Gay, Lesbian and Bisexual Issues which was sunset during the restructuring of APA components in 2008. Examples of questions received include: How can primary caregivers best nurture a child with GID? Does any APA documentation define what is considered humane and ethical treatment of individuals, especially children, with GID? What constitutes medically necessary treatment for individuals of different age groups who meet criteria for GID? To what level of GID-related care are individuals entitled if their care is provided, or paid for, by governmental bodies (e.g., adolescents in foster care, prisoners, military personnel and veterans)? Is SRS a standard treatment that should be routinely covered by insurance?

The APA first introduced GID as a category of diagnostic entities in 1980. Thirty years later, other than the DSM diagnoses, the APA has no official position statements pertaining to, or even mentioning, these diagnostic entities. In particular, the APA has not addressed the issue of what constitutes either ethical and humane or medically necessary treatment for the GID diagnoses. Requests for psychotherapeutic, hormonal and surgical treatments for GID, or their reimbursement, are not infrequently denied because they are perceived by private and public third party payers as cosmetic or unnecessary procedures rather than medically necessary or standard medical and mental health care (67). A document by the WPATH board of directors and executive officers discusses the term, medically necessary, as it is commonly used among health insurers in the United States and lists those aspects of GID treatment that meet the definition (68). While the existence of the diagnosis contributes to the stigma of affected individuals, the unintended result of the APA's silence is a failure to facilitate full access to care for those diagnosed with GID. The Task Force, therefore, recommends that the APA consider drafting a resolution, similar to Resolution 122 of the American Medical Association (62). This resolution concludes that medical research demonstrates the effectiveness and necessity of mental health care, hormone therapy and sex reassignment surgery for many individuals diagnosed with GID and resolves that the AMA supports public and private health insurance coverage for medically necessary treatments and opposes categorical exclusions of coverage for treatment of GID when prescribed by a physician.

- 3) This Task Force strongly endorses recent medical and psychological guidelines that emphasize the desirability of, and need for, mental health service providers with expertise in providing services to individuals with gender dysphoria, GID and DSDs (29, 49, 51, 54, 56). It is the opinion of this Task Force, however, that detailed restrictions on required qualifications of the mental health practitioners who provide these services are not desirable. Such restrictions might jeopardize existing providers rather than contribute to closing the gap in the availability of mental health service providers. Instead, the Task Force recommends that the APA create opportunities for educating mental healthcare providers in this area of care. Such opportunities could include continuing medical education activities as well as workshops and similar venues at national meetings such as the APA and AACAP.
- 4) The Task Force recommends that a structure, or structures, within the APA be either identified or newly created and charged to follow-up on the recommendations of this report, to periodically review and update resulting treatment recommendations, to identify areas where research is particularly needed to optimize treatment, and to identify means to facilitate such research.

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LITERATURE REVIEWS

Gender Variance in Childhood

Edgardo J. Menvielle, M.D., M.S.H.S. Richard R. Pleak, M.D.

The optimal approach to treating prepubertal children with GV including DSM-defined GID is much more controversial than treating these phenomena in adults and adolescents for several reasons. Intervention, or the lack thereof, in childhood as opposed to later may have a greater impact on long range outcome (219); however, consensus is lacking regarding the definition of desirable outcomes. Further, children have limited capacity to participate in decision making regarding their own treatment and must rely on caregivers to make treatment decisions on their behalf. An additional obstacle to consensus is the lack of randomized controlled treatment outcome studies of children with GID or with any degree of GV (2). In the absence of such studies, the highest level of evidence currently available for treatment recommendations for these children is expert opinion. Such opinions do not occur in a complete vacuum of relevant data, but are enlightened by a body of literature (mostly APA level C and lower) including systematic experimental single-case trials as well as both uncontrolled and inadequately controlled treatment studies, longitudinal studies without intervention and clinical case reports. Opinions vary widely among experts depending on a host of factors including their theoretical orientation as well as their assumptions and beliefs (including religious) relating to the origins, meanings and fixity/malleability of gender identity. For example, do gender variations represent natural variations, not assimilated into the social matrix, or pathological mental processes? Even among secular practitioners there is a lack of consensus regarding some of the most fundamental issues: What are indications for treatment? What outcomes with respect to gender identity, gender role behaviors and sexual orientation are desirable? Is the likelihood of a particular outcome altered by intervention? What constitutes ethical treatment aimed at bringing about the desired changes/outcomes? Adding to this complexity, service seekers as well as providers differ in their religious and cultural beliefs as well as in their world views regarding gender identity, appropriate gender role behaviors, and sexual orientation. Primary caregivers may, therefore, seek out providers for their children who mirror their own world views, believing that goals consistent with their views are in the best interest of their children.

We begin by examining the natural history of GID as defined by outcome without treatment. We then discuss the goals of interventions in treating these children and the factors that influence clinicians in goal selection. Next, we describe various interventions that have been proposed. The empirical data available to inform the selection of goals and interventions are then reviewed and an opinion is offered regarding the status of current credible evidence upon which treatment recommendations could be based.

Outcome Without Treatment

The natural history or outcome of untreated children with GID is that a minority will identify as transsexual or transgender in adulthood (a phenomenon termed persistence), while the majority will become comfortable with their natal gender over time (a phenomenon termed desistence) (3-6). As reviewed by Wallien and Cohen-Kettenis (2008), the rate of persistence into adulthood was initially reported to be exceedingly low, but more recent studies suggest that it may be 20% or higher. In one recent study of gender dysphoric children (59 boys, 18 girls; mean age 8.4 years, age range 5-12 years), 27% (out of 54 who agreed to participate in the follow-up study) remained gender dysphoric at follow-up 10 years later (5). At followup, nearly all male and female participants in the persistence group reported having a homosexual or bisexual sexual orientation. In the desistance group, all of the girls and half of the boys reported having a heterosexual orientation. The other half of the boys in the desistance group had a homosexual or bisexual sexual orientation.

A more recent study (69) assessed 25 girls in childhood (mean age, 8.88 years; range, 3-12 years) and again as adolescents or adults (mean age, 23.24 years; range, 15-36 years). At the assessment in childhood, 60% of the girls met the DSM criteria for GID, and 40% were subthreshold for the diagnosis. At follow-up, 3 participants (12%) were judged to have GID or gender dysphoria. Regarding sexual orientation, 8 participants (32%) were classified as bisexual/homosexual in fantasy, and 6 (24%) were classified as bisexual/homosexual in behavior. The remaining participants were classified as either heterosexual or asexual. At follow-up, the rates of GID and bisexual/ homosexual sexual orientation were substantially higher than base rates in the general female population derived from epidemiological or survey studies.

Desistence develops gradually over the preadolescent period (primarily between 8 and 12 years) for unknown reasons which have been postulated to include social ostracism, early pubertal hormonal changes, and cognitive development (5). It has also been noted that compared to "persisters," "desisters" may experience less gender dysphoria in childhood (5). The reliability of adult transsexuals' reports of childhood gender nonconformity has been discussed by Lawrence (34). A substantial proportion of adult transsexuals retrospectively report gender conformity as children and/or gender dysphoria that was kept private, never leading to clinical referral (70, 71). Some may also reinterpret childhood memories in light of later life events and recall greater degrees of gender nonconformity than were apparent in childhood, thereby making the decision to transition gender more easily explicable to self and others (72). Some patients report exaggerating the history of gender nonconformity in order to be regarded by mental health and other professionals as appropriate candidates for medical services related to gender transition (73).

In Green's longitudinal study of gender-referred boys, psychotherapy as children did not appear to have any effect on gender identity or sexual orientation in young Case: 24-108 Document: 2-3 Page: 57 Filed: 01/25/2024

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adulthood, but the numbers of boys in various types of therapy were too small to draw strong conclusions (4). To date, no long-term follow-up data have demonstrated that any modality of treatment has a statistically significant effect on later gender identity or sexual orientation.

Treatment Goals and Objectives

The overarching goal of psychotherapeutic treatment for childhood GID is to optimize the psychological adjustment and wellbeing of the child. The literature reflects a broad consensus regarding several other goals, including appropriate diagnosis and treatment of concomitant psychopathology as well as disorders or conflicts whose manifestations may be confused with GID, and building the child's self-esteem (7, 17, 18, 29, 74). Although the child is the designated patient, there is also consensus regarding the need for parental psychoeducation, assessment, and adequate attention to parental psychopathology and parent-child conflicts (7, 25).

What is viewed as essential for optimizing the wellbeing of the child differs among clinicians, as does the manner in which the various potential goals of treatment should be prioritized relative to one another. For example, should reshaping the child's gender behaviors (e.g., increasing gender-conforming behaviors and/or decreasing gender nonconforming behaviors) be a primary therapeutic goal? Some have argued against directly targeting noncomforming behaviors (12-14), while recognizing that some forms of co-existing psychopathology in children with GID (e.g., depression) may be secondary to poor peer relations resulting from peer rejection due to the cross-gender identification. Modifying the child's cross-gender behaviors has been suggested by others to alleviate short term distress by improving peer relations and perhaps preventing the development of other psychopathological sequelae (75).

Opinions also differ regarding the question of whether or not prevention of adult transsexualism should be a goal of therapy. Zucker concludes that "there is little controversy in this rationale, given the emotional distress experienced by gender dysphoric adults and the physically and often socially painful measures required to align an adult's phenotypic sex with his or her subjective gender identity (75). Given the absence of any evidence that therapy is effective in preventing transsexualism in adulthood, together with concerns that therapy with that aim may be damaging to self-esteem, others challenge prevention as an acceptable goal. Among clinicians who share this second view, some endorse allowing the child to live in their preferred gender role to the extent that it is deemed safe to do so (12, 19). Some children may choose to present in the gender congruent with their biological sex in most social settings in order to avoid teasing and ridicule, but may present as their preferred gender at home and in other "safe" environments. Other children may become extremely depressed and even suicidal if not permitted to live in their preferred gender in all settings. Thus, some clinicians endorse childhood gender transition in at least some cases (12, 19).

The rationale for supporting transition before puberty is based on the belief that in some children a long term transgender outcome is to be expected and that these children can be identified so that primary caregivers and clinicians may opt for early social transition. An additional argument is that children who transition this way can always revert to their originally assigned gender if necessary, since the transition is only done at a social level and without medical intervention (9) although this may not be without complications (24). The main counterarguments to this approach hinge on the finding that GID in children usually does not persist into adolescence and adulthood. Thus, supporting gender transition in childhood might hinder the child's development or perhaps increase the likelihood of persistence (20). Furthermore, the peer-reviewed literature does not support the view that desisters and persisters can currently be distinguished reliably as children (5, 21-23).

Yet another approach to working with children with GID is to remain neutral with respect to gender identity and to have no goal with respect to gender identity outcome. Instead, the goal is to allow the developmental trajectory of gender/sexuality to unfold naturally without pursuing or encouraging a specific outcome (12-14). The position in favor of supporting free gender expression is centered on the assumption that self-esteem may be damaged by conveying to the child that his/her likes and dislikes as well as mannerisms are somehow intrinsically wrong. The counter argument proposes that self-esteem can be best served by improved social integration, including the ability to make same-sex friendships. Here the assumption is that the derived psychological benefits brought about by conforming to social expectations outweigh the benefits of expressing the putative "true gender self" (12) freely when it deviates significantly from social gender norms. Alternatively, the child's selfrecognition of a gender variant and stigmatized status may be actively encouraged with the goal of mastery, e.g., developing cognitive, emotional and behavioral coping

As reviewed by Zucker, there is currently widespread recognition among mental health professionals that homosexuality is not inherently related to general psychopathology or mental disorders (75). Nevertheless, it has been suggested that treatment of gender variant children for the prevention of homosexuality can be justified on other grounds, including parental values (4) as well as religious values (8). Given the absence of evidence that any form of therapy has an effect on future sexual orientation, however, such efforts are presently controversial, and this point should be addressed in the psychoeducation of primary caregivers. Further, it has been argued that offering therapy aimed at preventing homosexuality could have the effect of labeling homosexuality as an inferior and undesirable condition, thereby increasing prejudice and discrimination towards lesbians and gay men (76). Parallel arguments could be made regarding attempts aimed at preventing transsexualism.

Types of Interventions

A variety of intervention modalities has been proposed to achieve the above goals. Therapeutic approaches to Case: 24-108 Document: 2-3 Page: 58 Filed: 01/25/2024

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work with children with GID include individual insightoriented psychoanalytic or psychodynamic psychotherapy (25); protocol-driven psychotherapy such as behavior modification (26); parent and peer-relations focused therapy (18) and, parent and child therapeutic groups (12, 13, 15). Other proposed interventions are best characterized as self-advocacy and educational: support groups for primary caregivers, community education through websites and conferences, school-based curricula, and specialized youth summer camps. As in other disorders, the recommendation for a particular therapy often hinges on the therapist's preferences and training. This is especially true for GID, however, in light of the lack of consensus regarding either the goals for therapy or the malleability of gender identity, as well as the controversies surrounding the ethics of aiming to influence identity development.

Even though the child should be the ultimate beneficiary of treatment, the primary focus of intervention is sometimes the primary caregivers (e.g., via parenting support and psychoeducation as well as guidance in reinforcing behavior modification, and building selfacceptance and resilience in the child) and often multipronged interventions are necessary that involve not only the child and family, but the community (e.g., via bullying prevention and diversity education). Some approaches may center on the primary caregivers to minimize therapist contact with the child in order to avoid placing the child squarely in the clinical spotlight which can be stigmatizing (12, 18). This is particularly true of work with very young children in which the primary caregivers may be targeted with the aim of empowering them with the understanding and skills necessary for optimally parenting their child with GID (12). Additionally, psychodynamic theories have sometimes focused on the primary caregivers (77) or parent-child conflict (78) as possible causal factors in GID, providing a different rationale for primary caregivers as the target(s) of intervention. Problems in parent-child attachment interacting with temperamental dispositions in the child have been suggested to be causally implicated in GID and cited as a focus for psychodynamic therapy of the child (25).

Zucker and Bradley observed higher levels of psychopathology in clinical samples of primary caregivers and suggested that parental psychological abnormalities may contribute to GID (79). These observations, however, do not distinguish between cause and effect. Whatever the directionality of the cause and effect relationship, parental distress and psychopathology should be assessed and appropriately addressed as part of a comprehensive treatment approach.

Outcome Research

Very few studies have systematically researched any given mode of intervention with respect to an outcome variable in GID, and no studies have systematically compared results of different interventions. Some of the earliest treatment studies of children with GID were done in the 1970s by Rekers and colleagues in individual and small case series using behavioral methods (80, 81). These authors tested behavior modification in boys through contingency management including punishment of feminine behaviors, with a stated goal being prevention of later homosexuality and transsexualism. Short-term treatment success was reported with a decrease in gender nonconforming behaviors. Long term follow-up studies, however, were not reported so there is no evidence that these effects were enduring or that intervention influenced either gender identity or sexual orientation. Although Rekers' reports were widely criticized for using punishment and religious persuasion with the goal of prevention of homosexuality (13, 82, 83), his general goals for interventions with children with GID have been shared by other clinicians, e.g., (84, 85) and endorsed by controversial mental health organizations such as the National Association for Research and Therapy of Homosexuality (www.narth.org).

A parent- and peer relations focused protocol for boys with GID was tested by Meyer-Bahlburg (18). The treatment focused on the interaction of the child with the primary caregivers and with the same gender peer group. The goals were developing a positive relationship with the father (or father figure), developing positive relationships with male peers, developing gender-typical skills and habits, fitting into the male peer group, and feeling good about being a boy. To minimize the child's stigmatization, only the primary caregivers attended treatment sessions which focused on such issues as parents' gender attitudes, changing family dynamics when the father increases positive interaction with the boy, selection of appropriate same-sex peers for play dates, selection of summer camp, supporting artistic interests and talents, etc. The therapy also involved ignoring rather than prohibiting or bluntly criticizing the boy's cross-gender behaviors and distracting him in contexts typically leading to cross-gender behaviors, while giving him positive attention when he engaged in gender-neutral or masculine activities.

The sample consisted of 11 boys. Age at evaluation ranged from 3 years, 11 months to 6 years with a median of 4 years, 9 months. Eight boys were diagnosed as having GID of childhood, and three as having GID NOS. Treatment was terminated in most cases when the goals stated above were judged to have been fully reached. Ten of the 11 cases showed such marked improvement; only one did not and was, therefore, judged to be unsuccessful. The total number of treatment visits per family ranged from 4-19 (with a median of 10). In some cases, treatment for other family problems, such as marital conflict or individual psychiatric problems of the primary caregivers, continued after treatment of the child's GID was completed. Follow-up was done mostly by telephone. The duration of follow-up was left to the primary caregivers and varied up to several years. There was no significant recurrence of GID or GID NOS in the 10 successful cases, although several primary caregivers reported occasional recurrence of some cross-gender activities, especially during the first winter following treatment when the children were homebound and peer contacts diminished.

Some therapists, including the present authors, modify Meyer-Bahlburg's parent- and peer-centered approach Case: 24-108 Document: 2-3 Page: 59 Filed: 01/25/2024

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(18). This entails working with the family in a psychoeducational and supportive approach, promoting the child's self-esteem and decreasing family dysfunction, while assisting the family with the child's positive adaptation regardless of gender identity. This approach involves much work with the primary caregivers and other family members, as well as with the school or other facilities, and can include support groups for the primary caregivers (13, 14, 86). The goals are to allow the child to have a variety of experiences and to promote positive adaptation to whatever gender identity and sexual orientation the child will have as an adolescent and adult, and to assist the family in accepting and supporting their child regardless of outcome. The present authors (unpublished) have observed improved self-esteem, decreased behavioral disturbance, improved family functioning, and generally less cross-gender behavior using this approach. One of the authors (Pleak, unpublished) has followed up 10 boys with GID who were in treatment between ages 3 to 12 years old. In young adulthood, 7 identify as gay men, one as bisexual, one has undergone sex reassignment and is now a woman, and one who has Asperger's disorder has no romantic or sexual relationships with other people, but identifies entirely as male and reports sexual fantasies about women. As adults, all acknowledge their previous GV in behavior and identity, and the 9 who did not become transsexual say they have not felt cross-gendered since adolescence.

Conclusions and Opinion Regarding Treatment Recommendations

Web-based literature searches failed to reveal any randomized controlled studies related to any of the issues germane to treatment of children with GID. The majority of studies would be categorized as APA evidence category G such as individual case reports and APA evidence category C such as longitudinal follow-up studies without any specific intervention (4). A few reports might be categoryized as APA level B (clinical trials), however, these lacked control groups (or an adequate control group) and/or the follow-up interval was brief (18, 26, 87).

In light of the limited empirical evidence and disagreements about treatment approaches and goals among experts in the field and other stakeholders, recommenddations supported by the available literature are largely limited to the areas of consensus identified above and would be in the form of general suggestions and cautions. One such caution would be to inform primary caregivers and children (in an age-appropriate manner) of the realistic therapeutic goals, available treatment options and the lack of rigorous evidence favoring any particular treatment over another for attaining a particular goal. Families should be informed about potential outcomes including the possibility that the child's experience/ perception of the gendered self may change as they mature. The range of possible long-term outcomes discussed should include homosexuality, heterosexuality, varying degrees of discomfort with sex of birth, and variance in gender expression in relation to stereotypes, including the pursuit of medical/surgical interventions for sex reassignment. Clinicians should be sensitive to the primary caregivers' values and wishes but also be alert to the possibility of parental decisions being driven by a wish to normalize the child through therapy intended to increase gender conformity (or heterosexuality) or through premature gender role transition. At the same time, clinicians should be cautioned against wholesale rejection of gender role transition when this may be in the best interest of the child, even if in a relatively small number of cases (88). Clearly, therapy cannot be offered with the promise of preventing either transsexualism homosexuality. Even offering treatment with such aims raises ethical concerns, and these have been addressed elsewhere (13, 89).

Gender Variance in Adolescence

Susan Bradley, M.D. Richard Green, M.D., J.D.

For purposes of this Task Force report, adolescence is defined as the developmental period from 12 to 18 years of age. Problems of gender identity present as a spectrum with some adolescents having longstanding gender dysphoria and wishes to be the other sex (typically evident in childhood) while others present with a more recent onset of gender dysphoria, sometimes in the context of more broad identity confusion and less clear definition of their identity as the other sex. For example we have seen several adolescent females with recent onset of a wish for SRS following a sexual assault. Other adolescents may present with clear body dysmorphic disorder, psychosis, severe depression and Asperger's disorder, with the wish for SRS appearing almost as a secondary phenomenon. Those adolescents with GID whose GID symptoms were clearly present in childhood and have continued into adolescence are generally less complicated to manage. According to Cohen-Kettenis and van Goozen (90) this "persistent" group may have less overt psychopathology. Those whose GID symptoms emerge later, often with pubertal changes and/or in the context of a psychiatric disorder or following Transvestic Fetishism, present with a more complicated management picture. Although many of the same issues arise for both early and later onset groups, the timing at which particular issues arise and how they are managed clinically may vary between the two groups. The consensus among the clinicians with the most experience in this area is that it is important to address major co-occurring psychiatric issues prior to the gender issues in both early and later onset groups (23, 91). In the absence of other contributory issues, as is more common with the early onset group, supportive work towards transition may be appropriate (23, 91).

Searches of PubMed and PsychInfo databases failed to reveal any randomized controlled trials (RCTs) related to any of the issues germane to treatment of adolescents with GID. The majority of studies would be categorized as APA evidence category G such as individual case reports (92); APA evidence category C such as longitudinal follow-up studies without control groups [e.g., (31, 93, 94)]; APA evidence category B such as follow-up studies with control Case: 24-108 Document: 2-3 Page: 60 Filed: 01/25/2024

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groups of limited utility and without random assignment [e.g., (30, 88)], and APA evidence category F such as reviews of the above, some of which were exhaustive [e.g., (21, 23, 27, 95)]. There are two clinics (The Gender Clinic of Vrije University Medical Center, Amsterdam, The Netherlands, and The Child and Adolescent Gender Identity Service of The Centre for Addiction and Mental Health, Toronto, Canada) that have sufficient numbers of subjects and where there is systematic data collection to act as an "experience base" from which to guide both the inquiry and possibly expert opinion on the main issues in adolescence. Unfortunately, additional studies to either corroborate or challenge the findings of these clinics are not available.

This report will begin by considering the assessment of adolescents presenting with a wish for gender reassignment, and then consider the evidence for psychotherapy, the real-life experience, medical suspension of puberty, and cross-sex hormones. An assessment of the evidence base regarding each of these issues is given as well as an opinion regarding the development of treatment recommenddations. SRS is not performed on adolescents in the United States and is, therefore, not addressed in detail.

Assessment

Follow-up studies of adolescents and adults from the Dutch clinic emphasize the importance of good assessment with respect to comorbid psychopathology (30, 31, 96-98). Better outcomes from SRS were seen in female-tomale transsexuals (FTMs) and male-to-female transsexuals (MTFs) who were primarily erotically attracted to individuals of their natal sex than in MTFs who were not primarily attracted to individuals of their natal sex. MTF individuals in the latter category with more psychopathology and cross-gender symptoms in childhood, vet less gender dysphoria at initial consultation, were more likely to drop out from follow up prematurely. Such clients with considerable psychopathology and body dissatisfaction reported the worst post-operative outcomes. As described below, the most systematic information is available on the adults (N=162) while the adolescent samples were smaller (N=22 and N=20).

Although the studies from the Dutch clinic are suggestive, the predictors are hardly either well tested or strong enough alone to use in assessing prospective candidates for SRS. Generally, both clinics believe that those adolescents with higher levels of psychopathology, less gender dysphoria and/or more recent onset of their wish for sex reassignment should be followed over a period of time in order to treat the more obvious psychopathology (e.g., depression, psychosis, body dysmorphic disorder) and to see if treatment of the psychopathology will lead to a reduction in the wish to proceed to SRS (see case reports of change in wish for SRS with treatment of comorbid psychopathology (99-102)).

The position of the Toronto clinic has been to aim for neutrality with respect to the issue of gender transition in those situations in which the GID is of recent onset and accompanied by more obvious psychopathology. With those adolescents where there is longstanding GID and the

adolescent is already engaged in the "real-life experience" or prepared to do so, the Toronto clinic tends to be more positive with respect to supporting transition. Both groups may, however, be offered pubertal suspension as a way of delaying puberty and/or the development of secondary sex characteristics in order to allow more time either for psychotherapy or for planning for the future. Future planning issues include how to present oneself socially as the other sex, how to change one's name, who to tell, and similar issues. Clearly, for the younger adolescent this means agreement of the primary caregivers. In some cases older, "emancipated" adolescents may proceed without parental agreement.

The Dutch group supports full gender transition, assisted by hormone administration for adolescents who are generally well adjusted and functioning socially in the preferred gender role, are older than 12 years of age and have reached Tanner stage 2-3. In a follow-up study of such individuals (N=20), they reported that with cross-sex hormone treatment in adolescence and SRS at age 18, or shortly thereafter, the outcomes were overall quite positive (as assessed by satisfaction with surgery and lack of regrets) and generally better compared to individuals who underwent SRS later in adulthood (30). They also followed a group of adolescents who were refused SRS or chose not to pursue it (N= 21). The reasons for refusal were elevated levels of psychopathology, lack of clarity or consistency regarding the nature and extent of the gender identity concerns resulting in diagnostic uncertainty, and gross psychological instability. Those who did not have SRS showed reductions in gender dysphoria but continued to have more social and emotional difficulties than the SRS group. The difficulty in interpreting this study is that the subjects who were refused or not encouraged to proceed generally had higher levels of psychopathology to begin with. Although there were reductions in psychopathology across all groups it is impossible to draw conclusions about the efficacy of SRS in reducing comorbid psychopathology because the groups were not matched for level of psychopathology at the outset. There are no controlled studies with matching of subjects at the outset and random assignment to SRS or supportive therapy. Overall, those who were refused did not regret not being able to pursue SRS. The investigators emphasize the importance of careful evaluation as the initial step in SRS and referral for comorbid psychopathology in those who do not meet careful criteria for gender dysphoria. Clearly, clinical judgment is involved with it being easier to assess and evaluate those with longstanding GID as opposed to the later onset group who tend to present not only with more psychopathology but more uncommon requests such as the desire for drugs to reduce testosterone levels with no overt desire to pursue SRS.

In the Toronto sample there is significant psychopathology in the adolescent sample, particularly in the late onset group (103). As indicated above, many of these adolescents also present with a shorter duration of crossgender feelings and less clarity or consistency regarding the nature of their gender concerns as well as histories of trauma, psychosis, body dysmorphic disorder and severe Case: 24-108 Document: 2-3 Page: 61 Filed: 01/25/2024

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depression that seem related to their cross-gender feelings. Despite these observations, often these adolescents are very certain that SRS is the "only" solution to their dilemmas and because of this may become very pressuring of doctors in their quest for SRS. Access to Internet sites that uncritically support their wishes appears to facilitate their intense desire for hormones and surgery. In order to deal with these issues, both the Dutch and the Toronto groups generally insist on some form of involvement in supportive psychotherapy with a focus on comorbid psychopathology and family issues as well as support around pursuing or not pursuing SRS. Some of these adolescents and their families, however, are reluctant to proceed with psychotherapy or family therapy.

Based on the above, it is important to do a thorough assessment of adolescents presenting with a wish for SRS. This should include an assessment for comorbid psychopathology, particularly any disorder that may have as a secondary phenomenon a tendency to produce gender confusion such as schizophrenia or psychotic depression, or emergence of the SRS wish in the context of trauma.

Psychotherapy

As indicated above, psychotherapeutic involvement is used not only to explore issues related to the individual's commitment to living in the cross gender role but also to explore whether the individual has fully explored other options, such as living as a homosexual person without SRS. Attempts to engage the individual in more in-depth psychotherapy to "cure" them of their gender dysphoria are currently not considered fruitful by the mental health professionals with the most experience working in this area (79, 91). Instead of psychotherapy aimed at "curing" gender dysphoria, supportive therapy and psychoeducation seem justified on the basis of ensuring that the individual understands and is committed to a long and difficult process and has considered alternatives to SRS. Generally, some time is devoted to supporting the individual's efforts to live and present oneself as the other sex. There have been no systematic studies of the effects of this supportive psychotherapy.

A survey of Dutch psychiatrists who did not work in GID clinics found that 49 percent had treated at least one "cross-gender confused" patient. Of 584 patients reported on in the survey, GID was regarded as the primary diagnosis for 39 percent. In the other 61 percent of cases, cross-gender issues were comorbid with other psychiatric disorders and in the majority of those cases, the gender issues were interpreted as epiphenomena of the comorbid disorder (104). The most frequently reported disorders in which "cross-gender confusion" was reported were personality, mood, dissociative and psychotic disorders (104, 105), with gender confusion or cross-gender delusions occurring in up to 20 percent of individuals with schizophrenia over the course of the illness (106). Campo (2003) concluded that the survey emphasizes the need for articulated rules to assist mental health specialists in distinguishing GID with a comorbid psychiatric disorder from gender confusion that is an epiphenomenon of another disorder. Knowledgeable clinicians can make this distinction based on the patient's history, including collateral history from friends and family members, and longitudinal follow-up. Most experienced clinicians would agree that, when the adolescent is motivated, supportive psychotherapy is very helpful either to assist in the transition to the other gender or to assist in the individual's decision as to whether to pursue SRS or not.

Expectations for Period of Living as the Other Sex (The Real-Life Experience)

Since the original guidelines drafted in 1979 (107) by the Harry Benjamin International Gender Dysphoria Association (HBIGDA), now WPATH, subjects wishing SRS have been expected by the mental health professionals assessing them for suitability, to live as the other gender for one to two years prior to being approved for surgery. These recommendations for living or presenting oneself as the other gender have been modified over time and there is no absolute agreement as to what length of time nor what aspects of real-life experience are critical either to acceptance for SRS or to later outcomes. Many adolescents who have longstanding gender dysphoria may be living as the other gender at the time of assessment, some of them quite convincingly. Others, often in the late onset group, do not appear to have considered how they would begin to present themselves as the other gender and often create a sense of dissonance in the examiners between their wish and their appearance. The extent to which an individual seems engaged in presenting as the other sex often reflects the extent of anatomical gender dysphoria and commitment to hormonal and/or surgical interventions.

Although there has been some loosening in the application of the real-life experience over the years and no consensus as to what is a required minimum length of time of such an experience, the majority of professionals working in this area believe that some period of real-life experience is important. Further research is needed before a guideline on this issue can be established.

Issues Regarding Suspension of Puberty

Puberty is the critical developmental milestone in the continuation, or not, of GID. Associated body changes can have a negative short- and long-term impact. A person born male who is convinced that he should have the body of a female is distraught at experiencing the testosteronemediated changes of male puberty. A person born female convinced that she should be male is distraught at the changes of female development. Assuming that the GID endures, the consequences of undesired pubertal changes are substantial. In the long term, they are typically more troublesome for the person born male. The stigmata of pubertal body development including height, bony configuration, hair and voice are a substantial handicap when later attempting to integrate socially as a woman. For the person born female there can be a height handicap as well as the need for surgery which could have been avoided by suppression of puberty. Clinicians experienced with GID in adult patients burdened by the pubertal changes of the "wrong sex" and clinicians attempting to help patients with GID who are entering adolescence recognize the need

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for intervention to prevent both the short- and long-term consequences of the "wrong puberty."

The gonads secrete sex steroids in response to the gonadotropins from the pituitary. These are secreted in response to hypothalamic gonadotropin releasing hormones (GnRH). Synthetic GnRH agonists bind to the pituitary so that GnRH no longer acts. Gonadal sex steroid production ceases within 4-12 weeks, and upon discontinuance, hormonal puberty is resumed within 3 months (108). Thus, current endocrinological sophistication provides a therapeutic strategy. Puberty, as it begins, can be suspended (29). Administration of GnRH analogues can delay the sex steroid induced progression of body changes. During this period of "time out" the patient and clinician can explore the options available and decide on the optimal future direction of living as a man or as a woman.

The duration of pubertal suspension that can be safely implemented has been of concern. This has focused primarily on the effect of sex steroid deficiency on bone metabolism with its potential for deficient mineralization and possible osteoporosis. Research has demonstrated that a period of up to several years appears to be safe with the deficiency of progressive mineralization being remedied once sex steroids, either those expected by birth sex or those administered for cross-sex development, are available. Peak bone mass occurs at about 25 years of age and long term treatment data have yet to be reported (91, 109). Significant safety issues connected with the use of hormone suppressing agents have not emerged to date; however, long term follow-up data are lacking.

Adolescence is also a developmental period of substantial brain maturation and concerns have been expressed over possible cognitive deficits consequent to pubertal suspension. There is some evidence in hamsters of a detriment to development or changes in behavior (110); however, there has been no evidence clinically of any consequence of pubertal suspension on brain functioning in humans (109). Concerns about consequences of pubertal suspension may be tempered by the fact that there is substantial variation in the age of onset of normal puberty (e.g., between the ages of 11 and 16 years).

A critical treatment issue is the diagnostic challenge of selecting patients for whom GID is on a continuing developmental trajectory. The majority of prepubertal patients diagnosed with GID do not continue with GID into adolescence (111). Most ultimately manifest sexual attracttion to persons of their birth sex but have no desire to modify their body to that of the other sex. However, most children whose anatomical gender dysphoria intensifies as pubertal development ensues will ultimately desire SRS. The fit is not perfect. Therefore, pubertal suspension for a year or two provides breathing space for the young person and clinician to experience and to explore the continuing evolution of gender identity.

Adolescent patient selection criteria have included an intense pattern of cross-gender identity and behavior from early childhood, and an increase in gender dysphoria with the onset of puberty in a patient otherwise psychologically stable and in a supportive family environment (91). Clinical experience with pubertal suspension demonstrates that

with thorough clinical screening the large majority of patients whose puberty has been suspended continue to experience GID and do not want the body changes typical of their birth sex. They are then administered sex steroids to enable body changes consistent with their cross-sex identity (28). For the small number of patients who conclude that developing along the lines expected by birth sex is preferable, GnRH analogues can be discontinued, and pubertal development as typical of their natal sex resumes (29). On the other hand, if gender transition is desired, GnRH analogues are continued during cross-sex steroid treatment prior to gonadectomy.

In the most experienced treatment center in the Netherlands, GnRH analogues are prescribed shortly after the onset of puberty (Tanner stage 2-3). Triptorelin is administered in a dose of 3.75 mg every 4 weeks. At the introduction of treatment an extra dose is given at 2 weeks. Gonadotrophins are suppressed after a brief period of stimulation (109). Feminizing/masculinizing endocrine therapy in that center can begin at 16 years with recommendation of the mental health professional who has engaged with the adolescent for a minimum of 6 months. Sex reassignment surgery for continuing GID can be performed at 18 years and must be preceded by a 2 year real-life experience of full-time cross-gender living. As a 12 cm height difference is a typical sex difference, it is advantageous to retard the growth of natal males and enhance the growth of natal females. The Endocrine Society guideline addresses management of this important issue (29).

The most extensive series of cases with pubertal suspension is reported from the Netherlands (APA level B, longitudinal follow-up after an intervention). From 2001 to 2009, 118 adolescents were treated (50 natal males and 68 natal females). Mean age was 14.3 years in 2009. None had discontinued pubertal suspension. Behavioral and emotional problems (as measured by the Child Behavior Check List and Youth Self-Report) and depressive symptoms (as measured by the Beck depression inventory) decreased while general functioning (Global Assessment Scale) improved significantly during puberty suppression. Crosssex hormone treatment had been started with 71, at a mean age of 16.6 years (28).

The experience of the Toronto group to date has been recently published (33). This group examined demographic, behavior problem, and psychosexual measures to see if any of them correlated with the clinical decision to recommend, or not recommend, pubertal suspension in a consecutive series of 109 adolescents (55 females, 54 males) with GID evaluated between 2000 and 2009. Of the 109 adolescents, 66 (60.6%) were recommended for pubertal suspension and 43 (39.4%) were not. A combination of five (of 15) demographic, behavior problem, and psychosexual measures were identified in a logistic regression analysis to significantly (p<.10) predict this clinical recommendation (Zucker et al. 2011). The quantitative data were complemented by clinical case descripttions; however, follow-up data were not adequate for statistical comparison of any outcome measures between those for whom pubertal suspension was recommended Case: 24-108 Document: 2-3 Page: 63 Filed: 01/25/2024

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compared to those for whom it was not. Other centers in Los Angeles and Boston have similarly instituted programs of pubertal suspension but have not vet published systematic evaluations of their case series. Because of cost, GnRH analogues are not affordable for many in the U.S. Less expensive alternatives (e.g., spironolactone) may be used in natal males (29).

Issues Regarding the Use of Cross-Sex Hormones

The major issue with respect to use of cross-sex hormones concerns the timing of administration. There are no established criteria for use of cross-sex hormones in adolescents. Generally, however, these are now used following suspension of puberty when it is increasingly clear that the adolescent meets readiness criteria to move towards SRS and is functioning reasonably well psychologically and socially. There are no studies addressing the issue of timing. The Dutch follow-up study (94) concluded that those adolescents who transitioned earlier presented a more convincing physical appearance than did those with a later age of transition. This follows logically as there was less development of secondary sex characteristics of the natal sex as indicated above. There are currently inadequate data for development of an evidencebased guideline regarding the timing of cross-sex hormone treatment.

Issues Regarding the Timing of SRS

SRS is not generally an issue for adolescent populations in the United States as surgery is normally not performed before the age of 18. However, occasionally surgery has been done during adolescence in other countries. Given the irreversible nature of surgery, most clinicians advise waiting until the individual has attained the age of legal consent and a degree of independence. In some jurisdictions (e.g., UK), there is no fixed legal age of consent to medical procedures. Instead, a comprehensive understanding of the procedure, with options, risks, and benefits must be demonstrated by the patient (30). At present, there is inadequate evidence to develop a guideline regarding the timing of sex reassignment surgery although medical advice is important with respect to removal of ovaries within a reasonable time after use of cross-sex hormones (29).

Gender Variance in Adults

A. Evan Eyler, M.D., M.P.H. D. Andrew Tompkins, M.D. Eli Coleman, Ph.D.

Here we address the care of transgender and other gender variant adults from the perspective of the practicing psychiatrist. First, the principal concerns of these individuals in a clinical context are described. Psychiatric assessment, treatment options and the processes employed in clinical decision making are discussed. The quality of evidence currently available to guide the selection of practice options and to support treatment recommendations is then evaluated using the American Psychiatric Association coding system. The professional literature regarding treatment of adults with GID/GV is more extensive than the literature regarding the treatment of children or adolescents. This section of the report is, therefore, correspondingly longer than those sections.

Gender Identity Concerns in Adulthood

GV is sufficiently common that even adult psychiatrists whose practice does not focus on transgender care encounter patients who are transitioning gender, or contemplating gender transition. Gender variant persons choose different means to express the gendered self authentically or to attain relief of psychological distress due to lack of congruence between the psychological and socially-presented selves, or between physical characteristics and gender identity. Many seek both hormonal and surgical transition; however, some seek hormonal treatment but do not feel the need for any, or particular (e.g., genital) surgical procedures. Others may choose surgical but not hormonal treatments. Mental health services may be sought for many reasons, including a desire for professional assistance with exploring gender identity, or to gain comfort with the gendered self or preferred gender presentation. Some also seek counseling regarding the decision of whether or not to transition publicly, and, if so, to what extent. Additional concerns include preparing to initiate hormonal treatment; monitoring psychological functioning as the physical effects of the administered hormones become apparent; choosing whether or not to undergo various surgical procedures, such as breast, genital, or facial modifying surgeries; and adjusting to post-transition living in the preferred gender presentation. Psychiatrists who treat transgender adults may also be called upon to assist their patients with the legal and financial concerns associated with gender transition in the current social system. These include coding and payment of insurance claims for mental health and other medical services related to transgender care; management of identity documentation during and after transition; the treatment of transgender and transitioning persons in the military and in incarceration settings; discrimination based on gender identity or gender presentation, and many others.

Adults who conclude that transition is the best solution to the psychological discomfort they experience face different challenges than children and adolescents with strong cross-gender identification. Some individuals who publicly transition in adulthood have been aware of a sense of gender incongruence since childhood or adolescence, but have adopted a social presentation that is at least somewhat conforming to gender expectations. This may have occurred (consciously or unconsciously) in order to reduce the level of difficulty encountered in settings such as education, employment and partnered relationships (112). They may take the risks inherent in transitioning publicly when they are older and have more autonomy, or when they are naturally going through stages of individuation. Concerns regarding transgender awareness or transition may emerge during the course of treatment of some other presenting complaint. For example, some transgender adults initially seek treatment for depression, substance abuse, or other clinical problems that have

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developed in the context of chronic suppression, or repression, of feelings related to GV. Initial disclosure, particularly in a clinical setting, is usually a time of high emotional vulnerability for the person sharing this confidence with the psychiatrist or other professional (112), and requires knowledgeable and empathic management.

Acknowledging the awareness of cross-gender identification to oneself and to others, and integrating this awareness into one's identity, is sometimes referred to as "coming out transgender" or "coming out trans." This has been described as a multi-stage process by mental health professionals with extensive clinical experience with transgender phenomena, as well as on the basis of observational or qualitative research (112-116). These observations suggest a process somewhat analogous to that proposed for identity development among gay men (117-120), lesbian women (121, 122) and bisexuals (123, 124). Though particular stages or milestones may be recognized in the process of coming out, they do not necessarily progress in the same sequence in all individuals (125). Persons who come out as transgender, or who transition during the adult years, are usually in the position of balancing the drive to live in a more authentic gender presentation with the needs created by years of living a more gender conforming public and private life.

Transition Goals and Outcomes

The process of integration of transgender identity may also demonstrate substantial complexity due to the variation in outcome that individuals seek. For example, some never publicly transition gender, while some may delay openly transitioning for a variety of reasons, such as concern about the impact of disclosing the transgender identity on employment or child custody arrangements. These individuals may, nevertheless, utilize hormonal treatments to facilitate presentation in the psychological (trans)gender in private settings - sometimes for years prior to public transition. Others find that their best sense of psychological relief and self-comfort is obtained through adopting a combination of social gender signifiers, with or without reinforcing medical treatments, to facilitate private reinforcement, though not public recognition, of the transgender identity. For example, an older male whose gender identity is female, may spend his leisure time at a club frequented by transgendered individuals, dressed as a woman, but may continue to present as male in his retirement community. He may also take a small dose of estrogen for psychological relief, even if this does not result in full physical feminization.

The range of transition goals sought has also evolved over time. Among the male-to-female (MTF) transsexual adults in Lewin's qualitative work (1995), the final stage of transition was described as "invisibility," i.e., assimilation into the general female population. Such "invisibility," however, is not currently a desired outcome for many transgender individuals and other gender variant adults. As transgender people and groups have become more visible in society, and have gained a measure of relative acceptance, the possibility of a transgender identity as such, rather than as a transitional stage within a male-female

divided social system, has become a more realistic option. The film Transgender Stories (126) provides some firstperson accounts in that regard. Some individuals do hope to fully assimilate as women or as men; however, others find authenticity in presenting a blend of gendered characteristics, or of fully transitioning gender while continuing to value the earlier life experience in the other gender role, such as by maintaining interests and activities developed during the pre-transition years. The process of integration of the transgender identity can also continue after the completion of surgical transformation of the body.

The possibility of stopping the process of gender transition prior to completion, or of reversing some of the physical changes that have been attained, has gained more acceptance in recent years. Some individuals find that a measure of bodily change, without genital surgery, clarifies their understanding of their gender identity and desired gender presentation. For example, some adults who begin FTM transition discontinue androgen use after some physical masculinization has been achieved, finding that a masculine female (butch) identity is more authentically representative of the self than living as a man. Some adults who initially present with transgender concerns decide, during the process of psychotherapy, not to proceed with any form of public gender transition (31). This can be a reasonable outcome to an exploratory psychotherapy, but elimination or "correction" of transgender identity is no longer considered a reasonable therapeutic goal. Pfafflin and colleagues (48, 127), for example, describe the evolution in treatment of gender dysphoria from historic psychoanalytic approaches aimed at achieving gender congruence through resolution of presumed intrapsychic conflict, to a contemporary model of offering psychotherapy or mental health evaluations that are often followed by hormonal treatments and surgeries.

Diagnostic and Mental Health Needs Assessment

Adults desiring hormonal or surgical treatments in the process of transitioning gender sometimes initially seek psychotherapy to clarify their gender identity and personal goals. Some individuals present directly to a surgeon, endocrinologist or other prescribing clinician, and are referred for mental health consultation prior to initiation of hormone therapy or preparation for surgery. Exploration of the gender identity, assessment of realistic understanding of transition treatments and outcomes, and detection and treatment of any concurrent psychiatric pathology are some of the usual goals of this process. At least brief (several months) participation in psychotherapy is recommended in many clinical settings, in order to allow sufficient time for this work to unfold prior to initiating physical treatments that produce effects that are not fully reversible. Mental health evaluation and treatment, and the medical transition treatments that may follow, are discussed in more detail below.

Psychotherapy and Mental Health Support

The skills used by mental health professionals in caring for adults who are in the process of transgender coming out are similar to those used in other clinical situations in Case: 24-108 Document: 2-3 Page: 65 Filed: 01/25/2024

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which concerns regarding personal identity, individuation versus conformity, or adaptation to minority identification within nonaffirming majority culture are involved. Decisions such as whether and when to transition publicly, whether hormonal and surgical treatments will be needed or whether some other accommodation can be reached; if, when and how to come out regarding the transgender identity or history; and how to manage the concerns associated with family, employment and education, etc. are best addressed in a supportive clinical environment, at the pace that is acceptable to the transgender individual, and in some cases, couple.

Most of the literature addressing psychotherapy with gender variant adults is descriptive in nature; case reports. review articles based on practice experience, theoretical schemas based on clinical observation or qualitative work. The vast majority would be categorized as APA levels F and G. The lack of more statistically robust forms of evidence, such as RCTs, is representative of the history of this aspect of clinical practice, and the fact that psychotherapy is often (though not always) followed by hormonal or surgical treatments. The relatively low, and apparently declining, rate of regret following gender reassignment surgery (as discussed below) in a number of studies is believed to reflect the overall effectiveness of current treatment of gender dysphoria, including psychotherapy aimed at clarifying the social and physical changes needed to achieve comfort with the gendered self. The available literature (48, 128, 129) suggests that adequate pre-surgical psychotherapy is predictive of good post-surgical outcomes.

Bockting, Knudson and Goldberg (130) offer fairly comprehensive recommendations for assessment and treatment of gender concerns, concurrent mental health difficulties, and elements of general counseling that are transgender specific. Their recommendations are based on a model of "transgender-affirmative approach, clientcentered care, and harm reduction." Based on the available literature, it would not be possible to recommend one particular style of psychotherapy over another for working with patients who are transgender; however, it is possible to identify the issues that therapy should address. These include concerns related to gender identity, gender expression and sexuality; social functioning and support; personal goals for public and private life, and related matters. Reasonable understanding of the effects of contemplated medical treatments and ability to adhere to a therapeutic regimen also should be assessed (107, 130) consistent with usual principles of decision-making capacity and informed consent. Assessment of cooccurring mental illness, particularly psychopathology that may influence the transgender presentation or that may be mistaken for transgender (e.g., Skoptic syndrome, in which a person is preoccupied with or engages in genital selfmutilation such as castration, penectomy or clitoridectomy) and psychotic disorders, etc. is paramount (29, 131).

Adults with gender identity concerns have also often experienced stigmatization or victimization related to gender variant appearance or behavior, or on the basis of actual or presumed sexual orientation as documented in the Report of the National Transgender Discrimination Survey (132). In fact, some authors have concluded that such stigmatization largely accounts for mental illness among individuals with GID (133). The American Psychological Association's Task Force on Gender Identity and Gender Variance concludes that "...there is adequate research concerning discrimination and stereotyping to support the development of clinical guidelines addressing these areas specifically." As with clinical work with individuals who are lesbian, gay or bisexual identified, an openminded and nonjudgmental psychotherapy approach that affirms the autonomy and lived experience of the individual is a fundamental part of psychiatric care of gender variant adults.

Medical Aspects of Gender Transition and Their Mental Health Implications

Mental health professionals who work with individuals who plan to transition using hormonal or surgical treatments, or who are in the process of doing so, need to be knowledgeable about these procedures and their mental health implications. These are, therefore, briefly reviewed here. Some individuals who transition, either female-tomale (FTM) or male-to-female (MTF), do so without hormonal therapy. Some seek mental health services while clarifying the decision to do so, and others do not find this necessary or feasible.

FTM transition usually includes use of androgens, which produce (or enhance) male secondary sex characteristics, such as beard growth and male distribution of body hair, deepening of the voice, and often mild coarsening of the facial features and skin. Androgen supplementation also causes enlargement of the clitoris, often to the extent that metaoidoplasty (one form of masculinizing genital surgery, discussed below) becomes feasible. MTF transition often consists of both estrogen supplementation and reduction in circulating androgens through use of anti-androgen agents, such as spironolactone or cyproterone (29). Estrogen effects include breast development and mild feminizing changes to skin and hair, though for many who transition MTF after completion of male pubertal development, depilation will be needed. Many also need surgical reduction of the laryngeal cartilage or feminizing facial surgeries. Use of hormonal preparations is much more effective in "adding" physical characteristics than in "subtracting" those that have already developed with natural puberty. Body habitus, including both fat distribution and potential for muscular development, is altered by use of cross-sex hormones. Utilization of either androgens or estrogens carries with it potential for both added health risks and, in some cases, physiologic benefits. The technical aspects of transgender hormonal treatment are discussed elsewhere (29, 109, 134) as is the associated general medical and preventive care (135-137).

Emotional changes may occur with use of either androgen or estrogen supplementation, though these are often relatively subtle and consistent with the pretransition personality (135). Increase in libido usually occurs with androgen use (29), though some individuals

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transitioning as MTF also experience a stronger interest in sex, perhaps due to the affirming aspects of attaining the bodily changes that have been desired for years, such as development of female breasts (135). Individuals in transition often benefit from ongoing psychiatric care (138). In addition to the psychotherapeutic work involved when individuals choose major life-changing experiences fueled by ongoing distress, monitoring the psychiatric effects of hormone use, along with the prescribing internist, family physician, gynecologist or endocrinologist, is advisable. For example, if excessive lability is noted, such as moodiness, weepiness or aggression (similar to the "steroid rage" that can accompany use of anabolic steroids by competitive male athletes and body builders), checking serum levels of circulating hormones is indicated (135). Safer sex information, and instruction in self-protective negotiation in sexual settings, is often provided by the psychiatrist or other mental health professional if this has not been done by the prescribing clinician. It is important that this information be tailored to the needs and experiences of transgender persons (136, 139).

Surgeries for purposes of gender transition include breast and chest ("top") surgeries and genital ("bottom") procedures. It is believed that most adults who transition from FTM have chest reconstruction surgery, because the visible contours of female breasts are such a powerful social cue and aspect of gender presentation as a woman, whereas a flatter chest facilitates presentation as a man (140). Some individuals may not require breast surgery if the body habitus is more masculine. The goal of FTM top surgery is not mastectomy, as would be performed for treatment of carcinoma of the breast, but creation of a natural appearing male chest, such that some of the subcutaneous fat is retained, in proportion to the general body habitus of the individual. Some adults who transition MTF have breast augmentation surgery due to achieving minimal breast development with hormonal treatment alone, though others develop fully morphologically normal female breasts with estrogen, and sometimes progestin, use. Some also choose breast augmentation due to dissatisfaction with the level of breast development achieved, similar to some non-transsexual women.

Many adults undergoing MTF genital surgery receive penile inversion vaginoplasty with clitoroplasty, labiaplasty, and orchiectomy. FTM genial surgery can consist of either metaiodoplasty with limited scrotoplasty, or more extensive surgery, including phalloplasty with grafted tissue from another body site, urethral extension, scrotoplasty and vaginectomy. Hysterectomy and oophorectomy are performed in either case. Information regarding the rationale for surgery (141), as well as current information regarding specific techniques (141, 142), is readily available to patients and professionals in a variety of sources, including professional sources, the popular press and the Internet; however, comparative outcome data among the providers and techniques are not similarly available.

Review of Literature with Respect to Support for **Treatment Recommendations**

Prior to considering whether current literature provides sufficient evidence to support treatment recommendations by the APA, it is necessary to define what constitutes successful treatment and to determine the quality of evidence that compares treatment options in terms of outcome. These issues will be discussed in turn.

Outcome Criteria

The definition of treatment success is complex, because gender identity and gender dysphoria, as well as any perceived benefit of treatment of gender dysphoria, are subjective experiences. Individuals seeking gender transition may also experience psychiatric symptoms or disorders that are unrelated to the gender identity concern, or that may have developed as a response to the distress of the gender dysphoria (e.g., addictive disorders) and require specific treatment.

DSM-IV-TR criterion D for GID states that "[t]he disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning." From this perspective, treatment can be considered successful if it relieves this distress or facilitates improvement in function in some substantive way. Some early outcome studies emphasized functional indices such as "job, education, marital, and domiciliary stability" (143). However, many persons who present for medical services for transition are already functioning very well socially and occupationally. In these cases, relief of the gender dysphoria, satisfaction with treatment, and lack of regret regarding the decision to transition, represent the primary measureable outcomes. (Among patients who experience some level of functional impairment, these may still be most important). Some clinical situations are complex. For example, an individual with high levels of personality pathology and gender dysphoria may experience substantial emotional relief with transition, and yet remain disabled from employment by the co-existing psychiatric illness.

The importance of subjective satisfaction as opposed to regret on the part of the patient has gained emphasis in the literature during the last two decades (38, 128, 144-146). This may reflect a combination of factors, including a relaxation of prevailing biases regarding gender and sexual orientation, a greater commitment to patient autonomy in mental health and general medical services, and the emergence of transgender and gender variant persons as a recognizable political group with reasonable claims to civil rights and responsibilities, rather than a population regarded primarily as patients and clients. Cole and collaborators (70) note that treatment of gender dysphoria during the early and mid-twentieth century was based on prevailing gender stereotypes: "Transsexualism itself was considered a liminal state, a transitory phase, to be negotiated as rapidly as possible on one's way to becoming a 'normal' man or 'normal' woman." This viewpoint has Case: 24-108 Document: 2-3 Page: 67 Filed: 01/25/2024

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gradually evolved to accommodate a greater variety of transgender experiences, and recognition of the importance of subjective outcomes as opposed to the ability to conform to majority cultural expectations. Kuiper and Cohen-Kettenis (1998) concluded, "...an evaluation of SRS can be made only on the basis of subjective data, because SRS is intended to solve a problem that cannot be determined objectively."

Evidence Regarding Effectiveness of Treatment for Gender Dysphoria in Adults

Satisfaction versus Regret. Pfafflin and Junge (48) reviewed the 79 available follow-up studies regarding gender transition treatment conducted between 1961 and 1991, including a total of more than 1,000 MTF patients and more than 400 FTM patients. Although a variety of outcome criteria were used, when the key subjective criteria (such as general satisfaction and lack of regret) were examined, results were supportive of treatment as a means of relieving psychological distress. Most of the studies reviewed were case series, case reports or reviews (APA level D or lower) though some included sufficient longitudinal follow-up and standardization to meet APA level C or B. "Big" regrets (such as reversion to the original gender role, rather than some lesser degree of regret or ambivalence) were estimated to have occurred in only 1-1.5% of patients. Other sizeable reviews (of numerous smaller studies, APA level F) also suggested hormonal and surgical treatments as successful therapies for gender dysphoria (39, 147). Interpretation of these findings is limited by the analysis of nonrandom samples based on recruitment and/or response rate. One study avoided these problems by using German registry data to assess reversal of name changes following reassignment as a measure of regret (148). Only one person of 733 who applied for legal change of sex between 1981 and 1990 subsequently applied for reversal, suggesting profound regret; 57 of 1,422 (0.4%) of adults who obtained gendered changes of first name requested a second legal name change, suggesting at least some degree of regret. Though this indirect approach (APA level G) does not provide robust evidence, the results are consistent with other approaches. A recent systematic review and meta-analysis reported that 80% experienced subjective improvement in terms of gender dysphoria and other psychological symptoms and quality of life (149).

Some relatively long-term, follow-up data (APA level B) are available, though sample sizes are generally modest. Smith and collaborators evaluated 162 Dutch adolescent and adult patients who were eligible for gender transition services based on "gender dysphoria, psychological stability, and physical appearance" after completion of treatment. Approximately half of the original consecutive applicants for sex reassignment completed hormonal and surgical transition (98). Two patients had regrets; most others experienced relief of gender dysphoria and were found to be functioning well "psychologically, socially and sexually." Johansson and collaborators followed 42 MTF adults and 17 FTM adults, who met diagnostic criteria for GID and were accepted into treatment in a transgender treatment program, for 5 years or longer (150). At the time of publication, 32 had received genital reassignment surgery, 5 were anticipating surgery, and 5 had decided not to proceed. No one regretted his or her decision; 95% of participants rated their global outcome as favorable, though only 62% of the clinician assessments concurred. There were no differences between subgroups. Conversely, Kuhn et al. (151) used the King's Health Questionnaire and Visual Analogue Scale to measure quality of life in 52 MTF adults and 3 FTMs recruited from a Swiss tertiary medical center gender program (151). All subjects were 15 or more years post-gender reassignment surgery. Overall quality of life and life satisfaction levels were lower than matched controls, particularly in the domains of general health, role limitation, physical limitation, and personal limitation. However, the control group was chosen from the "healthy female medical staff with at least one previous abdominal or pelvic operation," rather than from a more appropriate sample, such as transgender adults who did not receive surgery. The quality of life assessments are, therefore, likely to be valid in absolute terms, but the question of whether the participants' quality of life was improved by transition (relative to having not transitioned) remains unresolved. Similarly, a recent population-based matched cohort study (APA level D) compared 191 MTF subjects and 133 FTM subjects with random controls matched by birth year and natal sex, as well as by birth year and reassigned sex (152). The transsexual subjects had received sex reassignment surgery in Sweden between the years 1973-2003. Although higher risks for psychiatric morbidity, suicidal behavior, and mortality were found in the transsexual groups, relative to non-transsexual controls, no comparison was made to transsexual persons who did not receive treatment. As with the Kuhn study (151) questions regarding the magnitude of improvement in quality of life attributable to gender transition and SRS were not addressed, though the authors noted that the gender dysphoria had been alleviated.

Correlates of Satisfaction and Regret. Much of the research literature that employs an outcome perspective has focused on identifying correlates of treatment satisfaction and lack of regret among persons seeking transition with hormonal and surgical treatments, particularly those who transition MTF. In theory, these data could be used in the formulation of treatment recommendations, to assist clinicians in identifying individuals who are most likely to benefit from hormonal and surgical treatments as well as those most likely to have post-treatment regrets. Particularly controversial in this research, MTF psychological and social characteristics have often been dichotomized by the typology of "early onset/androphilic" versus "late onset/ gynephilic" transsexual adults. Lawrence (38) summarizes this distinction as follows:

Many researchers have proposed that there are two types of MTF transsexuals. One category includes persons who typically transition at a younger age, report more sexual attraction to and sexual experience with males, are unlikely to have married or to have become biologic parents, and recall more childhood femininity. The other category includes persons who typically transition at an older age, report more sexual attraction to and sexual

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experience with females, are more likely to have married and to have become biologic parents, report more past or current sexual arousal to cross-dressing and cross-gender fantasy, and recall less childhood femininity [p.300].

Transgender MTF adults with early onset/androphilic characteristics have been more often found to have higher rates of satisfaction with gender transition and fewer regrets (35-37). However, Lawrence (38) notes that the population of persons applying for gender transition surgeries has undergone a demographic shift, particularly in the United States and Canada. For example, at the Clarke Institute of Psychiatry in Toronto, the percentage of MTF adults seeking SRS who were "nonhomosexual relative to biologic sex," increased from 25% (153) to 59% (154) in a single decade. In a related phenomenon, the average age of MTF transgender adults presenting for gender reassignment services in Sweden increased by 8 years during two decades (155). Younger age at the time of transition had previously been found to correlate with both androphilia and better outcome satisfaction. However, rates of regret following surgery have decreased during this time, as discussed below, suggesting the possibility that cooccurring social changes, or other factors, have eroded the strength of these previously somewhat predictive relationships.

Interviews with subjects who express substantial regret following genital reassignment surgery, and related case reviews, have identified several correlates of regret. These include: inadequate diagnosis of major pathology (e.g., psychosis, personality disorder, alcohol dependency), misdiagnosis, absence of or a disappointing real-life experience, and poor family support (39-48). Given the magnitude of the social changes associated with gender transition, these correlates are intuitively appealing, as strong family support and good emotional health are associated with positive adjustment to many other life changes. However, cases have been reported in which the individual was both suffering from severe co-occurring psychopathology, and was a "late-onset, gynephilic" MTF transgender adult, and yet experienced a long-term, positive outcome with hormonal and surgical gender transition (156). Several members of this Task Force have treated patients with severe co-existing psychiatric illness who successfully transitioned gender and experienced improved quality of life. Delaying therapy with hormones or surgery until serious mental health difficulties are addressed may promote adherence to needed psychiatric and other mental health treatment, such that the individual experiences benefit with regard to both the gender dysphoria and the concurrent psychiatric illness. The co-occurrence of serious psychiatric pathology is further discussed below.

The quality of the surgical result, including function and appearance, has also correlated positively with patient satisfaction or other positive outcome measures among both MTF adults (42, 45, 47, 48, 128) and FTM adults (157), though it remains difficult to achieve surgically excellent results with phalloplasty (158) relative to vulvovaginoplasty (38). In her anonymous mailed questionnaire study of 232 MTF transsexual adults operated on between 1994 and 2000 by one surgeon using a consistent technique, Lawrence (2003) found poor surgical outcome to be the strongest predictor of regret. Overall, no participants reported "consistent regret" and only 15 (6%) were "sometimes regretful" (p. 305). Kuiper and Cohen-Kettenis (1998) recommended the use of multidisciplinary teams in order to minimize poor outcomes through lack of complete information or individual clinician bias. Although few systematic studies of suicide among gender transitioning persons have been conducted, the case report literature suggests that this is a relatively rare outcome (39). Dhejne et al. (152) found an increased risk of death by suicide, and of suicide attempts, among subjects who had received SRS, relative to age-matched population controls, but also noted that the difference in suicide attempts did not reach statistical significance for the most recent cohort, those who had transitioned gender during 1989-2003.

The majority of the satisfaction/regret outcome studies described above suggests that most subjects experience subjective improvement following gender transition; however, most lacked a control group. Studies assessing correlates of satisfaction through interviews or case reviews would be categorized as APA level G. For some important aspects of transgender care, it would be impossible or unwise to engage in more robust study designs due to ethical concerns and lack of volunteer enrollment. For example, it would be extremely problematic to include a "long-term placebo treated control group" in an RCT of hormone therapy efficacy among gender variant adults desiring to use hormonal treatments.

Review of the available literature also documents a downward trend in rates of post-surgical regrets over the last three decades. Though satisfaction with transition outcome is believed to be the norm in recent years, earlier studies (143, 159) found rates of regret of 30% or higher, and even in 1997, one study found a 6% regret rate (47). Reasons for this trend are not completely clear, but it is temporally correlated with fairly widespread adoption of flexible but less idiosyncratic pre-surgical criteria (the WPATH SOC); improved surgical techniques and outcomes, particularly for vulvovaginoplasty; and an improved social climate for members of sexual and gender minorities. This has been suggested as indirect evidence of the utility of the WPATH SOC in pre-surgical evaluation and treatment of gender transitioning patients (39, 160).

Options and Evidence for Psychiatric Evaluation and Mental Health Care

Adults who make use of conventional medical services for gender transition historically received mental health evaluation prior to beginning this process (161), unless they had already been living as a member of the psychological (post-transition) gender for a significant period of time (107). The principal area of current clinical controversy with regard to use of hormonal medications by persons in gender transition concerns the nature of and extent of preparation for beginning hormonal transition, particularly the mental health evaluation. Options currently in use include the following: extensive mental Case: 24-108 Document: 2-3 Page: 69 Filed: 01/25/2024

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health evaluation or real-life experience prior to beginning treatment with hormonal medications, brief evaluation by a mental health professional prior to hormonal prescripttion, mental health screening by the prescribing clinician, and prescription without specific evaluation. Additional possibilities, such as the creation of certified "gender specialists" who would assess readiness have been suggested (162). Evaluation prior to genital surgery is similar but usually more extensive. The basis for each of these approaches is discussed below. This discussion applies only to the treatment of patients who seek medical services through licensed health care facilities in the United States and Canada. Some individuals obtain hormonal preparations without any medical or mental health contact, such as via the Internet or veterinary supply. Some travel to other countries to obtain surgical treatments without specific pre-surgical requirements. Outcome data for treatment obtained through these routes are lacking.

Mental Health Evaluation Options Prior to Hormonal Therapy

Comprehensive Mental Health Evaluation. Although some reasonable evidence supporting the clinical effecttiveness of hormonal and surgical methods in the treatment of "gender dysphoria" (principally case series by Benjamin, Green, Money, and Stoller [e.g., (163-166), reviewed in (167)] had accumulated by the 1960s, the use of these physical modalities, rather than psychoanalysis or extended psychotherapy aimed at resolving the intrapsychic conflict believed to underlie the transsexualism, and its associated implicit homosexuality, remained controversial and politicized. For example, the first university-affiliated transgender program, at Johns Hopkins University was founded in the 1960s and then disbanded in an ideological sea change in 1979 (though gender identity concerns subsequently became part of the scope of practice of the Johns Hopkins Sexual Behaviors Consultation Unit). Psychiatrists and psychologists approached individuals seeking medical services for gender transition idiosyncratically, without consistency in regard to recommending, or attempting to dissuade the use of, hormonal and surgical treatments. Several recent reviews and policy papers (161, 162, 168, 169) have described the intertwined clinical and political difficulties that existed in that era.

The Harry Benjamin International Gender Dysphoria Association (HBIGDA) was founded in 1979, to address the need for professional guidance in treating individuals with GID. Standards of Care (SOC) were developed by an international consensus panel, initially for the purpose of providing some protection to patients and their treating physicians (107). These have been subsequently revised at intervals, with a 7th revision in process at the time of this writing. HBIGDA has been renamed, and is now the World Professional Association for Transgender Health (WPATH).

The current, sixth version (107) of the WPATH SOC recommends evaluation by a psychiatrist, psychologist, clinical social worker, or other master's or doctoral level mental health clinician, prior to beginning treatment with hormonal medications. Areas of emphasis include identifying and beginning treatment of any pathology that may exist concurrent with the transition, and assessing readiness for hormonal treatment based on consolidation of the gender identity and demonstration of general psychiatric stability sufficient to withstand the social or medical complications that may ensue during the physical transition process. Adults seeking treatment with hormonal medications should also have either engaged in psychotherapy (usually for 3 months or longer) or have engaged in a documented period of having lived in the psychological gender (a "real-life experience") for at least 3 months. In addition, patients should experience further consolidation of the gender identity during this time and make progress with regard to any ongoing mental health problems, such as substance abuse. They should also be considered likely to "take hormones in a responsible manner [p.14]." In other words, the use of hormonal medications is regarded as part of an ongoing process of physical and psychosocial transition, undertaken with informed consent, in the context of mental health and general medical care.

The WPATH SOC recommend different levels of preparation for breast and genital surgeries. FTM breast surgery may be obtained at the time of beginning hormonal treatment, as the breast morphology will be minimally affected by use of testosterone, and because FTM chest reconstruction may be necessary for social presentation as a male. MTF individuals should defer breast augmentation surgery until after at least 18 months of treatment with feminizing hormones, in order to reduce the likelihood of unnecessary procedures. WPATH Standards for preparation for genital surgery are more comprehensive than those addressing hormonal treatment eligibility and readiness, and the time course is longer: twelve months of hormonal therapy unless this is medically contraindicated, and twelve months of real-life experience. The current WPATH SOC (version 6) require documentation of a GID diagnosis and recommendation for surgery by two mental health professionals, at least one of whom must be a psychiatrist or doctoral level psychologist.

The Oxford Centre for Evidence-Based Medicine Level of Evidence system has been used to evaluate the evidence regarding the key components of the WPATH SOC for sex reassignment surgery, described as eligibility and readiness criteria (e.g., pre-treatment psychotherapy, real-life experience, sequence of transition steps), as predictors of favorable post-surgical outcome (39). Overall evidence supported these components; however, the level of evidence was generally low, mostly corresponding to APA level D and lower. Some studies, however, [e.g, (31, 37, 170)], that tracked patients longitudinally after intervention could be categorized as APA level B. The evidence in support of gender reassignment surgery as an "effective and medically indicated" treatment in cases of "severe GID" was similarly evaluated (140). Results were not uniformly supportive of surgical transition, but reports of post-surgical regret have become much less common over time; studies published since the late 1990s have been more consistently positive. Due to the lack of RCTs or large,

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well-designed follow-up studies most evidence is estimated to be at or below APA level C. Outcome measures varied across the studies reviewed, but were largely based on satisfaction and similar subjective measures.

In 2009, a consensus group of European and American endocrinological professional societies produced an evience based practice guideline (29) based on extensive literature review using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system (171). Strong recommendations (based on GRADE criteria) were made regarding the involvement of mental health professionals in gender transition treatment, including that the diagnosis of GID be made by a mental health professional and that the endocrinologist and mental health professional agree on the advisability of surgical reassignment prior to surgery. The type of mental health professional was not specified. The endocrine guideline notes that mental health professionals usually adhere to the WPATH SOC (29).

Some other clinical guidelines, such as the Vancouver Transgender Health Program/Vancouver Coastal Health also recommend full psychological and/or psychiatric mental health evaluation before genital surgery. Although many, and perhaps most, adults who seek transgender hormonal transition or surgical procedures may have sufficient mental and emotional wellbeing to manage the associated physical and experiential impacts, the smaller number who do not may be spared devastating outcomes through timely (especially presurgical) evaluation and treatment of co-existing psychiatric illness.

The mental health evaluation component of these guidelines is included in an effort to promote good transition outcomes through management of the psychological stress of the transition process and any accompanying axis I or II disorders, rather than simply through assuring accurate diagnosis of the GID as such. In some cases, gender concerns or preoccupations are a manifestation of other intrapsychic conflicts (e.g., a male sex offender who covertly desires castration) or epiphenomena of other illnesses (e.g., bipolar mania or psychosis with delusional beliefs about gender). A recent Dutch study found that mental health professionals most valued consultation that provided guidance in distinguishing between transgender with concurrent psychiatric illness and psychopathology manifesting features that could be confused with GID (104, 105). Similarly, a British psychiatrist was sanctioned by the General Medical Council for prescribing hormonal medications and recommending surgeries based on insufficient evaluation, in cases such as those described above, to the detriment of the patient; in effect, for failing to follow the WPATH SOC current at the time (173, 174).

Although clinical guidelines that restrict access to hormonal or surgical treatments may reflect a variety of implicit assumptions regarding the experience of persons who transition gender, one important basis for their development has been the finding that, although GV is not in itself evidence of medical or psychiatric pathology, neither is it protective from concurrent psychiatric illness

(175-178). Further, Meyer (160) notes that although some clinicians have observed that proceeding with transition planning can sometimes alleviate other axis I related symptoms (41, 43, 48, 155, 175), others have reported lower likelihood of good long-term outcome (e.g., poor adjustment or regret) when concurrent disorders are present. It is probable that both findings have validity. Gender transition can foster social adjustment, improve selfesteem, and relieve the anxiety and mood symptoms that can accompany gender dysphoria, but significant cooccurring mental illness can mitigate against positive outcomes of any medical treatment, whether or not it is related to gender identity. Bockting et al. (2006) provide an approach to consultation regarding gender transition, including a list of co-occurring factors that should be specifically evaluated, such as associated obsessivecompulsive features, delusions about sex or gender, dissociation, personality disorders, Asperger's disorder and internalized homophobia. Their approach has substantial face validity and is consistent with general principles of psychiatric diagnosis, although it is supported primarily by low levels of evidence (generally level D and below).

Other Options Prior to Initiating Hormones. Although the WPATH SOC have been utilized in clinical practice with gender transitioning persons in a variety of geographic areas and settings, their implementation presupposes significant resources on the part of the individual seeking transition. Many people who seek hormonal treatment have neither the funds to obtain a psychiatric evaluation and three months of psychotherapy nor insurance coverage of mental health services. However, both estrogens and androgens are available via the internet, over the counter in Mexico and other countries, without prescription in certain settings (e.g., testosterone preparations at some gyms), and through veterinary supply. Individuals who lack financial resources, or who do not wish to participate in usual medical and mental health care for other reasons, therefore, have the option of selftreatment with informally obtained hormone preparations. This entails significant medical risk. Potential problems include needle sharing (179) as well as administration of inappropriately high hormone dosages together with lack of monitoring for deleterious hormonal effects (180). Despite the apparent widespread use of nonprescribed hormonal preparations [reviewed by Lawrence (180)], there is currently little information available concerning complications of this practice given that it occurs outside of the medical setting. Some clinicians and practices have adopted a harm reduction model of hormonal care for gender transitioning persons, consisting of hormone prescription and basic laboratory services with few additional treatment requirements on the part of the patient.

The Protocols for Hormonal Reassignment of Gender of the Tom Waddell Health Center (TWHC) note that "[t]here exists a large group of individuals self-identified as transgenders who are at high risk for HIV transmission, are homeless or nearly homeless, and who are in need of general primary care services. This group has historically

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been averse to accessing medical services for a number of reasons..." (181). The decision regarding hormone prescription is, therefore, left to the individual physician or nurse practitioner, based on psychosocial evaluation, physical examination, and informed consent. However, psychiatric evaluation is required for adolescents, with family participation unless the youth is legally emancipated. Although specific data regarding measurable aspects of treatment success from this approach have not been published, the authors of the TWHC protocol documenttation (2006) note that their center has treated nearly 1,200 patients, with over 400 in active medical care. Most practices that use similar treatment approaches are located in urban centers with substantial populations of high-risk transgender adults and youth. Evidence regarding the effectiveness of these approaches is currently lacking with regard to treatment of gender dysphoria, though the harm reduction basis is similar to other evidence-based public health programs aimed at reducing HIV risk.

In some settings, psychiatric or psychological evaluation is not required prior to initiation of hormonal therapies if the prescribing clinician is able to assume responsibility for the associated aspects of mental health care. For example, in the Transgender Health Program of Vancouver Coastal Health (172) primary care providers, including family physicians and nurse practitioners, may choose to have sole responsibility for evaluating eligibility and readiness for hormone therapy, and for initiating and monitoring this treatment, if their clinical expertise and practice structure support this level of involvement. (In this protocol, nurse practitioners may prescribe estrogens but not androgens.) However, the British Columbia Medical Services Plan will not approve applications for transgender surgical coverage unless this is recommended by two psychiatrists or one psychiatrist and one Ph.D. psychologist, both of whom must be registered with the Plan (182). Evidence regarding the efficacy of this approach is not available, though the pre-surgical criteria are similar to the WPATH SOC in some respects.

Some practices employ a modified treatment protocol, such as a medical evaluation with hormone prescription, followed by a later visit with a mental health provider, for at least some transgender patient groups. In New York City, the Callen-Lorde Community Health Center treatment protocol for hormone therapy for "men of transgender experience, hormone experienced" provides an example in that regard (227). Other physicians informally waive any requirement for mental health evaluation if the individual has already been using hormonal medications for a substantial length of time, even if they were obtained without prescription. Some clinicians place a very high emphasis on patient autonomy, and provide hormone prescriptions on patient request, unless a strong medical contraindication is present. This is consistent with the principles articulated by the International Conference on Transgender Law and Employment Policy, Inc. (ICTLEP) (183). No studies comparing treatment guided by these different policies have been carried out with respect to any outcome measure.

Fraser (184) has recommended expanded use of the

internet for education and psychotherapy for transgender persons and for clinician training in transgender mental health care. The creation of "gender specialists" among masters- and doctoral-level clinicians has been suggested by Lev (162). Although the gender specialist was concepttualized as having a supportive/informed consent role rather than acting as a "gatekeeper," letters of recommendation would be required prior to the initiation of hormonal and surgical treatments. Thus, the distinction between this role and that of gatekeeper is subtleevaluation by a mental health professional would still be required prior to receiving desired medical treatments. Although the informal use of the term "gender specialist" appears to be increasing among some mental health practitioners, formalization seems unlikely in the near future given the absence of consensus regarding formal training requirements, training institutions and licensing bodies. The Task Force does not support development of specific gender specialist criteria or certification as this might inadvertently create restrictions for mental health professionals already working with patients with GV/GID.

Mental Health Evaluation Prior to Surgical Care

At the time of this writing, many surgeons performing genital gender reassignment surgery in the United States utilize the WPATH SOC (version 6) as part of the preoperative evaluation, though these are neither mandatory nor universally accepted, and some surgeons select patients through other means. In some other countries, surgical eligibility criteria are even more stringent than the WPATH SOC, such as the requirement by the British Columbia Medical Services Plan that both evaluating clinicians be of doctoral level and approved by the Plan, and at least one a psychiatrist. Waiver of the mental health evaluation has been recommended as a matter of policy (ICTLEP, 1997) or on ethical grounds (185) but it is not clear that either of these arguments has gained extensive support within the surgical community. No direct evidence is available to address the safety and efficacy of evaluation for suitability for surgery by the surgeon, without the assistance of mental health professionals, though Lawrence's (38) work is somewhat related.

Given the magnitude of bodily change involved, its profound social significance, and the irreversible nature of these procedures, it seems unlikely that many more surgeons in the United States and Europe will decide to perform genital reassignment surgeries without preoperative mental health consultation, prior hormonal transition and real life experience, or some other substantial evaluative process. However, it should be noted that the ultimate decision regarding whether or not to operate in a particular case rests with the surgeon, i.e., he/she can decline to perform surgery even if the patient has been recommended according to the WPATH SOC or other evaluative means. As Richard Green (167) has noted, "If gender patients can procure surgeons who do not require psychiatric or psychological referrals, research should address outcomes for those who are professionally referred versus the self-referred."

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Gender Variance in Persons with Somatic Disorders of Sex Development (aka Intersexuality)

Heino F. L. Meyer-Bahlburg, Dr. rer. nat. William Byne, M.D., Ph.D.

Overview

The process of decisions on gender assignment at birth is strongly emphasized in the clinical management of individuals with somatic disorders of sex development (DSD; the term includes, but is not limited to, what was formerly called intersexuality). Patient-initiated gender reassignment at later ages, from late pre-school age through adulthood, varies with the specific DSD syndrome, from 0% to about two-thirds of persons (60). Among individuals who meet DSM-IV-TR criteria A and B for GID, those who have a DSD differ markedly in several respects from those who do not. These differences include variations in presentation, medical implications and clinical context (168). As a consequence, the DSM-IV-TR (187) placed individuals with gender dysphoria and a DSD under the category GID Not Otherwise Specified (GID NOS), rather than under the more specifically defined term GID. GID NOS is commonly used also for individuals without a DSD who meet some but not all required GID criteria (often referred to as "subthreshold cases"). Thus, GID NOS is often applied to both groups of individuals with a DSD and gender identity concerns, those who meet all required GID criteria A and B, and those who meet only some of them. As the DSM-5 will be published in 2013 at the earliest, and the revision process is in progress at the time of this writing, the current discussion will use the DSM-IV-TR formulations. Given the very limited literature on DSDrelated GID and the fact that sex reassignment in individuals with DSD-related GID can occur at any age, we will deviate from the strictly age-defined outline of the previous sections and will present the DSD-related issues in a more integrated fashion.

The present discussion will be limited to individuals with DSDs who present with clinically significant gender dysphoria or frank desire for gender reassignment. Clinical management of gender reassignment of such patients overlaps to some extent with that of persons with GID in the absence of a DSD. However, for individuals with a DSD, there are fewer barriers to legal gender reassignment, and the barriers to hormonal and surgical treatments in conjunction with gender reassignment are much lower. An example would be a 46,XY individual who was born with penile agenesis, assigned to the female gender and gonadectomized (although the testes were entirely normal and had provided for male-typical androgen exposure of the fetal brain), and who chooses to transition to the male gender in late adolescence (61). Another example would be a 46,XX legally female individual with congenital adrenal hyperplasia (CAH) and an associated history of marked fetal masculinization and marked postnatal virilization (due to insufficient cortisol replacement therapy) who in adulthood requests reassignment to the male gender (188).

As illustrated by the above examples, several factors contribute to the lowered threshold for gender reassignment in individuals with a DSD. One is the fact that many of the underlying medical conditions require hormone administration as part of routine care. Moreover, many DSD syndromes involve infertility, which may either be congenital or due to gonadectomy performed according to past or present management guidelines, e.g., because of cancer risk (51). In addition, genital surgery has often been performed in infancy so that genital anatomy more closely corresponds to the assigned gender and is suitable for penile-vaginal intercourse at a later age (51, 54). Legal and medical gender reassignment of individuals with a DSD may, therefore, take place at much younger ages than in persons with GID in the absence of a DSD. The evolution of clinical thinking and management guidelines concerning the indications for gonadectomy and genital surgery in infancy, and current controversies in these areas, are discussed in several recent reviews (50-52, 54, 55, 168, 189-191). Decisions regarding hormonal and surgical procedures are complicated by the highly variable somatic presentations of the many diverse DSD conditions. [A review of these syndromes is beyond the scope of the present review; see Grumbach et al. (192).] In addition, appropriate mental health care includes the often delicate task of disclosure of the medical history along with psychoeducation about the underlying biological condition (56, 193, 194).

Several major clinical management concerns that arise with patients with a DSD who experience gender dysphoria can be expected to profit from mental health interventions and treatment guidelines. These include: 1) the evaluation of gender and the respective psychiatric diagnosis, if any, in cases with incongruence between gender identity and assigned gender. This issue will be addressed largely in DSM-5 and only briefly touched upon in this report; 2) the process and validation of decisions regarding gender reassignment including the identification and validation of the criteria on which such decisions are based; 3) the management of clinically significant gender dysphoria in individuals with a DSD who do not transition to gender change; 4) selected psychological and psychiatric aspects of the endocrine management of puberty in the context of gender reassignment; 5) selected psychological and psychiatric aspects of care involving genital surgery in the context of gender reassignment; 6) psychological implications of gonadectomy and their management; 7) disclosure of the DSD and treatment history to the patient; 8) the impact of DSD support groups; and 9) the qualifications of professionals who provide mental health services to patients with DSDs and gender identity concerns.

Treatment of individuals with DSDs, in general, needs to address a variety of additional issues with mental health implications. Among these are the management of the gender assignment at birth and its implications for the risk of developing gender dysphoria later; the clinical and ethical issues involved in the disclosure of medical history and biological status to the patient; the patient's selfdisclosure to others; evaluation and management of any associated psychiatric conditions, especially depression

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and suicide risk; the management of DSD-related stigma; assessment of adherence to hormone-replacement therapy and reasons for nonadherence; providing continuity of care from childhood and adolescence into adulthood; and many others (50, 55, 56).

Gender Evaluation

The assessment of gender-related behavior and identity in individuals with DSDs has been greatly improved by the development of a number of psychometrically sound questionnaires and interview schedules, based on self-report or parent report [e.g., (195, 196)]. The evaluation procedures and related clinical considerations have been described in several publications (49, 56, 197, 198). The validation of such gender-assessment tools is based primarily on the demonstration of significant differences, preferably with large effect sizes: 1) between males and females in general; 2) between individuals with gender dysphoria who do not have a DSD versus control individuals without either gender dysphoria or a DSD (separately for males and females); and later, when available, 3) between individuals with both a DSD and gender dysphoria and controls.

Clinical experience has demonstrated that, in children and young adolescents, the evaluation of gender identity and related medical decisions regarding potential hormonal and surgical treatments requires cautious shielding of the young patient from family and peer pressures. Strong rapport building is also required by the clinician who must avoid unwittingly "leading" the child or adolescent. The process demands an extensive commitment of time. To date no systematic studies of related techniques and their outcomes are available.

Decisions on Gender Reassignment

When an individual with a DSD meets GID criteria A and B of DSM-IV-TR, the clinician and the patient, or in the case of minors, the primary caregivers and the clinician (with the child's participation increasing with cognitive maturation), through discussion arrive at a consensus regarding a decision for or against gender reassignment. In this context, reassignment usually means reassignment to the "other gender" relative to the patient's natal or legal gender, although occasionally adult patients self-identify as "neither – nor," "third gender," "intersex," or some other category that implicitly rejects an exclusively binary system of gender classification. This decision is also influenced by a number of factors in addition to the A and B criteria. These include: 1) the known or assumed implications of the individual's particular DSD syndrome for genetic and hormonal effects on the sexual differentiation of the brain and behavior (199); 2) available knowledge regarding the long-term gender outcome of other individuals with this particular syndrome (e.g., likelihood of long-term satisfaction with the new gender identity and/or gender role versus regret and request for re-transition, degree of confidence in one's gender identity, etc.); and 3) the potential benefits and risks of gender-confirming genital surgery.

Readiness criteria for the various steps of gender reassignment, for instance in terms of cognitive and

emotional development, especially in children and adolescents, have not been formulated for individuals with DSDs. Clinical experience and published case reports suggest that these factors should be considered along with the duration and consistency of gender incongruence and desire for gender change. In addition, different cultures and even subcultures within a given country may differ in the prevailing gender categories and the salience and weight of criteria used in decision making on gender assignment (200).

A stringent evaluation of gender reassignment decisions by RCT with long-term follow-up has never been attempted. Moreover, such a study is highly unlikely to be done for a variety of reasons. These include the distress likely to be involved when gender assignment is done randomly rather than based on what clinicians and parents decide on as best on the basis of existing information, the expected low participation rate, and the large costs of longterm follow up. A short-term, waiting list type study design might be acceptable to an institutional review board, but would be logistically difficult to implement and probably not even be very informative given the slow processes involved in gender development. A less stringent validation of gender reassignment decisions (without RCT) in terms of long-term gender outcome by systematic prospective follow-up studies into at least mid-adulthood has also not yet been made because of the obvious logistical and financial problems involved.

Long-term follow-up studies of gender outcome that are available at this time include individual case reports [e.g., (188, 201)]. There are also one time, cross-sectional studies, such as follow-up of all patients seen within a clinic starting at birth or any time later [e.g., (202-206)], or studies of patients recruited from support groups or from multiple sources, without analyzing systematically for patient-initiated gender reassignment [e.g., (207-209)]. These studies typically cover a wide range of ages. Moreover, the time intervals between assignment and follow up vary widely, and there are usually no attempts to do case-control comparisons of individuals with the same syn-drome and the same degree of syndrome severity in terms of genital atypicality. Missing altogether is a validation of the specific criteria upon which gender reassignment decisions in patients with DSDs have been based, e.g., which factors best predict a stable gender identity and/or quality of life.

The best available evidence is a combination of Levels [B] Clinical trial (with reassignment as the intervention for gender-dysphoric cases) and [C] Longitudinal follow-up, without any specific intervention for cases without gender dysphoria. These observational follow-up studies often have significant methodological weaknesses, including small sample sizes, syndrome heterogeneity, high attrition rates in long-term follow-ups, large variations in the follow-up intervals, and noncomparability of (reassignment) cases and (nonreassignment) controls in regard to reassignment-relevant medical characteristics and/or social contexts. A few summary reports integrate data from accessible existing case reports and small group studies and, thereby, fit the APA evidence category of [F] Review

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(57-61)]. The GRADE system of evidence categorization (210) is not applicable because a systematic analysis of the risk/benefit ratio has typically not been attempted in these reports.

Gender Dysphoria Without Transition to Gender Change

As gender roles in industrialized societies have gained flexibility and the (non-DSD) transgender spectrum has diversified, the spectrum of gender outcomes in patients with DSDs has also expanded. Gender dysphoria does not always lead to gender reassignment and even if legal gender change is obtained, the individual may not necessarily seek to obtain all facets of available hormonal and surgical treatment. By way of self-reflection alone, or in conjunction with discussions in support groups or psychotherapy sessions, the patient may decide against a gender transition altogether or only for a partial transition. No systematic work has addressed the psychological processes underlying such decisions in patients with DSDs.

Gender Reassignment and the Endocrine Management of Puberty

In young persons with gender dysphoria who do not have a DSD, the aversive reaction to endogenous puberty is considered an indicator of cross-gender identification and recent years have seen an increase in the use of pubertal suspension, mostly by the administration of GnRH analogs, to give the early adolescent more time to come to a conclusion regarding gender reassignment, to reduce the development of unwanted secondary sex characteristics before cross-sex hormone treatment is started, and to reduce the emotional distress associated with such developments (29).

Medical suspension of puberty is not relevant to the management of gender dysphoria in those patients with DSDs who do not have functional gonadal tissue (whether congenitally or due to gonadectomy). However, such an approach could in principle be considered for patients with functioning gonadal tissue and a DSD such as 46,XX CAH, where the excess androgen production of the adrenal is suppressed by glucocorticoid replacement therapy, but no such study has been published to date. It is noted, however, that some adult patients with 46,XX CAH have simply stopped taking glucocorticoids to self-induce somatic virilization (188).

In hypogonadal or agonadal persons with a DSD, puberty is usually induced by sex hormone treatment, and when the decision for gender reassignment has been made, the sex hormone treatment is done in line with the gender desired by the patient. The details of sex hormone administration (specific medication, dosing, and mode of administration) are decided by the endocrinologist. On psychological grounds, the age when the patient's peers begin noticeable pubertal development is usually recommended as the starting age for the initiation of puberty in patients with DSDs. The supporting evidence for this is clinical experience and some evidence from early observational follow-up reports of patients with Turner's syndrome or hypopituitarism and late initiated puberty [summarized in (211)], not based on systematic study. However, such early timing might also be recommended on the basis of recent data on nonhuman mammals showing continued capacity of the brain for organizational effects of sex hormones which gradually diminishes from early puberty to adulthood (212).

A number of retrospective studies have reported past periods of gender uncertainty in patients with DSDs who at the time of later evaluation in adulthood were content with their originally assigned gender (209, 213, 214). Whether the resolution of such transient gender uncertainties of patients with DSDs is supported by sex-hormone treatment and its timing or other factors has not been studied. The question of postnatal hormone effects is raised in this context. For example, female-assigned 46,XX individuals with CAH who transition gender at later ages tend to be those with a history of high postnatal androgen exposure. Causes of such high exposure include delayed onset of glucocorticoid treatment or prolonged interruption of treatment (usually due to the unavailability of appropriate services or a lack of money), even if their prenatal androgen exposure and their genital masculinization at birth were not extreme (188). Available evidence is yet too limited for firm conclusions regarding the role of postnatal sex-hormone exposure in gender-identity development.

Gender Reassignment and Gender-Confirming Genital

Detailed case reports [e.g., (201)], clinical observations [e.g., (215)], and the first systematic qualitative studies (186, 190, 202, 216) have documented the widespread social stigmatization in patients with DSDs, which is in part related to gender-atypical appearance, especially of the genitals. The "optimal gender policy" for the management of DSD introduced in the mid-1950s by John Money and colleagues at Johns Hopkins included recommendations for corrective genital surgery in early childhood. The aim was to bring the genital appearance in line with the assigned gender in order to facilitate the acceptance of the child as a member of the assigned gender in the social environment. This would, in turn, facilitate genderappropriate rearing, and, thereby minimize the occurrence of later body image problems and gender doubts on the part of the patient. An additional aim was to provide the capacity for penile-vaginal intercourse in adulthood. Because it was easier to surgically construct a vagina than a penis, this policy entailed a bias towards female assignment in 46,XY patients with a DSD and a markedly undersized phallus (an extreme example is the syndrome of penile agenesis mentioned earlier). In the last 15 years, testimonials of individuals with DSDs whose care followed the "optimal gender policy," detailed case reports, and long-term, observational follow-up studies on gender outcome and sexual functioning have raised significant doubts about the policy (60). Many patients initiate gender change later despite early gender-confirming surgery, especially among 46,XY patients raised female (although the frequency varies considerably with the particular DSD syndrome). Furthermore, body-image problems and even stigmatization can occur despite early genital surgery, especially if the latter is not well done. Additionally, genital Case: 24-108 Document: 2-3 Page: 75 Filed: 01/25/2024

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surgery entails a significant risk of impaired sexual functioning, which has led to a rethinking of gender assignment decisions in newborns and increased conservatism regarding genital surgery (51, 194, 217), a process that is still ongoing.

In the course of this debate, numerous outcome studies of genital surgery in individuals with DSDs have been published, which increasingly evaluate not only cosmesis (i.e., quality of the anatomic outcome) but also functional outcome (216, 218-221). Yet, the surgical techniques utilized are highly variable; the existing cross-sectional follow-up studies usually involve only modest sample sizes of patients with DSDs, often with considerable variability in the particular DSD syndromes represented among the subjects as well as in the ages at evaluation; RCT approaches to compare surgical techniques, even for cosmetic outcome, have not been attempted; and the existing follow-up studies commonly do not even attempt to systematically compare different surgical techniques. It is, therefore, difficult to draw conclusions sufficient for evidence-based recommendations. This applies especially to the numerous functional outcome criteria that are of clinical relevance (222). The question of optimal timing of such genital surgery runs into similar difficulties and existing consensus recommendations are uncomfortably nonspecific (51, 54). While many aspects of the evaluation of surgical technique fall within the purview of surgery, the indications and patient readiness for surgery as well as the impact of surgery on sexual satisfaction and psychological wellbeing should ideally involve mental health professsionals. Considerations of the implications of a patient's present or emerging sexual orientation are also typically missing in existing discussions regarding the indications for genital surgery. The capacity for penile-vaginal intercourse may be valued differently depending on the sexual orientation of the individual, especially relative to the difficulties that the required surgeries sometimes entail (223).

Psychological Implications of Gonadectomy

Particularly in DSD syndromes involving Y chromosomes, various forms of gonadal dysgenesis, gonadal dysfunction, and/or the risk of malignant transformation, removal of the gonads may be recommended regardless of sex reassignment decisions (51, 53). Although there is a rich non-DSD literature on the consequences of infertility, gonadectomy, and iatrogenic and endogenous hypogonadism, there has been no systematic study of these issues in individuals with DSDs, except for the inclusion of related clinical observations in occasional case reports.

Disclosure of the DSD History

Because of the potential for DSD-related social stigmatization and self-image problems, the "optimal gender policy" of the Johns Hopkins group recommended that provision of information on the biological status and medical information about the child with a DSD be limited to a few family members along with a carefully paced disclosure to the patient him/herself and detailed suggestions on disclosure procedures [e.g., (197, 224)]. Although Money recommended full disclosure by the time a child

completed high school unless there were significant cognitive limitations, our experience is that other clinicians frequently advised permanent withholding of disclosure from the patient and sometimes even from the parent. This approach has been challenged on ethical grounds, is clearly at variance with the patients' rights movement of recent decades, and may entail serious medical risks. This approach may also lead to a situation when an adult discovers his/her DSD status in a setting that does not include medical supervision (e.g., self-initiated review of medical records, self-diagnosis with the aid of web-based materials or Internet contacts). Moreover, many case reports and patient testimonials have documented the negative psychological outcomes of such secrecy-for example, shame, distress to the point of suicidality, and distrust of primary caregivers and doctors, the latter in some patients leads to avoidance of routine medical services altogether (190, 201, 205, 225). Yet, the questions of timing and techniques of disclosure as described by Money (197) and Meyer-Bahlburg (56), for instance, have never undergone systematic study, and formal clinical trials are highly unlikely given the difficult logistics of such trials with patients with rare disorders as well as the complexity of clinical considerations involved. For quite a few patients with DSDs and gender uncertainty or gender dysphoria, the disclosure of their medical information can be of help to their understanding of their behavioral gender atypicality and may add arguments to their initiation of gender change, but this has been documented only in occasional case reports, not by systematic studies.

DSD Support Groups

Feelings of isolation are widespread among persons with DSDs, as in individuals with other uncommon medical conditions. Clinical experience and many patient testimonials have documented the tremendous beneficial effects many people experience when they are finally able to contact or meet face-to-face with others with the same or a similar condition through a DSD support group [e.g., (190, 225, 226)]. Such groups are usually organized by persons with DSDs or their families rather than by medical or mental health professionals. Despite the emotional relief that they can provide, support group contacts sometimes also may cause additional concerns (56). For instance, the composition of the group (e.g., the DSD syndromes represented within the group, the personalities of group members) may not meet the patient's expectations, and the information provided may not always be correct. Thus, patients who choose to participate in support groups should be encouraged to check back with their clinicians if they receive conflicting information or advice. Systematic research on the value of support groups in the clinical management of persons with DSDs has not yet been done.

Qualifications of Providers of Mental Health Services

The selected topics above provide a cursory overview of the issues with which mental health professionals (psychiatrists, psychologists, social workers, etc.) ought to be familiar and be able to manage clinically. Although recent medical guidelines emphasize the need for mental

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health service providers with expertise in this area of care (29, 51, 54), currently very few mental health professionals are knowledgeable about treatment of persons with GID, and even fewer have much clinical experience with individuals with DSDs who have gender identity concerns. Given the dearth of specialized mental health service providers in this area, the gender evaluation and preparation for management decisions, including hormone treatment and genital surgery, are primarily made by endocrinologists and surgeons. Currently there exist no formal programs for specialized training of mental health personnel in this area. This Task Force strongly endorses the involvement of psychiatrists and other mental health professionals in the care of persons with DSDs and gender dysphoria; however, we conclude that it is premature to recommend detailed guidelines on required qualifications. To do so might jeopardize existing providers rather than contribute to closing the gap in the availability of mental health professionals in this area of clinical service.

APPENDIX I: OTHER APA CONCERNS REGARDING GENDER VARIANCE

In addition to the issue of treatment recommendations, several concerns regarding gender identity and the rights of persons who are gender variant are potential subjects for policy development within the American Psychiatric Association. These include:

- (1) Support for treatment resources for gender variant and gender transitioning adults, and removal of barriers to care, including insurance coverage for accepted treatments, similar to AMA House of Delegates' Resolutions 114 (A-08) and 122, and the American Psychological Association Council of Representatives' Policy Statement regarding Gender Identity, Transgender and Gender Expression Nondiscrimination.
- (2) Support for reasonable revision of identity documents for gender transitioning persons, including United States passports and birth certificates which currently are difficult to correct.
- (3) Specific support for the marriage, adoption and parenting rights of transgender and gender transitioning persons, similar to existing American Psychiatric Association policies regarding same gender couples.
- (4) Support for the rights of incarcerated persons who are gender variant or gender transitioning to personal safety and comprehensive healthcare, including transgender health services.
- (5) Support for transgender health services for members of the uniformed services and veterans, and opposition to the use of transgender or GV as grounds for discharge or rejection from enlistment.
- (6) Support for the most appropriate placement of persons who are transgender in gender-segregated treatment facilities, including inpatient psychiatric units, residential addiction treatment programs, and geriatric
- (7) Support for the inclusion and fair, collegial treatment of gender variant persons in all aspects of professsional life, including medical schools, residency programs

and fellowships in psychiatry, and the American Psychiatric Association.

- (8) Support for professional and public education regarding transgender and GV, including:
 - (a) Scientifically sound, non-stigmatizing information about GV for patients and members of the general public.
 - (b) The inclusion of affirming, nondiscriminatory information regarding GV and gender transition in the curricula of medical schools and psychiatric residencies and fellowships.
 - (c) Sponsorship of continuing medical education (CME) activities regarding transgender, such as presentations at the APA annual meeting and written materials in CME publications, particularly those used for maintenance of certification (MOC).
 - (d) Inclusion of questions about transgender on the ABPN certifying and MOC examinations.
 - (e) Tasking a specific APA component or other group within the APA to monitor progress with regard to these activities.

APPENDIX II: OTHER APA CONCERNS REGARDING DSD

Because of the multiplicity of DSDs, the complex differences among them and their implications for integrated interdisciplinary care that includes mental health services; because not all DSDs are associated with either gender ambiguity or gender dysphoria; and because the needs of individuals with DSDs and gender dysphoria overlap incompletely with the needs of individuals with gender dysphoria in the absence of a DSD, the Task Force recommends that the APA create a separate mechanism for assessing the mental health needs of individuals with DSDs, whether or not gender dysphoria is present, and work towards better integration of mental health professsionals into the interdisciplinary teams that provide their care. This would include involvement with parents as soon as the DSD comes to attention, which increasingly occurs during pregnancy.

Areas identified to be addressed within this mechanism include 1) psychoeducation of parents or primary caregivers; 2) assessment of indications and readiness for gender confirming surgeries and procedures related to them; 3) age appropriate disclosure of DSD status and related medical/surgical history; 4) issues related to gonadectomy and infertility; 5) DSD-associated stigma includeing that related to genital anomalies and other body image issues as well as feelings of shame and guilt; 6) revealing DSD status to others; and 7) the impact of DSD status on relationship issues including sexual intimacy.

This recommendation to create a mechanism to address the mental health needs of individuals with DSDs, whether or not gender concerns are present, is not intended to exclude individuals with DSDs from APA recommendations pertaining to GID, GID NOS or other manifestations of GV.

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CLINICAL PRACTICE GUIDELINE

Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline

Wylie C. Hembree,¹ Peggy T. Cohen-Kettenis,² Louis Gooren,³ Sabine E. Hannema,⁴ Walter J. Meyer,⁵ M. Hassan Murad,⁶ Stephen M. Rosenthal,⁷ Joshua D. Safer,⁸ Vin Tangpricha,⁹ and Guy G. T'Sjoen¹⁰

¹New York Presbyterian Hospital, Columbia University Medical Center, New York, New York 10032 (Retired); ²VU University Medical Center, 1007 MB Amsterdam, Netherlands (Retired); ³VU University Medical Center, 1007 MB Amsterdam, Netherlands (Retired); ⁴Leiden University Medical Center, 2300 RC Leiden, Netherlands; ⁵University of Texas Medical Branch, Galveston, Texas 77555; ⁶Mayo Clinic Evidence-Based Practice Center, Rochester, Minnesota 55905; ⁷University of California San Francisco, Benioff Children's Hospital, San Francisco, California 94143; ⁸Boston University School of Medicine, Boston, Massachusetts 02118; ⁹Emory University School of Medicine and the Atlanta VA Medical Center, Atlanta, Georgia 30322; and ¹⁰Ghent University Hospital, 9000 Ghent, Belgium

*Cosponsoring Associations: American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Pediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society, and World Professional Association for Transgender Health.

Objective: To update the "Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline," published by the Endocrine Society in 2009.

Participants: The participants include an Endocrine Society–appointed task force of nine experts, a methodologist, and a medical writer.

Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation approach to describe the strength of recommendations and the quality of evidence. The task force commissioned two systematic reviews and used the best available evidence from other published systematic reviews and individual studies.

Consensus Process: Group meetings, conference calls, and e-mail communications enabled consensus. Endocrine Society committees, members and cosponsoring organizations reviewed and commented on preliminary drafts of the guidelines.

Conclusion: Gender affirmation is multidisciplinary treatment in which endocrinologists play an important role. Gender-dysphoric/gender-incongruent persons seek and/or are referred to endocrinologists to develop the physical characteristics of the affirmed gender. They require a safe and effective hormone regimen that will (1) suppress endogenous sex hormone secretion determined by the person's genetic/gonadal sex and (2) maintain sex hormone levels within the normal range for the person's affirmed gender. Hormone treatment is not recommended for prepubertal gender-dysphoric/gender-incongruent persons. Those clinicians who recommend gender-affirming endocrine treatments—appropriately trained diagnosing clinicians (required), a mental health provider for adolescents (required) and mental health

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Abbreviations: BMD, bone mineral density; DSD, disorder/difference of sex development; DSM, Diagnostic and Statistical Manual of Mental Disorders; GD, gender dysphoria; GnRH, gonadotropin-releasing hormone; ICD, International Statistical Classification of Diseases and Related Health Problems; MHP, mental health professional; VTE, venous thromboembolism.

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professional for adults (recommended)—should be knowledgeable about the diagnostic criteria and criteria for gender-affirming treatment, have sufficient training and experience in assessing psychopathology, and be willing to participate in the ongoing care throughout the endocrine transition. We recommend treating gender-dysphoric/gender-incongruent adolescents who have entered puberty at Tanner Stage G2/B2 by suppression with gonadotropin-releasing hormone agonists. Clinicians may add gender-affirming hormones after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent to this partially irreversible treatment. Most adolescents have this capacity by age 16 years old. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to age 16 years, although there is minimal published experience treating prior to 13.5 to 14 years of age. For the care of peripubertal youths and older adolescents, we recommend that an expert multidisciplinary team comprised of medical professionals and mental health professionals manage this treatment. The treating physician must confirm the criteria for treatment used by the referring mental health practitioner and collaborate with them in decisions about gender-affirming surgery in older adolescents. For adult gender-dysphoric/gender-incongruent persons, the treating clinicians (collectively) should have expertise in transgender-specific diagnostic criteria, mental health, primary care, hormone treatment, and surgery, as needed by the patient. We suggest maintaining physiologic levels of gender-appropriate hormones and monitoring for known risks and complications. When high doses of sex steroids are required to suppress endogenous sex steroids and/or in advanced age, clinicians may consider surgically removing natal gonads along with reducing sex steroid treatment. Clinicians should monitor both transgender males (female to male) and transgender females (male to female) for reproductive organ cancer risk when surgical removal is incomplete. Additionally, clinicians should persistently monitor adverse effects of sex steroids. For gender-affirming surgeries in adults, the treating physician must collaborate with and confirm the criteria for treatment used by the referring physician. Clinicians should avoid harming individuals (via hormone treatment) who have conditions other than gender dysphoria/gender incongruence and who may not benefit from the physical changes associated with this treatment. *U Clin Endocrinol* Metab 102: 3869-3903, 2017)

Summary of Recommendations

1.0 Evaluation of youth and adults

- 1.1. We advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/ gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/ gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)
- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).

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1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$

Case: 24-108

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 $|\oplus \oplus \oplus \bigcirc$)

2.0 Treatment of adolescents

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$
- 2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$
- 2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$
- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. (1 $|\oplus\oplus\bigcirc\bigcirc$).
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/ gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 $|\oplus\bigcirc\bigcirc\bigcirc$)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$

3.0 Hormonal therapy for transgender adults

3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and

- the criteria for the endocrine phase of gender transition before beginning treatment. $(1 | \oplus \oplus \oplus \bigcirc)$
- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. $(1 \mid \oplus \oplus \oplus \bigcirc)$

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- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 l⊕⊕⊖⊖)
- 3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. $(2 \mid \oplus \bigcirc \bigcirc \bigcirc)$

4.0 Adverse outcome prevention and long-term care

- 4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 $\mid \oplus \oplus \bigcirc \bigcirc$)
- 4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. $(2 \mid \oplus \oplus \bigcirc\bigcirc)$
- 4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$
- 4.4. We recommend that clinicians obtain bone mineral density (BMD) measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 I⊕⊕○○)
- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for non-transgender females. (2 I⊕⊕○○)
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 $|\oplus\bigcirc\bigcirc\bigcirc$)
- 4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

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5.0 Surgery for sex reassignment and gender confirmation

- 5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 l⊕⊕○○)
- 5.2. We advise that clinicians approve genital genderaffirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 |⊕○○○)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 l⊕⊕○○).
- 5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 |⊕○○○)

Changes Since the Previous Guideline

Both the current guideline and the one published in 2009 contain similar sections. Listed here are the sections contained in the current guideline and the corresponding number of recommendations: Introduction, Evaluation of Youth and Adults (5), Treatment of Adolescents (6), Hormonal Therapy for Transgender Adults (4), Adverse Outcomes Prevention and Long-term Care (7), and Surgery for Sex Reassignment and Gender Confirmation (6). The current introduction updates the diagnostic classification of "gender dysphoria/gender incongruence." It also reviews the development of "gender identity" and summarizes its natural development. The section on

clinical evaluation of both youth and adults, defines in detail the professional qualifications required of those who diagnose and treat both adolescents and adults. We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional. We recommend against puberty blocking followed by gender-affirming hormone treatment of prepubertal children. Clinicians should inform pubertal children, adolescents, and adults seeking genderconfirming treatment of their options for fertility preservation. Prior to treatment, clinicians should evaluate the presence of medical conditions that may be worsened by hormone depletion and/or treatment. A multidisciplinary team, preferably composed of medical and mental health professionals, should monitor treatments. Clinicians evaluating transgender adults for endocrine treatment should confirm the diagnosis of persistent gender dysphoria/gender incongruence. Physicians should educate transgender persons regarding the time course of steroid-induced physical changes. Treatment should include periodic monitoring of hormone levels and metabolic parameters, as well as assessments of bone density and the impact upon prostate, gonads, and uterus. We also make recommendations for transgender persons who plan genital gender-affirming surgery.

Method of Development of Evidence-Based Clinical Practice Guidelines

The Clinical Guidelines Subcommittee (CGS) of the Endocrine Society deemed the diagnosis and treatment of individuals with GD/gender incongruence a priority area for revision and appointed a task force to formulate evidence-based recommendations. The task force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation group, an international group with expertise in the development and implementation of evidence-based guidelines (1). A detailed description of the grading scheme has been published elsewhere (2). The task force used the best available research evidence to develop the recommendations. The task force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase "we recommend" and the number 1, and weak recommendations use the phrase "we suggest" and the number 2. Cross-filled circles indicate the quality of the evidence, such that $\oplus \bigcirc \bigcirc \bigcirc$ denotes very low-quality evidence; $\oplus \oplus \bigcirc \bigcirc$, low quality; $\oplus \oplus \ominus \bigcirc$, moderate quality; and $\oplus \oplus \oplus \ominus$, high quality. The task force has confidence that persons who receive care according to the strong recommendations will derive, on average, more benefit than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each recommendation is a description of the evidence and the

values that the task force considered in making the recommendation. In some instances, there are remarks in which the task force offers technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the task force and their preferences; therefore, one should consider these remarks as suggestions.

In this guideline, the task force made several statements to emphasize the importance of shared decision-making, general preventive care measures, and basic principles of the treatment of transgender persons. They labeled these "Ungraded Good Practice Statement." Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles.

The Endocrine Society maintains a rigorous conflict-ofinterest review process for developing clinical practice guidelines. All task force members must declare any potential conflicts of interest by completing a conflict-of-interest form. The CGS reviews all conflicts of interest before the Society's Council approves the members to participate on the task force and periodically during the development of the guideline. All others participating in the guideline's development must also disclose any conflicts of interest in the matter under study, and most of these participants must be without any conflicts of interest. The CGS and the task force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined as remuneration in any amount from commercial interests; grants; research support; consulting fees; salary; ownership interests [e.g., stocks and stock options (excluding diversified mutual funds)]; honoraria and other payments for participation in speakers' bureaus, advisory boards, or boards of directors; and all other financial benefits. Completed forms are available through the Endocrine Society office.

The Endocrine Society provided the funding for this guideline; the task force received no funding or remuneration from commercial or other entities.

Commissioned Systematic Review

The task force commissioned two systematic reviews to support this guideline. The first one aimed to summarize the available evidence on the effect of sex steroid use in transgender individuals on lipids and cardiovascular outcomes. The review identified 29 eligible studies at moderate risk of bias. In transgender males (female to male), sex steroid therapy was associated with a statistically significant increase in serum triglycerides and low-density lipoprotein cholesterol levels. High-density lipoprotein cholesterol levels decreased significantly across all follow-up time periods. In transgender females (male to female), serum triglycerides were significantly higher without any changes in other parameters. Few myocardial infarction, stroke, venous thromboembolism (VTE), and death events were reported. These events were more frequent in transgender females. However, the

quality of the evidence was low. The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals and identified 13 studies. In transgender males, there was no statistically significant difference in the lumbar spine, femoral neck, or total hip BMD at 12 and 24 months compared with baseline values before initiating masculinizing hormone therapy. In transgender females, there was a statistically significant increase in lumbar spine BMD at 12 months and 24 months compared with baseline values before initiation of feminizing hormone therapy. There was minimal information on fracture rates. The quality of evidence was also low.

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Introduction

Throughout recorded history (in the absence of an endocrine disorder) some men and women have experienced confusion and anguish resulting from rigid, forced conformity to sexual dimorphism. In modern history, there have been numerous ongoing biological, psychological, cultural, political, and sociological debates over various aspects of gender variance. The 20th century marked the emergence of a social awakening for men and women with the belief that they are "trapped" in the wrong body (3). Magnus Hirschfeld and Harry Benjamin, among others, pioneered the medical responses to those who sought relief from and a resolution to their profound discomfort. Although the term transsexual became widely known after Benjamin wrote "The Transsexual Phenomenon" (4), it was Hirschfeld who coined the term "transsexual" in 1923 to describe people who want to live a life that corresponds with their experienced gender vs their designated gender (5). Magnus Hirschfeld (6) and others (4, 7) have described other types of trans phenomena besides transsexualism. These early researchers proposed that the gender identity of these people was located somewhere along a unidimensional continuum. This continuum ranged from all male through "something in between" to all female. Yet such a classification does not take into account that people may have gender identities outside this continuum. For instance, some experience themselves as having both a male and female gender identity, whereas others completely renounce any gender classification (8, 9). There are also reports of individuals experiencing a continuous and rapid involuntary alternation between a male and female identity (10) or men who do not experience themselves as men but do not want to live as women (11, 12). In some countries, (e.g., Nepal, Bangladesh, and Australia), these nonmale or nonfemale genders are officially recognized (13). Specific treatment protocols, however, have not yet been developed for these groups.

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Instead of the term transsexualism, the current classification system of the American Psychiatric Association uses the term gender dysphoria in its diagnosis of persons who are not satisfied with their designated gender (14). The current version of the World Health Organization's ICD-10 still uses the term transsexualism when diagnosing adolescents and adults. However, for the ICD-11, the World Health Organization has proposed using the term "gender incongruence" (15).

Treating persons with GD/gender incongruence (15) was previously limited to relatively ineffective elixirs or creams. However, more effective endocrinology-based treatments became possible with the availability of testosterone in 1935 and diethylstilbestrol in 1938. Reports of individuals with GD/gender incongruence who were treated with hormones and gender-affirming surgery appeared in the press during the second half of the 20th century. The Harry Benjamin International Gender Dysphoria Association was founded in September 1979 and is now called the World Professional Association for Transgender Health (WPATH). WPATH published its first Standards of Care in 1979. These standards have since been regularly updated, providing guidance for treating persons with GD/gender incongruence (16).

Prior to 1975, few peer-reviewed articles were published concerning endocrine treatment of transgender persons. Since then, more than two thousand articles about various aspects of transgender care have appeared.

It is the purpose of this guideline to make detailed recommendations and suggestions, based on existing medical literature and clinical experience, that will enable treating physicians to maximize benefit and minimize risk when caring for individuals diagnosed with GD/gender incongruence.

In the future, we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols. Specifically, endocrine treatment protocols for GD/gender incongruence should include the careful assessment of the following: (1) the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development); (2) the effects of treatment in adults on sex hormone levels; (3) the requirement for and the effects of progestins and other agents used to suppress endogenous sex steroids during treatment; and (4) the risks and benefits of gender-affirming hormone treatment in older transgender people.

To successfully establish and enact these protocols, a commitment of mental health and endocrine investigators is required to collaborate in long-term, large-scale studies across countries that use the same diagnostic and inclusion criteria, medications, assay methods, and response assessment tools (e.g., the European Network for the Investigation of Gender Incongruence) (17, 18).

Terminology and its use vary and continue to evolve. Table 1 contains the definitions of terms as they are used throughout this guideline.

Biological Determinants of Gender Identity Development

One's self-awareness as male or female changes gradually during infant life and childhood. This process of cognitive and affective learning evolves with interactions with parents, peers, and environment. A fairly accurate timetable exists outlining the steps in this process (19). Normative psychological literature, however, does not address if and when gender identity becomes crystallized and what factors contribute to the development of a gender identity that is not congruent with the gender of rearing. Results of studies from a variety of biomedical disciplines—genetic, endocrine, and neuroanatomic—support the concept that gender identity and/or gender expression (20) likely reflect a complex interplay of biological, environmental, and cultural factors (21, 22).

With respect to endocrine considerations, studies have failed to find differences in circulating levels of sex steroids between transgender and nontransgender individuals (23). However, studies in individuals with a disorder/difference of sex development (DSD) have informed our understanding of the role that hormones may play in gender identity outcome, even though most persons with GD/gender incongruence do not have a DSD. For example, although most 46,XX adult individuals with virilizing congenital adrenal hyperplasia caused by mutations in CYP21A2 reported a female gender identity, the prevalence of GD/gender incongruence was much greater in this group than in the general population without a DSD. This supports the concept that there is a role for prenatal/postnatal androgens in gender development (24–26), although some studies indicate that prenatal androgens are more likely to affect gender behavior and sexual orientation rather than gender identity per se (27, 28).

Researchers have made similar observations regarding the potential role of androgens in the development of gender identity in other individuals with DSD. For example, a review of two groups of 46,XY persons, each with androgen synthesis deficiencies and female raised, reported transgender male (female-to-male) gender role changes in 56% to 63% and 39% to 64% of patients, respectively (29). Also, in 46,XY female-raised individuals with cloacal

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Table 1. **Definitions of Terms Used in This Guideline**

Biological sex, biological male or female: These terms refer to physical aspects of maleness and femaleness. As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided.

Cisgender: This means not transgender. An alternative way to describe individuals who are not transgender is "non-transgender people.

Gender-affirming (hormone) treatment: See "gender reassignment"

Gender dysphoria: This is the distress and unease experienced if gender identity and designated gender are not completely congruent (see Table 2). In 2013, the American Psychiatric Association released the fifth edition of the DSM-5, which replaced "gender identity disorder" with "gender dysphoria" and changed the criteria for diagnosis.

Gender expression. This refers to external manifestations of gender, expressed through one's name, pronouns, clothing, haircut, behavior, voice, or body characteristics. Typically, transgender people seek to make their gender expression align with their gender identity, rather than their designated gender.

Gender identity/experienced gender: This refers to one's internal, deeply held sense of gender. For transgender people, their gender identity does not match their sex designated at birth. Most people have a gender identity of man or woman (or boy or girl). For some people, their gender identity does not fit neatly into one of those two choices. Unlike gender expression (see below), gender identity is

Gender identity disorder: This is the term used for GD/gender incongruence in previous versions of DSM (see "gender dysphoria"). The ICD-10 still uses the term for diagnosing child diagnoses, but the upcoming ICD-11 has proposed using "gender incongruence of childhood."

Gender incongruence: This is an umbrella term used when the gender identity and/or gender expression differs from what is typically associated with the designated gender. Gender incongruence is also the proposed name of the gender identity-related diagnoses in ICD-11. Not all individuals with gender incongruence have gender dysphoria or seek treatment.

Gender variance: See "gender incongruence"

Gender reassignment: This refers to the treatment procedure for those who want to adapt their bodies to the experienced gender by means of hormones and/or surgery. This is also called gender-confirming or gender-affirming treatment.

Gender-reassignment surgery (gender-confirming/gender-affirming surgery): These terms refer only to the surgical part of genderconfirming/gender-affirming treatment.

Gender role: This refers to behaviors, attitudes, and personality traits that a society (in a given culture and historical period) designates as masculine or feminine and/or that society associates with or considers typical of the social role of men or women.

Sex designated at birth: This refers to sex assigned at birth, usually based on genital anatomy.

Sex: This refers to attributes that characterize biological maleness or femaleness. The best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, the gonads, sex hormones, internal and external genitalia, and secondary sex

Sexual orientation: This term describes an individual's enduring physical and emotional attraction to another person. Gender identity and sexual orientation are not the same. Irrespective of their gender identity, transgender people may be attracted to women (gynephilic), attracted to men (androphilic), bisexual, asexual, or queer.

Transgender: This is an umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with their sex designated at birth. Not all transgender individuals seek treatment.

Transgender male (also: trans man, female-to-male, transgender male): This refers to individuals assigned female at birth but who identify and live as men.

Transgender woman (also: trans woman, male-to female, transgender female): This refers to individuals assigned male at birth but who identify and live as women.

Transition: This refers to the process during which transgender persons change their physical, social, and/or legal characteristics consistent with the affirmed gender identity. Prepubertal children may choose to transition socially.

Transsexual: This is an older term that originated in the medical and psychological communities to refer to individuals who have permanently transitioned through medical interventions or desired to do so.

exstrophy and penile agenesis, the occurrence of transgender male changes was significantly more prevalent than in the general population (30, 31). However, the fact that a high percentage of individuals with the same conditions did not change gender suggests that cultural factors may play a role as well.

With respect to genetics and gender identity, several studies have suggested heritability of GD/gender incongruence (32, 33). In particular, a study by Heylens et al. (33) demonstrated a 39.1% concordance rate for gender identity disorder (based on the DSM-IV criteria) in 23 monozygotic twin pairs but no concordance in 21 same-sex dizygotic or seven opposite-sex twin pairs. Although numerous investigators have sought to identify

specific genes associated with GD/gender incongruence, such studies have been inconsistent and without strong statistical significance (34–38).

Studies focusing on brain structure suggest that the brain phenotypes of people with GD/gender incongruence differ in various ways from control males and females, but that there is not a complete sex reversal in brain structures (39).

In summary, although there is much that is still unknown with respect to gender identity and its expression, compelling studies support the concept that biologic factors, in addition to environmental factors, contribute to this fundamental aspect of human development.

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Natural History of Children With

GD/Gender Incongruence

With current knowledge, we cannot predict the psychosexual outcome for any specific child. Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called "desisters"). Combining all outcome studies to date, the GD/gender incongruence of a minority of prepubertal children appears to persist in adolescence (20, 40). In adolescence, a significant number of these desisters identify as homosexual or bisexual. It may be that children who only showed some gender nonconforming characteristics have been included in the follow-up studies, because the DSM-IV text revision criteria for a diagnosis were rather broad. However, the persistence of GD/gender incongruence into adolescence is more likely if it had been extreme in childhood (41, 42). With the newer, stricter criteria of the DSM-5 (Table 2), persistence rates may well be different in future studies.

1.0 Evaluation of Youth and Adults

Gender-affirming treatment is a multidisciplinary effort. After evaluation, education, and diagnosis, treatment may include mental health care, hormone therapy, and/or surgical therapy. Together with an MHP, hormoneprescribing clinicians should examine the psychosocial impact of the potential changes on people's lives, including mental health, friends, family, jobs, and their role in society. Transgender individuals should be encouraged to experience living in the new gender role and assess whether this improves their quality of life. Although the focus of this guideline is gender-affirming hormone therapy, collaboration with appropriate professionals responsible for each aspect of treatment maximizes a successful outcome.

Diagnostic assessment and mental health care

GD/gender incongruence may be accompanied with psychological or psychiatric problems (43-51). It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient's understanding, mental health, and social conditions that can impact genderaffirming hormone therapy, and (6) regularly attend relevant professional meetings.

Because of the psychological vulnerability of many individuals with GD/gender incongruence, it is important that mental health care is available before, during, and sometimes also after transitioning. For children and adolescents, an MHP who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing GD/gender incongruence in children and adolescents is often extremely complex.

During assessment, the clinician obtains information from the individual seeking gender-affirming treatment. In the case

Table 2. DSM-5 Criteria for Gender Dysphoria in Adolescents and Adults

- A. A marked incongruence between one's experienced/expressed gender and natal gender of at least 6 mo in duration, as manifested by at least two of the following:
 - 1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
 - 2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
 - 3. A strong desire for the primary and/or secondary sex characteristics of the other gender
 - 4. A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
 - 5. A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
 - 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender)
- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning. Specify if:
 - 1. The condition exists with a disorder of sex development.
 - 2. The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

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of adolescents, the clinician also obtains information from the parents or guardians regarding various aspects of the child's general and psychosexual development and current functioning. On the basis of this information, the clinician:

- decides whether the individual fulfills criteria for treatment (see Tables 2 and 3) for GD/gender incongruence (DSM-5) or transsexualism (DSM-5 and/or ICD-10);
- informs the individual about the possibilities and limitations of various kinds of treatment (hormonal/ surgical and nonhormonal), and if medical treatment is desired, provides correct information to prevent unrealistically high expectations;
- assesses whether medical interventions may result in unfavorable psychological and social outcomes.

In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues. Literature on postoperative regret suggests that besides poor quality of surgery, severe psychiatric comorbidity and lack of support may interfere with positive outcomes (52–56).

For adolescents, the diagnostic procedure usually includes a complete psychodiagnostic assessment (57) and an assessment of the decision-making capability of the youth. An evaluation to assess the family's ability to endure stress, give support, and deal with the complexities of the adolescent's situation should be part of the diagnostic phase (58).

Social transitioning

A change in gender expression and role (which may involve living part time or full time in another gender role that is consistent with one's gender identity) may test the person's resolve, the capacity to function in the affirmed gender, and the adequacy of social, economic, and psychological supports. It assists both the individual and the clinician in their judgments about how to proceed (16). During social transitioning, the person's feelings about the social transformation (including coping with the responses of others) is a major focus of the counseling. The optimal timing for social transitioning may differ between individuals. Sometimes people wait until they

start gender-affirming hormone treatment to make social transitioning easier, but individuals increasingly start social transitioning long before they receive medically supervised, gender-affirming hormone treatment.

Criteria

Adolescents and adults seeking gender-affirming hormone treatment and surgery should satisfy certain criteria before proceeding (16). Criteria for gender-affirming hormone therapy for adults are in Table 4, and criteria for gender-affirming hormone therapy for adolescents are in Table 5. Follow-up studies in adults meeting these criteria indicate a high satisfaction rate with treatment (59). However, the quality of evidence is usually low. A few follow-up studies on adolescents who fulfilled these criteria also indicated good treatment results (60–63).

Recommendations for Those Involved in the Gender-Affirming Hormone Treatment of Individuals With GD/Gender Incongruence

- 1.1. We advise that only trained MHPs who meet the following criteria should diagnose GD/gender incongruence in adults: (1) competence in using the DSM and/or the ICD for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or ICD for diagnostic

Table 3. ICD-10 Criteria for Transsexualism

Transsexualism (F64.0) has three criteria:

- 1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
- 2. The transsexual identity has been present persistently for at least 2 y.
- 3. The disorder is not a symptom of another mental disorder or a genetic, DSD, or chromosomal abnormality.

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Table 4. Criteria for Gender-Affirming Hormone Therapy for Adults

- 1. Persistent, well-documented gender dysphoria/gender incongruence
- 2. The capacity to make a fully informed decision and to consent for treatment
- 3. The age of majority in a given country (if younger, follow the criteria for adolescents)
- 4. Mental health concerns, if present, must be reasonably well controlled

Reproduced from World Professional Association for Transgender Health (16).

purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

Evidence

Individuals with gender identity issues may have psychological or psychiatric problems (43–48, 50, 51, 64, 65). It is therefore necessary that clinicians making the diagnosis are able to make a distinction between GD/gender incongruence and conditions that have similar features. Examples of conditions with similar features are body dysmorphic disorder, body identity integrity disorder (a condition in which individuals have a sense that their anatomical configuration as an able-bodied person is somehow wrong or inappropriate) (66), or certain forms of eunuchism (in which a person is preoccupied with or engages in castration and/or penectomy for

Table 5. Criteria for Gender-Affirming Hormone Therapy for Adolescents

Adolescents are eligible for GnRH agonist treatment if:

- 1. A qualified MHP has confirmed that:
- •the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed),
- •gender dysphoria worsened with the onset of puberty,
- any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
- •the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment,
- 2 And the adolescent:
- •has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
- 3. And a pediatric endocrinologist or other clinician experienced in pubertal assessment
- agrees with the indication for GnRH agonist treatment,
- has confirmed that puberty has started in the adolescent (Tanner stage ≥G2/B2),
- •has confirmed that there are no medical contraindications to GnRH agonist treatment.

Adolescents are eligible for subsequent sex hormone treatment if:

- 1. A qualified MHP has confirmed:
- •the persistence of gender dysphoria,
- •any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment
- •the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
- 2. And the adolescent:
- has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
- 3. And a pediatric endocrinologist or other clinician experienced in pubertal induction:
- •agrees with the indication for sex hormone treatment,
- has confirmed that there are no medical contraindications to sex hormone treatment.

reasons that are not gender identity related) (11). Clinicians should also be able to diagnose psychiatric conditions accurately and ensure that these conditions are treated appropriately, particularly when the conditions may complicate treatment, affect the outcome of genderaffirming treatment, or be affected by hormone use.

Values and preferences

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The task force placed a very high value on avoiding harm from hormone treatment in individuals who have conditions other than GD/gender incongruence and who may not benefit from the physical changes associated with this treatment and placed a low value on any potential benefit these persons believe they may derive from hormone treatment. This justifies the good practice statement.

- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).
- 1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. (1 |⊕⊕○○)

Evidence

In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. The percentages differed among studies, probably dependent on which version of the DSM clinicians used, the patient's age, the recruitment criteria, and perhaps cultural factors. However, the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/ gender incongruent in adolescence (20). If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty (40). Social transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence. It may be that the presence of GD/gender incongruence in prepubertal children is the earliest sign that a child is destined to be transgender as an adolescent/adult (20). However, social transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence.

This recommendation, however, does not imply that children should be discouraged from showing gendervariant behaviors or should be punished for exhibiting such behaviors. In individual cases, an early complete social transition may result in a more favorable outcome, but there are currently no criteria to identify the

GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty.

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Values and preferences

The task force placed a high value on avoiding harm with gender-affirming hormone therapy in prepubertal children with GD/gender incongruence. This justifies the strong recommendation in the face of low-quality evidence.

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 l⊕⊕⊕○)

Remarks

Persons considering hormone use for gender affirmation need adequate information about this treatment in general and about fertility effects of hormone treatment in particular to make an informed and balanced decision (67, 68). Because young adolescents may not feel qualified to make decisions about fertility and may not fully understand the potential effects of hormonal interventions, consent and protocol education should include parents, the referring MHP(s), and other members of the adolescent's support group. To our knowledge, there are no formally evaluated decision aids available to assist in the discussion and decision regarding the future fertility of adolescents or adults beginning gender-affirming treatment.

Treating early pubertal youth with GnRH analogs will temporarily impair spermatogenesis and oocyte maturation. Given that an increasing number of transgender youth want to preserve fertility potential, delaying or temporarily discontinuing GnRH analogs to promote gamete maturation is an option. This option is often not preferred, because mature sperm production is associated with later stages of puberty and with the significant development of secondary sex characteristics.

For those designated male at birth with GD/gender incongruence and who are in early puberty, sperm production and the development of the reproductive tract are insufficient for the cryopreservation of sperm. However, prolonged pubertal suppression using GnRH analogs is reversible and clinicians should inform these individuals that sperm production can be initiated following prolonged gonadotropin suppression. This can be accomplished by spontaneous gonadotropin recovery after Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869-3903

(70, 71).

cessation of GnRH analogs or by gonadotropin treatment and will probably be associated with physical manifestations of testosterone production, as stated above. Note that there are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility. In males treated for precocious puberty, spermarche was reported 0.7 to 3 years after cessation of GnRH analogs (69). In adult men with gonadotropin deficiency, sperm are noted in seminal fluid by 6 to 12 months of gonadotropin

treatment. However, sperm numbers when partners of

these patients conceive are far below the "normal range"

In girls, no studies have reported long-term, adverse effects of pubertal suppression on ovarian function after treatment cessation (72, 73). Clinicians should inform adolescents that no data are available regarding either time to spontaneous ovulation after cessation of GnRH analogs or the response to ovulation induction following prolonged gonadotropin suppression.

In males with GD/gender incongruence, when medical treatment is started in a later phase of puberty or in adulthood, spermatogenesis is sufficient for cryopreservation and storage of sperm. In vitro spermatogenesis is currently under investigation. Restoration of spermatogenesis after prolonged estrogen treatment has not been studied.

In females with GD/gender incongruence, the effect of prolonged treatment with exogenous testosterone on ovarian function is uncertain. There have been reports of an increased incidence of polycystic ovaries in transgender males, both prior to and as a result of androgen treatment (74–77), although these reports were not confirmed by others (78). Pregnancy has been reported in transgender males who have had prolonged androgen treatment and have discontinued testosterone but have not had genital surgery (79, 80). A reproductive endocrine gynecologist can counsel patients before genderaffirming hormone treatment or surgery regarding potential fertility options (81). Techniques for cryopreservation of oocytes, embryos, and ovarian tissue continue to improve, and oocyte maturation of immature tissue is being studied (82).

2.0 Treatment of Adolescents

During the past decade, clinicians have progressively acknowledged the suffering of young adolescents with GD/gender incongruence. In some forms of GD/gender incongruence, psychological interventions may be useful and sufficient. However, for many adolescents with GD/ gender incongruence, the pubertal physical changes are unbearable. As early medical intervention may prevent psychological harm, various clinics have decided to start treating young adolescents with GD/gender incongruence with puberty-suppressing medication (a GnRH analog). As compared with starting gender-affirming treatment long after the first phases of puberty, a benefit of pubertal suppression at early puberty may be a better psychological and physical outcome.

In girls, the first physical sign of puberty is the budding of the breasts followed by an increase in breast and fat tissue. Breast development is also associated with the pubertal growth spurt, and menarche occurs ~2 years later. In boys, the first physical change is testicular growth. A testicular volume ≥4 mL is seen as consistent with the initiation of physical puberty. At the beginning of puberty, estradiol and testosterone levels are still low and are best measured in the early morning with an ultrasensitive assay. From a testicular volume of 10 mL, daytime testosterone levels increase, leading to virilization (83). Note that pubic hair and/or axillary hair/odor may not reflect the onset of gonadarche; instead, it may reflect adrenarche alone.

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment (Table 5), and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 l⊕⊕○○)
- 2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty (Tanner stages G2/B2). (2 I⊕⊕○○)

Evidence

Pubertal suppression can expand the diagnostic phase by a long period, giving the subject more time to explore options and to live in the experienced gender before making a decision to proceed with gender-affirming sex hormone treatments and/or surgery, some of which is irreversible (84, 85). Pubertal suppression is fully reversible, enabling full pubertal development in the natal gender, after cessation of treatment, if appropriate. The experience of full endogenous puberty is an undesirable condition for the GD/gender-incongruent individual and may seriously interfere with healthy psychological functioning and well-being. Treating GD/gender-incongruent adolescents entering puberty with GnRH analogs has been shown to improve psychological functioning in several domains (86).

Another reason to start blocking pubertal hormones early in puberty is that the physical outcome is improved compared with initiating physical transition after puberty has been completed (60, 62). Looking like a man or woman when living as the opposite sex creates difficult Case: 24-108 Document: 2-3 Page: 94 Filed: 01/25/2024

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barriers with enormous life-long disadvantages. We therefore advise starting suppression in early puberty to prevent the irreversible development of undesirable secondary sex characteristics. However, adolescents with early pubertal changes. GD/gender incongruence should experience the first changes of their endogenous spontaneous puberty, because their emotional reaction to these first physical changes has diagnostic value in establishing the persistence of GD/gender incongruence (85). Thus, Tanner stage 2 is the optimal time to start pubertal suppression. However, pubertal suppression treatment in early puberty will limit the growth of the penis and scrotum, which will have a potential effect on future surgical treatments (87). mones. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$

Clinicians can also use pubertal suppression in adolescents in later pubertal stages to stop menses in transgender males and prevent facial hair growth in transgender females. However, in contrast to the effects in early pubertal adolescents, physical sex characteristics (such as more advanced breast development in transgender boys and lowering of the voice and outgrowth of the jaw and brow in transgender girls) are not reversible.

Values and preferences

These recommendations place a high value on avoiding an unsatisfactory physical outcome when secondary sex characteristics have become manifest and irreversible, a higher value on psychological well-being, and a lower value on avoiding potential harm from early pubertal suppression.

Remarks

Table 6 lists the Tanner stages of breast and male genital development. Careful documentation of hallmarks of pubertal development will ensure precise timing when initiating pubertal suppression once puberty has started. Clinicians can use pubertal LH and sex steroid levels to confirm that puberty has progressed sufficiently before starting pubertal suppression (88). Reference ranges for sex steroids by Tanner stage may vary depending on the assay used. Ultrasensitive sex steroid and gonadotropin assays will help clinicians document

Irreversible and, for GD/gender-incongruent adolescents, undesirable sex characteristics in female puberty are breasts, female body habitus, and, in some cases, relative short stature. In male puberty, they are a prominent Adam's apple; low voice; male bone configuration, such as a large jaw, big feet and hands, and tall stature; and male hair pattern on the face and extremities.

2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hor-

Evidence

Clinicians can suppress pubertal development and gonadal function most effectively via gonadotropin suppression using GnRH analogs. GnRH analogs are long-acting agonists that suppress gonadotropins by GnRH receptor desensitization after an initial increase of gonadotropins during ~10 days after the first and (to a lesser degree) the second injection (89). Antagonists immediately suppress pituitary gonadotropin secretion (90, 91). Long-acting GnRH analogs are the currently preferred treatment option. Clinicians may consider longacting GnRH antagonists when evidence on their safety and efficacy in adolescents becomes available.

During GnRH analog treatment, slight development of secondary sex characteristics may regress, and in a later phase of pubertal development, it will stop. In girls, breast tissue will become atrophic, and menses will stop. In boys, virilization will stop, and testicular volume may decrease (92).

An advantage of using GnRH analogs is the reversibility of the intervention. If, after extensive exploration of his/her transition wish, the individual no longer desires transition, they can discontinue pubertal suppression. In subjects with

Table 6. Tanner Stages of Breast Development and Male External Genitalia

The description of Tanner stages for breast development:

- 1. Prepubertal
- 2. Breast and papilla elevated as small mound; areolar diameter increased
- 3. Breast and areola enlarged, no contour separation
- 4. Areola and papilla form secondary mound
- 5. Mature; nipple projects, areola part of general breast contour

For penis and testes:

- 1. Prepubertal, testicular volume <4 mL
- 2. Slight enlargement of penis; enlarged scrotum, pink, texture altered, testes 4–6 mL
- 3. Penis longer, testes larger (8–12 mL)
- 4. Penis and glans larger, including increase in breadth; testes larger (12-15 mL), scrotum dark
- 5. Penis adult size; testicular volume > 15 ml

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precocious puberty, spontaneous pubertal development has been shown to resume after patients discontinue taking GnRH analogs (93).

Recommendations 2.1 to 2.3 are supported by a prospective follow-up study from The Netherlands. This report assessed mental health outcomes in 55 transgender adolescents/young adults (22 transgender females and 33 transgender males) at three time points: (1) before the start of GnRH agonist (average age of 14.8 years at start of treatment), (2) at initiation of gender-affirming hormones (average age of 16.7 years at start of treatment), and (3) 1 year after "gender-reassignment surgery" (average age of 20.7 years) (63). Despite a decrease in depression and an improvement in general mental health functioning, GD/gender incongruence persisted through pubertal suppression, as previously reported (86). However, following sex hormone treatment and genderreassignment surgery, GD/gender incongruence was resolved and psychological functioning steadily improved (63). Furthermore, well-being was similar to or better than that reported by age-matched young adults from the general population, and none of the study participants regretted treatment. This study represents the first longterm follow-up of individuals managed according to currently existing clinical practice guidelines for transgender youth, and it underscores the benefit of the multidisciplinary approach pioneered in The Netherlands; however, further studies are needed.

Side effects

The primary risks of pubertal suppression in GD/ gender-incongruent adolescents may include adverse effects on bone mineralization (which can theoretically be reversed with sex hormone treatment), compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development. Few data are available on the effect of GnRH analogs on BMD in adolescents with GD/gender incongruence. Initial data in GD/gender-incongruent subjects demonstrated no change of absolute areal BMD during 2 years of GnRH analog therapy but a decrease in BMD z scores (85). A recent study also suggested suboptimal bone mineral accrual during GnRH analog treatment. The study reported a decrease in areal BMD z scores and of bone mineral apparent density z scores (which takes the size of the bone into account) in 19 transgender males treated with GnRH analogs from a mean age of 15.0 years (standard deviation = 2.0 years) for a median duration of 1.5 years (0.3 to 5.2 years) and in 15 transgender females treated from 14.9 (± 1.9) years for 1.3 years (0.5) to 3.8 years), although not all changes were statistically significant (94). There was incomplete catch-up at age 22 years after sex hormone treatment from age 16.6 (\pm 1.4) years for a median duration of 5.8 years (3.0 to 8.0 years) in transgender females and from age $16.4 (\pm 2.3)$ years for 5.4 years (2.8 to 7.8 years) in transgender males. Little is known about more prolonged use of GnRH analogs. Researchers reported normal BMD z scores at age 35 years in one individual who used GnRH analogs from age 13.7 years until age 18.6 years before initiating sex hormone treatment (65).

Additional data are available from individuals with late puberty or GnRH analog treatment of other indications. Some studies reported that men with constitutionally delayed puberty have decreased BMD in adulthood (95). However, other studies reported that these men have normal BMD (96, 97). Treating adults with GnRH analogs results in a decrease of BMD (98). In children with central precocious puberty, treatment with GnRH analogs has been found to result in a decrease of BMD during treatment by some (99) but not others (100). Studies have reported normal BMD after discontinuing therapy (69, 72, 73, 101, 102). In adolescents treated with growth hormone who are small for gestational age and have normal pubertal timing, 2-year GnRH analog treatments did not adversely affect BMD (103). Calcium supplementation may be beneficial in optimizing bone health in GnRH analog-treated individuals (104). There are no studies of vitamin D supplementation in this context, but clinicians should offer supplements to vitamin D-deficient adolescents. Physical activity, especially during growth, is important for bone mass in healthy individuals (103) and is therefore likely to be beneficial for bone health in GnRH analog-treated subjects.

GnRH analogs did not induce a change in body mass index standard deviation score in GD/gender-incongruent adolescents (94) but caused an increase in fat mass and decrease in lean body mass percentage (92). Studies in girls treated for precocious puberty also reported a stable body mass index standard deviation score during treatment (72) and body mass index and body composition comparable to controls after treatment (73).

Arterial hypertension has been reported as an adverse effect in a few girls treated with GnRH analogs for precocious/early puberty (105, 106). Blood pressure monitoring before and during treatment is recommended.

Individuals may also experience hot flashes, fatigue, and mood alterations as a consequence of pubertal suppression. There is no consensus on treatment of these side effects in this context.

It is recommended that any use of pubertal blockers (and subsequent use of sex hormones, as detailed below) include a discussion about implications for fertility (see recommendation 1.3). Transgender adolescents may

want to preserve fertility, which may be otherwise compromised if puberty is suppressed at an early stage and the individual completes phenotypic transition with the use of sex hormones.

Limited data are available regarding the effects of GnRH analogs on brain development. A single cross-sectional study demonstrated no compromise of executive function (107), but animal data suggest there may be an effect of GnRH analogs on cognitive function (108).

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Values and preferences

Our recommendation of GnRH analogs places a higher value on the superior efficacy, safety, and reversibility of the pubertal hormone suppression achieved (as compared with the alternatives) and a relatively lower value on limiting the cost of therapy. Of the available alternatives, depot and oral progestin preparations are effective. Experience with this treatment dates back prior to the emergence of GnRH analogs for treating precocious puberty in papers from the 1960s and early 1970s (109–112). These compounds are usually safe, but some side effects have been reported (113-115). Only two recent studies involved transgender youth (116, 117). One of these studies described the use of oral lynestrenol monotherapy followed by the addition of testosterone treatment in transgender boys who were at Tanner stage B4 or further at the start of treatment (117). They found lynestrenol safe, but gonadotropins were not fully suppressed. The study reported metrorrhagia in approximately half of the individuals, mainly in the first 6 months. Acne, headache, hot flashes, and fatigue were other frequent side effects. Another progestin that has been studied in the United States is medroxyprogesterone. This agent is not as effective as GnRH analogs in lowering endogenous sex hormones either and may be associated with other side effects (116). Progestin preparations may be an acceptable treatment for persons without access to GnRH analogs or with a needle phobia. If GnRH analog treatment is not available (insurance denial, prohibitive cost, or other reasons), postpubertal, transgender female adolescents may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see adult section).

Remarks

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Measurements of gonadotropin and sex steroid levels give precise information about gonadal axis suppression, although there is insufficient evidence for any specific short-term monitoring scheme in children treated with GnRH analogs (88). If the gonadal axis is not completely suppressed—as evidenced by (for example) menses, erections, or progressive hair growth—the interval of GnRH analog treatment can be shortened or the dose increased. During treatment, adolescents should be monitored for negative effects of delaying puberty, including a halted growth spurt and impaired bone mineral accretion. Table 7 illustrates a suggested clinical protocol.

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Anthropometric measurements and X-rays of the left hand to monitor bone age are informative for evaluating growth. To assess BMD, clinicians can perform dualenergy X-ray absorptiometry scans.

- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule (see Table 8) after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years (Table 5). (1 |⊕⊕○○)
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕○○○)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment (Table 9). (2 I⊕⊕○○)

Table 7. Baseline and Follow-Up Protocol During Suppression of Puberty

Every 3–6 mo

Anthropometry: height, weight, sitting height, blood pressure, Tanner stages

Every 6–12 mo

Laboratory: LH, FSH, E2/T, 25OH vitamin D

Every 1-2 y

Bone density using DXA

Bone age on X-ray of the left hand (if clinically indicated)

Adapted from Hembree et al. (118).

Table 8. **Protocol Induction of Puberty**

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Induction of female puberty with oral 17\beta-estradiol, increasing the dose every 6 mo:
  5 \mu g/kg/d
  10 \mu g/kg/d
  15 μg/kg/d
  20 µg/kg/d
  Adult dose = 2-6 mg/d
  In postpubertal transgender female adolescents, the dose of 17β-estradiol can be increased more rapidly:
     1 mg/d for 6 mo
    2 mg/d
Induction of female puberty with transdermal 17\beta-estradiol, increasing the dose every 6 mo (new patch is placed every 3.5 d):
  6.25–12.5 \mug/24 h (cut 25-\mug patch into quarters, then halves)
  25 \mu g/24 h
  37.5 \mu g/24 h
  Adult dose = 50-200 \mu g/24 h
  For alternatives once at adult dose, see Table 11.
  Adjust maintenance dose to mimic physiological estradiol levels (see Table 15).
Induction of male puberty with testosterone esters increasing the dose every 6 mo (IM or SC):
  25 mg/m<sup>2</sup>/2 wk (or alternatively, half this dose weekly, or double the dose every 4 wk)
  50 ma/m<sup>2</sup>/2 wk
  75 mg/m<sup>2</sup>/2 wk
  100 \text{ mg/m}^2/2 \text{ wk}
  Adult dose = 100-200 mg every 2 wk
  In postpubertal transgender male adolescents the dose of testosterone esters can be increased more rapidly:
     75 mg/2 wk for 6 mo
     125 mg/2 wk
  For alternatives once at adult dose, see Table 11.
  Adjust maintenance dose to mimic physiological testosterone levels (see Table 14).
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Adapted from Hembree et al. (118).

Abbreviations: IM, intramuscularly; SC, subcutaneously.

Evidence

Adolescents develop competence in decision making at their own pace. Ideally, the supervising medical professionals should individually assess this competence, although no objective tools to make such an assessment are currently available.

Many adolescents have achieved a reasonable level of competence by age 15 to 16 years (119), and in many countries 16-year-olds are legally competent with regard to medical decision making (120). However, others believe that although some capacities are generally achieved before age 16 years, other abilities (such as good risk assessment) do not develop until well after 18 years (121). They suggest that health care procedures should be divided along a matrix of relative risk, so that younger adolescents can be allowed to decide about low-risk procedures, such as most diagnostic tests and common therapies, but not about high-risk procedures, such as most surgical procedures (121).

Currently available data from transgender adolescents support treatment with sex hormones starting at age 16 years (63, 122). However, some patients may incur potential risks by waiting until age 16 years. These include the potential risk to bone health if puberty is suppressed

Table 9. Baseline and Follow-up Protocol During Induction of Puberty

Every 3-6 mo

• Anthropometry: height, weight, sitting height, blood pressure, Tanner stages

- •In transgender males: hemoglobin/hematocrit, lipids, testosterone, 250H vitamin D
- •In transgender females: prolactin, estradiol, 250H vitamin D

Every 1-2 v

- BMD using DXA
- Bone age on X-ray of the left hand (if clinically indicated)

BMD should be monitored into adulthood (until the age of 25–30 y or until peak bone mass has been reached). For recommendations on monitoring once pubertal induction has been completed, see Tables 14 and 15.

Adapted from Hembree et al. (118).

Abbreviation: DXA, dual-energy X-ray absorptiometry.

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for 6 to 7 years before initiating sex hormones (e.g., if someone reached Tanner stage 2 at age 9-10 years old). Additionally, there may be concerns about inappropriate height and potential harm to mental health (emotional and social isolation) if initiation of secondary sex characteristics must wait until the person has reached 16 years of age. However, only minimal data supporting earlier use of gender-affirming hormones in transgender adolescents currently exist (63). Clearly, long-term studies are needed to determine the optimal age of sex hormone treatment in GD/gender-incongruent adolescents.

The MHP who has followed the adolescent during GnRH analog treatment plays an essential role in assessing whether the adolescent is eligible to start sex hormone therapy and capable of consenting to this treatment (Table 5). Support of the family/environment is essential. Prior to the start of sex hormones, clinicians should discuss the implications for fertility (see recommendation 1.5). Throughout pubertal induction, an MHP and a pediatric endocrinologist (or other clinician competent in the evaluation and induction of pubertal development) should monitor the adolescent. In addition to monitoring therapy, it is also important to pay attention to general adolescent health issues, including healthy life style choices, such as not smoking, contraception, and appropriate vaccinations (e.g., human papillomavirus).

For the induction of puberty, clinicians can use a similar dose scheme for hypogonadal adolescents with GD/gender incongruence as they use in other individuals with hypogonadism, carefully monitoring for desired and undesired effects (Table 8). In transgender female adolescents, transdermal 17β -estradiol may be an alternative for oral 17β -estradiol. It is increasingly used for pubertal induction in hypogonadal females. However, the absence of low-dose estrogen patches may be a problem. As a result, individuals may need to cut patches to size themselves to achieve appropriate dosing (123). In transgender male adolescents, clinicians can give testosterone injections intramuscularly or subcutaneously (124, 125).

When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion. Gonadotropin secretion and endogenous production of testosterone may resume and interfere with the effectiveness of estrogen treatment, in transgender female adolescents (126, 127). Therefore, continuation of GnRH analog treatment is advised until gonadectomy. Given that GD/gender-incongruent adolescents may opt not to have gonadectomy, long-term studies are necessary to examine the potential risks of prolonged GnRH analog treatment. Alternatively, in transgender male adolescents, GnRH analog treatment can be discontinued once an adult dose of testosterone has been reached and the individual is well virilized. If uterine bleeding occurs, a progestin can be added. However, the combined use of a GnRH analog (for ovarian suppression) and testosterone may enable phenotypic transition with a lower dose of testosterone in comparison with testosterone alone. If there is a wish or need to discontinue GnRH analog treatment in transgender female adolescents, they may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see section 3.0 "Hormonal Therapy for Transgender Adults").

Values and preferences

The recommendation to initiate pubertal induction only when the individual has sufficient mental capacity (roughly age 16 years) to give informed consent for this partly irreversible treatment places a higher value on the ability of the adolescent to fully understand and oversee the partially irreversible consequences of sex hormone treatment and to give informed consent. It places a lower value on the possible negative effects of delayed puberty. We may not currently have the means to weigh adequately the potential benefits of waiting until around age 16 years to initiate sex hormones vs the potential risks/ harm to BMD and the sense of social isolation from having the timing of puberty be so out of sync with peers (128).

Remarks

Before starting sex hormone treatment, effects on fertility and options for fertility preservation should be discussed. Adult height may be a concern in transgender adolescents. In a transgender female adolescent, clinicians may consider higher doses of estrogen or a more rapid tempo of dose escalation during pubertal induction. There are no established treatments yet to augment adult height in a transgender male adolescent with open epiphyses during pubertal induction. It is not uncommon for transgender adolescents to present for clinical services after having completed or nearly completed puberty. In such cases, induction of puberty with sex hormones can be done more rapidly (see Table 8). Additionally, an adult dose of testosterone in transgender male adolescents may suffice to suppress the gonadal axis without the need to use a separate agent. At the appropriate time, the multidisciplinary team should adequately prepare the adolescent for transition to adult care.

3.0 Hormonal Therapy for **Transgender Adults**

The two major goals of hormonal therapy are (1) to reduce endogenous sex hormone levels, and thus reduce the secondary sex characteristics of the individual's designated gender, and (2) to replace endogenous sex hormone levels consistent with the individual's gender identity by using the principles of hormone replacement treatment of hypogonadal patients. The timing of these two goals and the age at which to begin treatment with the sex hormones of the chosen gender is codetermined in collaboration with both the person pursuing transition and the health care providers. The treatment team should include a medical provider knowledgeable in transgender hormone therapy, an MHP knowledgeable in GD/gender incongruence and the mental health concerns of transition, and a primary care provider able to provide care appropriate for transgender individuals. The physical changes induced by this sex hormone transition are usually accompanied by an improvement in mental well-being (129, 130).

- 3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. $(1 \mid \oplus \oplus \oplus \bigcirc)$
- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment (Table 10). $(1 \mid \oplus \oplus \oplus \bigcirc)$
- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 $|\oplus \oplus \bigcirc \bigcirc$)

Evidence

It is the responsibility of the treating clinician to confirm that the person fulfills criteria for treatment. The treating clinician should become familiar with the terms and criteria presented in Tables 1-5 and take a thorough history from the patient in collaboration with the other members of the treatment team. The treating clinician must ensure that the desire for transition is appropriate; the consequences, risks, and benefits of treatment are well understood; and the desire for transition persists. They also need to discuss fertility preservation options (see recommendation 1.3) (67, 68).

Transgender males

Clinical studies have demonstrated the efficacy of several different androgen preparations to induce masculinization in transgender males (Appendix A) (113, 114, 131–134). Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism (135). Clinicians can use either parenteral or transdermal preparations to achieve testosterone values in the normal male range (this is dependent on the specific assay, but is typically 320 to 1000 ng/dL) (Table 11) (136). Sustained supraphysiologic levels of testosterone increase the risk of adverse reactions (see section 4.0 "Adverse Outcome Prevention and Long-Term Care") and should be avoided.

Similar to androgen therapy in hypogonadal men, testosterone treatment in transgender males results in increased muscle mass and decreased fat mass, increased facial hair and acne, male pattern baldness in those genetically predisposed, and increased sexual desire (137).

Table 10. Medical Risks Associated With Sex Hormone Therapy

Transgender female: estrogen

Very high risk of adverse outcomes:

•Thromboembolic disease

Moderate risk of adverse outcomes:

- Macroprolactinoma
- Breast cancer
- •Coronary artery disease
- Cerebrovascular disease
- Cholelithiasis
- Hypertriglyceridemia

Transgender male: testosterone

Very high risk of adverse outcomes:

Erythrocytosis (hematocrit > 50%)

Moderate risk of adverse outcomes:

- Severe liver dysfunction (transaminases > threefold upper limit of normal)
- Coronary artery disease
- Cerebrovascular disease
- Hypertension
- Breast or uterine cancer

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Table 11. **Hormone Regimens in Transgender Persons**

Transgender females^a Estrogen Oral 2.0-6.0 mg/d Estradiol Transdermal Estradiol transdermal patch 0.025-0.2 mg/d (New patch placed every 3–5 d) Parenteral Estradiol valerate or cypionate 5-30 mg IM every 2 wk 2-10 mg IM every week Anti-androgens 100-300 mg/d Spironolactone Cyproterone acetate^b 25-50 mg/d **GnRH** agonist 3.75 mg SQ (SC) monthly 11.25 mg SQ (SC) 3-monthly Transgender males Testosterone Parenteral testosterone Testosterone enanthate or cypionate 100-200 mg SQ (IM) every 2 wk or SQ (SC) 50% per week Testosterone undecanoate^c 1000 mg every 12 wk Transdermal testosterone Testosterone gel 1.6%^d 50-100 mg/d Testosterone transdermal patch 2.5-7.5 mg/d

Abbreviations: IM, intramuscularly; SQ, sequentially; SC, subcutaneously.

In transgender males, testosterone will result in clitoromegaly, temporary or permanent decreased fertility, deepening of the voice, cessation of menses (usually), and a significant increase in body hair, particularly on the face, chest, and abdomen. Cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, clinicians may consider the addition of a progestational agent or endometrial ablation (138). Clinicians may also administer GnRH analogs or depot medroxyprogesterone to stop menses prior to testosterone treatment.

Transgender females

The hormone regimen for transgender females is more complex than the transgender male regimen (Appendix B). Treatment with physiologic doses of estrogen alone is insufficient to suppress testosterone levels into the normal range for females (139). Most published clinical studies report the need for adjunctive therapy to achieve testosterone levels in the female range (21, 113, 114, 132-134, 139, 140).

Multiple adjunctive medications are available, such as progestins with antiandrogen activity and GnRH agonists (141). Spironolactone works by directly blocking androgens during their interaction with the androgen receptor (114, 133, 142). It may also have estrogenic activity (143). Cyproterone acetate, a progestational compound with antiandrogenic properties (113, 132, 144), is widely used in Europe. 5α -Reductase inhibitors do not reduce testosterone levels and have adverse effects (145).

Dittrich et al. (141) reported that monthly doses of the GnRH agonist goserelin acetate in combination with estrogen were effective in reducing testosterone levels with a low incidence of adverse reactions in 60 transgender females. Leuprolide and transdermal estrogen were as effective as cyproterone and transdermal estrogen in a comparative retrospective study (146).

Patients can take estrogen as oral conjugated estrogens, oral 17β -estradiol, or transdermal 17β -estradiol. Among estrogen options, the increased risk of thromboembolic events associated with estrogens in general seems most concerning with ethinyl estradiol specifically (134, 140, 141), which is why we specifically suggest that it not be used in any transgender treatment plan. Data distinguishing among other estrogen options are less well established although there is some thought that oral routes of administration are more thrombogenic due to the "first pass effect" than are transdermal and parenteral routes, and that the risk of thromboembolic events is dose-dependent. Injectable estrogen and sublingual

^aEstrogens used with or without antiandrogens or GnRH agonist.

^bNot available in the United States.

^cOne thousand milligrams initially followed by an injection at 6 wk then at 12-wk intervals.

^dAvoid cutaneous transfer to other individuals.

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estrogen may benefit from avoiding the first pass effect, but they can result in more rapid peaks with greater overall periodicity and thus are more difficult to monitor (147, 148). However, there are no data demonstrating that increased periodicity is harmful otherwise.

Clinicians can use serum estradiol levels to monitor oral, transdermal, and intramuscular estradiol. Blood tests cannot monitor conjugated estrogens or synthetic estrogen use. Clinicians should measure serum estradiol and serum testosterone and maintain them at the level for premenopausal females (100 to 200 pg/mL and <50 ng/dL, respectively). The transdermal preparations and injectable estradiol cypionate or valerate preparations may confer an advantage in older transgender females who may be at higher risk for thromboembolic disease (149).

Values

3888

Our recommendation to maintain levels of genderaffirming hormones in the normal adult range places a high value on the avoidance of the long-term complications of pharmacologic doses. Those patients receiving endocrine treatment who have relative contraindications to hormones should have an in-depth discussion with their physician to balance the risks and benefits of therapy.

Remarks

Clinicians should inform all endocrine-treated individuals of all risks and benefits of gender-affirming hormones prior to initiating therapy. Clinicians should strongly encourage tobacco use cessation in transgender females to avoid increased risk of VTE and cardiovascular complications. We strongly discourage the unsupervised use of hormone therapy (150).

Not all individuals with GD/gender incongruence seek treatment as described (e.g., male-to-eunuchs and individuals seeking partial transition). Tailoring current protocols to the individual may be done within the context of accepted safety guidelines using a multidisciplinary approach including mental health. No evidence-based protocols are available for these groups (151). We need prospective studies to better understand treatment options for these persons.

3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 |⊕○○○)

Evidence

Transgender males

Physical changes that are expected to occur during the first 1 to 6 months of testosterone therapy include cessation of menses, increased sexual desire, increased facial and body hair, increased oiliness of skin, increased muscle, and redistribution of fat mass. Changes that occur within the first year of testosterone therapy include deepening of the voice (152, 153), clitoromegaly, and male pattern hair loss (in some cases) (114, 144, 154, 155) (Table 12).

Transgender females

Physical changes that may occur in transgender females in the first 3 to 12 months of estrogen and antiandrogen therapy include decreased sexual desire, decreased spontaneous erections, decreased facial and body hair (usually mild), decreased oiliness of skin, increased breast tissue growth, and redistribution of fat mass (114, 139, 149, 154, 155, 161) (Table 13). Breast development is generally maximal at 2 years after initiating hormones (114, 139, 149, 155). Over a long period of time, the prostate gland and testicles will undergo atrophy.

Although the time course of breast development in transgender females has been studied (150), precise information about other changes induced by sex hormones is lacking (141). There is a great deal of variability among individuals, as evidenced during pubertal development. We all know that a major concern for transgender females is breast development. If we work with estrogens, the result will be often not what the transgender female expects.

Alternatively, there are transgender females who report an anecdotal improved breast development, mood, or sexual desire with the use of progestogens. However, there have been no well-designed studies of the role of progestogens in feminizing hormone regimens, so the question is still open.

Our knowledge concerning the natural history and effects of different cross-sex hormone therapies on breast

Table 12. Masculinizing Effects in Transgender Males

Effect	Onset	Maximum
Skin oiliness/acne	1–6 mo	1–2 y
Facial/body hair growth	6-12 mo	4–5 y
Scalp hair loss	6-12 mo	a ˜
Increased muscle mass/strength	6-12 mo	2–5 y
Fat redistribution	1–6 mo	2–5 _b y
Cessation of menses	1–6 mo	b
Clitoral enlargement	1–6 mo	1–2 y
Vaginal atrophy	1–6 mo	1–2 y
Deepening of voice	6–12 mo	1–2 y

Estimates represent clinical observations: Toorians et al. (149), Asscheman et al. (156), Gooren et al. (157), Wierckx et al. (158).

^aPrevention and treatment as recommended for biological men.

^bMenorrhagia requires diagnosis and treatment by a gynecologist.

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Table 13. **Feminizing Effects in Transgender Females**

Effect	Onset	Maximum
Redistribution of body fat	3–6 mo	2–3 y
Decrease in muscle mass and strength	3–6 mo	1–2 y
Softening of skin/decreased oiliness	3–6 mo	Unknown
Decreased sexual desire	1–3 mo	3–6 mo
Decreased spontaneous erections	1–3 mo	3–6 mo
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 mo	2–3 y
Decreased testicular volume	3–6 mo	2-3 y
Decreased sperm production	Unknown	>3 y
Decreased terminal hair growth	6–12 mo	$>$ 3 y^a
Scalp hair	Variable	<i>b</i>
Voice changes	None	c

Estimates represent clinical observations: Toorians et al. (149), Asscheman et al. (156), Gooren et al. (157).

development in transgender females is extremely sparse and based on the low quality of evidence. Current evidence does not indicate that progestogens enhance breast development in transgender females, nor does evidence prove the absence of such an effect. This prevents us from drawing any firm conclusion at this moment and demonstrates the need for further research to clarify these important clinical questions (162).

Values and preferences

Transgender persons have very high expectations regarding the physical changes of hormone treatment and are aware that body changes can be enhanced by surgical procedures (e.g., breast, face, and body habitus). Clear expectations for the extent and timing of sex hormone-induced changes may prevent the potential harm and expense of unnecessary procedures.

4.0 Adverse Outcome Prevention and **Long-Term Care**

Hormone therapy for transgender males and females confers many of the same risks associated with sex hormone replacement therapy in nontransgender persons. The risks arise from and are worsened by inadvertent or intentional use of supraphysiologic doses of sex hormones, as well as use of inadequate doses of sex hormones to maintain normal physiology (131, 139).

4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 $\mid \oplus \oplus \bigcirc \bigcirc$)

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Evidence

Pretreatment screening and appropriate regular medical monitoring are recommended for both transgender males and females during the endocrine transition and periodically thereafter (26, 155). Clinicians should monitor weight and blood pressure, conduct physical exams, and assess routine health questions, such as tobacco use, symptoms of depression, and risk of adverse events such as deep vein thrombosis/pulmonary embolism and other adverse effects of sex steroids.

Transgender males

Table 14 contains a standard monitoring plan for transgender males on testosterone therapy (154, 159). Key issues include maintaining testosterone levels in the physiologic normal male range and avoiding adverse events resulting from excess testosterone therapy, particularly erythrocytosis, sleep apnea, hypertension, excessive weight gain, salt retention, lipid changes, and excessive or cystic acne (135).

Because oral 17-alkylated testosterone is not recommended, serious hepatic toxicity is not anticipated with parenteral or transdermal testosterone use (163, 164). Past concerns regarding liver toxicity with testosterone have been alleviated with subsequent reports that indicate the risk of serious liver disease is minimal (144, 165, 166).

Transgender females

Table 15 contains a standard monitoring plan for transgender females on estrogens, gonadotropin suppression, or antiandrogens (160). Key issues include avoiding supraphysiologic doses or blood levels of estrogen that may lead to increased risk for thromboembolic disease, liver dysfunction, and hypertension. Clinicians should monitor serum estradiol levels using laboratories participating in external quality control, as measurements of estradiol in blood can be very challenging (167).

VTE may be a serious complication. A study reported a 20-fold increase in venous thromboembolic disease in a large cohort of Dutch transgender subjects (161). This increase may have been associated with the use of the synthetic estrogen, ethinyl estradiol (149). The incidence decreased when clinicians stopped administering ethinyl estradiol (161). Thus, the use of synthetic estrogens and conjugated estrogens is undesirable because of the inability to regulate doses by measuring serum levels and the risk of thromboembolic disease. In a German gender clinic, deep vein thrombosis occurred in 1 of 60 of transgender females treated with a GnRH analog and oral

^aComplete removal of male sexual hair requires electrolysis or laser treatment or both.

^bFamilial scalp hair loss may occur if estrogens are stopped.

^cTreatment by speech pathologists for voice training is most effective.

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Table 14. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Male

- 1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of virilization and for development of adverse reactions.
- 2. Measure serum testosterone every 3 mo until levels are in the normal physiologic male range:^a
 - a. For testosterone enanthate/cypionate injections, the testosterone level should be measured midway between injections. The target level is 400–700 ng/dL to 400 ng/dL. Alternatively, measure peak and trough levels to ensure levels remain in the normal male range.
 - b. For parenteral testosterone undecanoate, testosterone should be measured just before the following injection. If the level is <400 ng/dL, adjust dosing interval.
 - c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 wk of daily application (at least 2 h after application).
- 3. Measure hematocrit or hemoglobin at baseline and every 3 mo for the first year and then one to two times a year. Monitor weight, blood pressure, and lipids at regular intervals.
- 4. Screening for osteoporosis should be conducted in those who stop testosterone treatment, are not compliant with hormone therapy, or who develop risks for bone loss.
- 5. If cervical tissue is present, monitoring as recommended by the American College of Obstetricians and Gynecologists.
- 6. Ovariectomy can be considered after completion of hormone transition.
- 7. Conduct sub- and periareolar annual breast examinations if mastectomy performed. If mastectomy is not performed, then consider mammograms as recommended by the American Cancer Society.

estradiol (141). The patient who developed a deep vein thrombosis was found to have a homozygous C677 T mutation in the methylenetetrahydrofolate reductase gene. In an Austrian gender clinic, administering genderaffirming hormones to 162 transgender females and 89 transgender males was not associated with VTE, despite an 8.0% and 5.6% incidence of thrombophilia (159). A more recent multinational study reported only 10 cases of VTE from a cohort of 1073 subjects (168). Thrombophilia screening of transgender persons initiating hormone treatment should be restricted to those with a personal or family history of VTE (159). Monitoring D-dimer levels during treatment is not recommended (169).

4.2. We suggest periodically monitoring prolacting levels in transgender females treated with estrogens. $(2 \mid \oplus \oplus \bigcirc\bigcirc)$

Evidence

Estrogen therapy can increase the growth of pituitary lactrotroph cells. There have been several reports of prolactinomas occurring after long-term, high-dose estrogen therapy (170–173). Up to 20% of transgender females treated with estrogens may have elevations in prolactin levels associated with enlargement of the pituitary gland (156). In most cases, the serum prolactin levels will return to the normal range with a reduction or discontinuation of the estrogen therapy or discontinuation of cyproterone acetate (157, 174, 175).

The onset and time course of hyperprolactinemia during estrogen treatment are not known. Clinicians should measure prolactin levels at baseline and then at least annually during the transition period and every 2 years thereafter. Given that only a few case studies reported prolactinomas, and prolactinomas were not reported in large cohorts of estrogen-treated persons, the risk is likely to be very low. Because the major presenting findings of microprolactinomas (hypogonadism and sometimes gynecomastia) are not apparent in transgender females, clinicians may perform radiologic examinations of the pituitary in those patients whose prolactin levels persistently increase despite stable or reduced estrogen levels. Some transgender individuals receive psychotropic medications that can increase prolactin levels (174).

Table 15. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Female

- 1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of feminization and for development of adverse reactions.
- 2. Measure serum testosterone and estradiol every 3 mo.
 - a. Serum testosterone levels should be <50 ng/dL.
 - b. Serum estradiol should not exceed the peak physiologic range: 100-200 pg/mL.
- 3. For individuals on spironolactone, serum electrolytes, particularly potassium, should be monitored every 3 mo in the first year and annually thereafter.
- 4. Routine cancer screening is recommended, as in nontransgender individuals (all tissues present).
- 5. Consider BMD testing at baseline (160). In individuals at low risk, screening for osteoporosis should be conducted at age 60 years or in those who are not compliant with hormone therapy.

^aAdapted from Lapauw et al. (154) and Ott et al. (159).

4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 |⊕⊕○○)

Evidence

Transgender males

doi: 10.1210/ic.2017-01658

Administering testosterone to transgender males results in a more atherogenic lipid profile with lowered high-density lipoprotein cholesterol and higher triglyceride and low-density lipoprotein cholesterol values (176–179). Studies of the effect of testosterone on insulin sensitivity have mixed results (178, 180). A randomized, open-label uncontrolled safety study of transgender males treated with testosterone undecanoate demonstrated no insulin resistance after 1 year (181, 182). Numerous studies have demonstrated the effects of sex hormone treatment on the cardiovascular system (160, 179, 183, 184). Long-term studies from The Netherlands found no increased risk for cardiovascular mortality (161). Likewise, a meta-analysis of 19 randomized trials in nontransgender males on testosterone replacement showed no increased incidence of cardiovascular events (185). A systematic review of the literature found that data were insufficient (due to very low-quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or VTE in transgender males (176). Future research is needed to ascertain the potential harm of hormonal therapies (176). Clinicians should manage cardiovascular risk factors as they emerge according to established guidelines (186).

Transgender females

A prospective study of transgender females found favorable changes in lipid parameters with increased high-density lipoprotein and decreased low-density lipoprotein concentrations (178). However, increased weight, blood pressure, and markers of insulin resistance attenuated these favorable lipid changes. In a meta-analysis, only serum triglycerides were higher at ≥24 months without changes in other parameters (187). The largest cohort of transgender females (mean age 41 years, followed for a mean of 10 years) showed no increase in cardiovascular mortality despite a 32% rate of tobacco use (161).

Thus, there is limited evidence to determine whether estrogen is protective or detrimental on lipid and glucose metabolism in transgender females (176). With aging, there is usually an increase of body weight. Therefore, as with nontransgender individuals, clinicians should monitor and manage glucose and lipid metabolism and blood pressure regularly according to established guidelines (186).

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4.4. We recommend that clinicians obtain BMD measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 $|\oplus \oplus \bigcirc \bigcirc$)

Evidence

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Transgender males

Baseline bone mineral measurements in transgender males are generally in the expected range for their pretreatment gender (188). However, adequate dosing of testosterone is important to maintain bone mass in transgender males (189, 190). In one study (190), serum LH levels were inversely related to BMD, suggesting that low levels of sex hormones were associated with bone loss. Thus, LH levels in the normal range may serve as an indicator of the adequacy of sex steroid administration to preserve bone mass. The protective effect of testosterone may be mediated by peripheral conversion to estradiol, both systemically and locally in the bone.

Transgender females

A baseline study of BMD reported T scores less than -2.5 in 16% of transgender females (191). In aging males, studies suggest that serum estradiol more positively correlates with BMD than does testosterone (192, 193) and is more important for peak bone mass (194). Estrogen preserves BMD in transgender females who continue on estrogen and antiandrogen therapies (188, 190, 191, 195, 196).

Fracture data in transgender males and females are not available. Transgender persons who have undergone gonadectomy may choose not to continue consistent sex steroid treatment after hormonal and surgical sex reassignment, thereby becoming at risk for bone loss. There have been no studies to determine whether clinicians should use the sex assigned at birth or affirmed gender for assessing osteoporosis (e.g., when using the FRAX tool). Although some researchers use the sex assigned at birth (with the assumption that bone mass has usually peaked for transgender people who initiate hormones in early adulthood), this should be assessed on a case-by-case basis until there are more data available. This assumption will be further complicated by the increasing prevalence of transgender people who undergo hormonal transition at a pubertal age or soon after puberty. Sex for comparison within risk assessment tools may be based on the age at which hormones were initiated and the length of exposure to hormones. In some cases, it may be

reasonable to assess risk using both the male and female calculators and using an intermediate value. Because all subjects underwent normal pubertal development, with known effects on bone size, reference values for birth sex were used for all participants (154).

- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for those designated female at birth. (2 $|\oplus \oplus \bigcirc \bigcirc$)
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. $(2 \mid \oplus \bigcirc \bigcirc)$

Evidence

Studies have reported a few cases of breast cancer in transgender females (197-200). A Dutch study of 1800 transgender females followed for a mean of 15 years (range of 1 30 years) found one case of breast cancer. The Women's Health Initiative study reported that females taking conjugated equine estrogen without progesterone for 7 years did not have an increased risk of breast cancer as compared with females taking placebo (137).

In transgender males, a large retrospective study conducted at the U.S. Veterans Affairs medical health system identified seven breast cancers (194). The authors reported that this was not above the expected rate of breast cancers in cisgender females in this cohort. Furthermore, they did report one breast cancer that developed in a transgender male patient after mastectomy, supporting the fact that breast cancer can occur even after mastectomy. Indeed, there have been case reports of breast cancer developing in subareolar tissue in transgender males, which occurred after mastectomy (201, 202).

Women with primary hypogonadism (Turner syndrome) treated with estrogen replacement exhibited a significantly decreased incidence of breast cancer as compared with national standardized incidence ratios (203, 204). These studies suggest that estrogen therapy does not increase the risk of breast cancer in the short term (<20 to 30 years). We need long-term studies to determine the actual risk, as well as the role of screening mammograms. Regular examinations and gynecologic advice should determine monitoring for breast cancer.

Prostate cancer is very rare before the age of 40, especially with androgen deprivation therapy (205). Childhood or pubertal castration results in regression of the prostate and adult castration reverses benign prostate hypertrophy (206). Although van Kesteren et al. (207) reported that estrogen therapy does not induce hypertrophy or premalignant changes in the prostates of transgender females, studies have reported cases of benign prostatic hyperplasia in transgender females treated with estrogens for 20 to 25 years (208, 209). Studies have also reported a few cases of prostate carcinoma in transgender females (210–214).

Transgender females may feel uncomfortable scheduling regular prostate examinations. Gynecologists are not trained to screen for prostate cancer or to monitor prostate growth. Thus, it may be reasonable for transgender females who transitioned after age 20 years to have annual screening digital rectal examinations after age 50 years and prostate-specific antigen tests consistent with U.S. Preventive Services Task Force Guidelines (215).

4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

Evidence

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Although aromatization of testosterone to estradiol in transgender males has been suggested as a risk factor for endometrial cancer (216), no cases have been reported. When transgender males undergo hysterectomy, the uterus is small and there is endometrial atrophy (217, 218). Studies have reported cases of ovarian cancer (219, 220). Although there is limited evidence for increased risk of reproductive tract cancers in transgender males, health care providers should determine the medical necessity of a laparoscopic total hysterectomy as part of a genderaffirming surgery to prevent reproductive tract cancer (221).

Values

Given the discomfort that transgender males experience accessing gynecologic care, our recommendation for the medical necessity of total hysterectomy and oophorectomy places a high value on eliminating the risks of female reproductive tract disease and cancer and a lower value on avoiding the risks of these surgical procedures (related to the surgery and to the potential undesirable health consequences of oophorectomy) and their associated costs.

Remarks

The sexual orientation and type of sexual practices will determine the need and types of gynecologic care required following transition. Additionally, in certain countries, the approval required to change the sex in a birth certificate for transgender males may be dependent on having a complete hysterectomy. Clinicians should help patients research nonmedical administrative criteria and Case: 24-108 Document: 2-3 Page: 106 Filed: 01/25/2024

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provide counseling. If individuals decide not to undergo hysterectomy, screening for cervical cancer is the same as all other females.

5.0 Surgery for Sex Reassignment and Gender Confirmation

For many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender role. The type of surgery falls into two main categories: (1) those that directly affect fertility and (2) those that do not. Those that change fertility (previously called sex reassignment surgery) include genital surgery to remove the penis and gonads in the male and removal of the uterus and gonads in the female. The surgeries that effect fertility are often governed by the legal system of the state or country in which they are performed. Other gender-conforming surgeries that do not directly affect fertility are not so tightly governed.

Gender-affirming surgical techniques have improved markedly during the past 10 years. Reconstructive genital surgery that preserves neurologic sensation is now the standard. The satisfaction rate with surgical reassignment of sex is now very high (187). Additionally, the mental health of the individual seems to be improved by participating in a treatment program that defines a pathway of gender-affirming treatment that includes hormones and surgery (130, 144) (Table 16).

Surgery that affects fertility is irreversible. The World Professional Association for Transgender Health Standards of Care (222) emphasizes that the "threshold of 18 should not be seen as an indication in itself for active intervention." If the social transition has not been satisfactory, if the person is not satisfied with or is ambivalent about the effects of sex hormone treatment, or if the person is ambivalent about surgery then the individual should not be referred for surgery (223, 224).

Gender-affirming genital surgeries for transgender females that affect fertility include gonadectomy, penectomy, and creation of a neovagina (225, 226). Surgeons often invert the skin of the penis to form the wall of the vagina, and several literatures reviews have

reported on outcomes (227). Sometimes there is inadequate tissue to form a full neovagina, so clinicians have revisited using intestine and found it to be successful (87, 228, 229). Some newer vaginoplasty techniques may involve autologuous oral epithelial cells (230, 231).

The scrotum becomes the labia majora. Surgeons use reconstructive surgery to fashion the clitoris and its hood, preserving the neurovascular bundle at the tip of the penis as the neurosensory supply to the clitoris. Some surgeons are also creating a sensate pedicled-spot adding a G spot to the neovagina to increase sensation (232). Most recently, plastic surgeons have developed techniques to fashion labia minora. To further complete the feminization, uterine transplants have been proposed and even attempted (233).

Neovaginal prolapse, rectovaginal fistula, delayed healing, vaginal stenosis, and other complications do sometimes occur (234, 235). Clinicians should strongly remind the transgender person to use their dilators to maintain the depth and width of the vagina throughout the postoperative period. Genital sexual responsivity and other aspects of sexual function are usually preserved following genital gender-affirming surgery (236, 237).

Ancillary surgeries for more feminine or masculine appearance are not within the scope of this guideline. Voice therapy by a speech language pathologist is available to transform speech patterns to the affirmed gender (148). Spontaneous voice deepening occurs during testosterone treatment of transgender males (152, 238). No studies have compared the effectiveness of speech therapy, laryngeal surgery, or combined treatment.

Breast surgery is a good example of gender-confirming surgery that does not affect fertility. In all females, breast size exhibits a very broad spectrum. For transgender females to make the best informed decision, clinicians should delay breast augmentation surgery until the patient has completed at least 2 years of estrogen therapy, because the breasts continue to grow during that time (141, 155).

Another major procedure is the removal of facial and masculine-appearing body hair using either electrolysis or

Table 16. Criteria for Gender-Affirming Surgery, Which Affects Fertility

- 1. Persistent, well-documented gender dysphoria
- 2. Legal age of majority in the given country
- 3. Having continuously and responsibly used gender-affirming hormones for 12 mo (if there is no medical contraindication to receiving such therapy)
- 4. Successful continuous full-time living in the new gender role for 12 mo
- 5. If significant medical or mental health concerns are present, they must be well controlled
- 6. Demonstrable knowledge of all practical aspects of surgery (e.g., cost, required lengths of hospitalizations, likely complications, postsurgical rehabilitation)

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laser treatments. Other feminizing surgeries, such as that to feminize the face, are now becoming more popular (239-241).

In transgender males, clinicians usually delay gender-affirming genital surgeries until after a few years of androgen therapy. Those surgeries that affect fertility in this group include oophorectomy, vaginectomy, and complete hysterectomy. Surgeons can safely perform them vaginally with laparoscopy. These are sometimes done in conjunction with the creation of a neopenis. The cosmetic appearance of a neopenis is now very good, but the surgery is multistage and very expensive (242, 243). Radial forearm flap seems to be the most satisfactory procedure (228, 244). Other flaps also exist (245). Surgeons can make neopenile erections possible by reinervation of the flap and subsequent contraction of the muscle, leading to stiffening of the neopenis (246, 247), but results are inconsistent (248). Surgeons can also stiffen the penis by imbedding some mechanical device (e.g., a rod or some inflatable apparatus) (249, 250). Because of these limitations, the creation of a neopenis has often been less than satisfactory. Recently, penis transplants are being proposed (233).

In fact, most transgender males do not have any external genital surgery because of the lack of access, high cost, and significant potential complications. Some choose a metaoidioplasty that brings forward the clitoris, thereby allowing them to void in a standing position without wetting themselves (251, 252). Surgeons can create the scrotum from the labia majora with good cosmetic effect and can implant testicular prostheses (253).

The most important masculinizing surgery for the transgender male is mastectomy, and it does not affect fertility. Breast size only partially regresses with androgen therapy (155). In adults, discussions about mastectomy usually take place after androgen therapy has started. Because some transgender male adolescents present after significant breast development has occurred, they may also consider mastectomy 2 years after they begin androgen therapy and before age 18 years. Clinicians should individualize treatment based on the physical and mental health status of the individual. There are now newer approaches to mastectomy with better outcomes (254, 255). These often involve chest contouring (256). Mastectomy is often necessary for living comfortably in the new gender (256).

5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically

- necessary and would benefit the patient's overall health and/or well-being. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$
- 5.2. We advise that clinicians approve genital genderaffirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormonetreated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 1⊕000)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. $(2 \mid \oplus \oplus \bigcirc\bigcirc)$.
- 5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. $(2 \mid \oplus \bigcirc \bigcirc)$

Evidence

Owing to the lack of controlled studies, incomplete follow-up, and lack of valid assessment measures, evaluating various surgical approaches and techniques is difficult. However, one systematic review including a large numbers of studies reported satisfactory cosmetic and functional results for vaginoplasty/neovagina construction (257). For transgender males, the outcomes are less certain. However, the problems are now better understood (258). Several postoperative studies report significant long-term psychological and psychiatric pathology (259–261). One study showed satisfaction with breasts, genitals, and femininity increased significantly and showed the importance of surgical treatment as a key therapeutic option for transgender females (262). Another analysis demonstrated that, despite the young average age at death following surgery and the relatively larger number of individuals with somatic morbidity, the study does not allow for determination of

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causal relationships between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality (263). Reversal surgery in regretful male-to-female transsexuals after sexual reassignment surgery represents a complex, multistage procedure with satisfactory outcomes. Further insight into the characteristics of persons who regret their decision postoperatively would facilitate better future selection of applicants eligible for sexual reassignment surgery. We need more studies with appropriate controls that examine long-term quality of life, psychosocial outcomes, and psychiatric outcomes to determine the long-term benefits of surgical treatment.

When a transgender individual decides to have genderaffirming surgery, both the hormone prescribing clinician and the MHP must certify that the patient satisfies criteria for gender-affirming surgery (Table 16).

There is some concern that estrogen therapy may cause an increased risk for venous thrombosis during or following surgery (176). For this reason, the surgeon and the hormone-prescribing clinician should collaborate in making a decision about the use of hormones before and following surgery. One study suggests that preoperative factors (such as compliance) are less important for patient satisfaction than are the physical postoperative results (56). However, other studies and clinical experience dictate that individuals who do not follow medical instructions and do not work with their physicians toward a common goal do not achieve treatment goals (264) and experience higher rates of postoperative infections and other complications (265, 266). It is also important that the person requesting surgery feels comfortable with the anatomical changes that have occurred during hormone therapy. Dissatisfaction with social and physical outcomes during the hormone transition may be a contraindication to surgery (223).

An endocrinologist or experienced medical provider should monitor transgender individuals after surgery. Those who undergo gonadectomy will require hormone replacement therapy, surveillance, or both to prevent adverse effects of chronic hormone deficiency.

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Correspondence and Reprint Requests: The Endocrine Society, 2055 L Street NW, Suite 600, Washington, DC 20036. E-mail: publications@endocrine.org; Phone: 202971-3636.

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Guidelines for Psychological Practice With Transgender and Gender Nonconforming People

American Psychological Association

Transgender and gender nonconforming¹ (TGNC) people are those who have a gender identity that is not fully aligned with their sex assigned at birth. The existence of TGNC people has been documented in a range of historical cultures (Coleman, Colgan, & Gooren, 1992; Feinberg, 1996; Miller & Nichols, 2012; Schmidt, 2003). Current population estimates of TGNC people have ranged from 0.17 to 1,333 per 100,000 (Meier & Labuski, 2013). The Massachusetts Behavioral Risk Factor Surveillance Survey found 0.5% of the adult population aged 18 to 64 years identified as TGNC between 2009 and 2011 (Conron, Scott, Stowell, & Landers, 2012). However, population estimates likely underreport the true number of TGNC people, given difficulties in collecting comprehensive demographic information about this group (Meier & Labuski, 2013). Within the last two decades, there has been a significant increase in research about TGNC people. This increase in knowledge, informed by the TGNC community, has resulted in the development of progressively more trans-affirmative practice across the multiple health disciplines involved in the care of TGNC people (Bockting, Knudson, & Goldberg, 2006; Coleman et al., 2012). Research has documented the extensive experiences of stigma and discrimination reported by TGNC people (Grant et al., 2011) and the mental health consequences of these experiences across the life span (Bockting, Miner, Swinburne Romine, Hamilton, & Coleman, 2013), including increased rates of depression (Fredriksen-Goldsen et al., 2014) and suicidality (Clements-Nolle, Marx, & Katz, 2006). TGNC people's lack of access to trans-affirmative mental and physical health care is a common barrier (Fredriksen-Goldsen et al., 2014; Garofalo, Deleon, Osmer, Doll, & Harper, 2006; Grossman & D'Augelli, 2006), with TGNC people sometimes being denied care because of their gender identity (Xavier et al., 2012).

In 2009, the American Psychological Association (APA) Task Force on Gender Identity and Gender Variance (TFGIGV) survey found that less than 30% of psychologist and graduate student participants reported familiarity with issues that TGNC people experience (APA TFGIGV, 2009). Psychologists and other mental health professionals who have limited training and experience in TGNC-affirmative care may cause harm to TGNC people (Mikalson, Pardo, & Green, 2012; Xavier et al., 2012). The significant level of societal stigma and discrimination that TGNC people face, the associated mental health consequences, and psychologists' lack of familiarity with trans-affirmative care led the APA Task Force to recommend that psycho-

logical practice guidelines be developed to help psychologists maximize the effectiveness of services offered and avoid harm when working with TGNC people and their families.

Purpose

The purpose of the Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (hereafter Guidelines) is to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people. Trans-affirmative practice is the provision

The American Psychological Association's (APA's) Task Force on Guidelines for Psychological Practice with Transgender and Gender Nonconforming People developed these guidelines. lore m. dickey, Louisiana Tech University, and Anneliese A. Singh, The University of Georgia, served as chairs of the Task Force. The members of the Task Force included Walter O. Bockting, Columbia University; Sand Chang, Independent Practice; Kelly Ducheny, Howard Brown Health Center; Laura Edwards-Leeper, Pacific University; Randall D. Ehrbar, Whitman Walker Health Center; Max Fuentes Fuhrmann, Independent Practice; Michael L. Hendricks, Washington Psychological Center, P.C.; and Ellen Magalhaes, Center for Psychological Studies at Nova Southeastern University and California School of Professional Psychology at Alliant International University.

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This document will expire as APA policy in 2022. After this date, users should contact the APA Public Interest Directorate to determine whether the guidelines in this document remain in effect as APA policy.

Correspondence concerning this article should be addressed to the Public Interest Directorate, American Psychological Association, 750 First Street, NE, Washington, DC 20002.

¹ For the purposes of these guidelines, we use the term *transgender* and gender nonconforming (TGNC). We intend for the term to be as broadly inclusive as possible, and recognize that some TGNC people do not ascribe to these terms. Readers are referred to Appendix A for a listing of terms that include various TGNC identity labels.

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of care that is respectful, aware, and supportive of the identities and life experiences of TGNC people (Korell & Lorah, 2007). The *Guidelines* are an introductory resource for psychologists who will encounter TGNC people in their practice, but can also be useful for psychologists with expertise in this area of practice to improve the care already offered to TGNC people. The *Guidelines* include a set of definitions for readers who may be less familiar with language used when discussing gender identity and TGNC populations (see Appendix A). Distinct from TGNC, the term "cisgender" is used to refer to people whose sex assigned at birth is aligned with their gender identity (E. R. Green, 2006; Serano, 2006).

Given the added complexity of working with TGNC and gender-questioning youth² and the limitations of the available research, the Guidelines focus primarily, though not exclusively, on TGNC adults. Future revisions of the Guidelines will deepen a focus on TGNC and genderquestioning children and adolescents. The Guidelines address the strengths of TGNC people, the challenges they face, ethical and legal issues, life span considerations, research, education, training, and health care. Because issues of gender identity are often conflated with issues of gender expression or sexual orientation, psychological practice with the TGNC population warrants the acquisition of specific knowledge about concerns unique to TGNC people that are not addressed by other practice guidelines (APA, 2012). It is important to note that these Guidelines are not intended to address some of the conflicts that cisgender people may experience due to societal expectations regarding gender roles (Butler, 1990), nor are they intended to address intersex people (Dreger, 1999; Preves, 2003).

Documentation of Need

In 2005, the APA Council of Representatives authorized the creation of the Task Force on Gender Identity and Gender Variance (TFGIGV), charging the Task Force to review APA policies related to TGNC people and to offer recommendations for APA to best meet the needs of TGNC people (APA TFGIGV, 2009). In 2009, the APA Council of Representatives adopted the Resolution on Transgender, Gender Identity, & Gender Expression Non-Discrimination, which calls upon psychologists in their professional roles to provide appropriate, nondiscriminatory treatment; encourages psychologists to take a leadership role in working against discrimination; supports the provision of adequate and necessary mental and medical health care; recognizes the efficacy, benefit, and medical necessity of gender transition; supports access to appropriate treatment in institutional settings; and supports the creation of educational resources for all psychologists (Anton, 2009). In 2009, in an extensive report on the current state of psychological practice with TGNC people, the TFGIGV determined that there was sufficient knowledge and expertise in the field to warrant the development of practice guidelines for TGNC populations (APA TFGIGV, 2009). The report identified that TGNC people constituted a population with

unique needs and that the creation of practice guidelines would be a valuable resource for the field (APA TFGIGV, 2009). Psychologists' relative lack of knowledge about TGNC people and trans-affirmative care, the level of societal stigma and discrimination that TGNC people face, and the significant mental health consequences that TGNC people experience as a result offer a compelling need for psychological practice guidelines for this population.

Users

The intended audience for these *Guidelines* includes psychologists who provide clinical care, conduct research, or provide education or training. Given that gender identity issues can arise at any stage in a TGNC person's life (Lev, 2004), clinicians can encounter a TGNC person in practice or have a client's presenting problem evolve into an issue related to gender identity and gender expression. Researchers, educators, and trainers will benefit from use of these *Guidelines* to inform their work, even when not specifically focused on TGNC populations. Psychologists who focus on TGNC populations in their clinical practice, research, or educational and training activities will also benefit from the use of these *Guidelines*.

Distinction Between Standards and Guidelines

When using these *Guidelines*, psychologists should be aware that APA has made an important distinction between *standards* and *guidelines* (Reed, McLaughlin, & Newman, 2002). Standards are mandates to which all psychologists must adhere (e.g., the *Ethical Principles of Psychologists and Code of Conduct*; APA, 2010), whereas guidelines are aspirational. Psychologists are encouraged to use these *Guidelines* in tandem with the *Ethical Principles of Psychologists and Code of Conduct*, and should be aware that state and federal laws may override these *Guidelines* (APA, 2010).

In addition, these *Guidelines* refer to psychological practice (e.g., clinical work, consultation, education, research, and training) rather than treatment. Practice guidelines are practitioner-focused and provide guidance for professionals regarding "conduct and the issues to be considered in particular areas of clinical practice" (Reed et al., 2002, p. 1044). Treatment guidelines are client-focused and address intervention-specific recommendations for a clinical population or condition (Reed et al., 2002). The current *Guidelines* are intended to complement treatment guidelines for TGNC people seeking mental health services, such as those set forth by the World Professional Association for Transgender Health Standards of Care (Coleman et al., 2012) and the Endocrine Society (Hembree et al., 2009).

 $^{^2}$ For the purposes of these guidelines, "youth" refers to both children and adolescents under the age of 18.

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Compatibility

These Guidelines are consistent with the APA Ethical Principles of Psychologists and Code of Conduct (APA, 2010), the Standards of Accreditation for Health Service Psychology (APA, 2015), the APA TFGIGV (2009) report, and the APA Council of Representatives Resolution on Transgender, Gender Identity, & Gender Expression Non-Discrimination (Anton, 2009).

Practice Guidelines Development Process

To address one of the recommendations of the APA TF-GIGV (2009), the APA Committee on Sexual Orientation and Gender Diversity (CSOGD; then the Committee on Lesbian, Gay, Bisexual, and Transgender Concerns) and Division 44 (the Society for the Psychological Study of Lesbian, Gay, Bisexual and Transgender Issues) initiated a joint Task Force on Psychological Practice Guidelines with Transgender and Gender Nonconforming People in 2011. Task Force members were selected through an application and review process conducted by the leadership of CSOGD and Division 44. The Task Force included 10 members who had substantial psychological practice expertise with TGNC people. Of the 10 task force members, five individuals identified as TGNC with a range of gender identities and five identified as cisgender. In terms of race/ethnicity, six of the task force members identified as White and four identified as people of color (one Indian American, one Chinese American, one Latina American, and one mixed race).

The Task Force conducted a comprehensive review of the extant scholarship, identified content most pertinent to the practice of psychology with TGNC people, and evaluated the level of evidence to support guidance within each guideline. To ensure the accuracy and comprehensiveness of these Guidelines, Task Force members met with TGNC community members and groups and consulted with subject matter experts within and outside of psychology. When the Task Force discovered a lack of professional consensus, every effort was made to include divergent opinions in the field relevant to that issue. When this occurred, the Task Force described the various approaches documented in the literature. Additionally, these Guidelines were informed by comments received at multiple presentations held at professional conferences and comments obtained through two cycles of open public comment on earlier Guideline drafts.

This document contains 16 guidelines for TGNC psychological practice. Each guideline includes a Rationale section, which reviews relevant scholarship supporting the need for the guideline, and an Application section, which describes how the particular guideline may be applied in psychological practice. The *Guidelines* are organized into five clusters: (a) foundational knowledge and awareness; (b) stigma, discrimination, and barriers to care; (c) life span development; (d) assessment, therapy, and intervention; and (e) research, education, and training.

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APA Office on Lesbian, Gay, Bisexual, and Transgender (LGBT) Concerns; a grant from the Committee on Division/APA Relations (CODAPAR); and donations from Randall Ehrbar and Pamela St. Amand. Some members of the Task Force have received compensation through presentations (e.g., honoraria) or royalties (e.g., book contracts) based in part on information contained in these *Guidelines*.

Selection of Evidence

Although the number of publications on the topic of TGNC-affirmative practice has been increasing, this is still an emerging area of scholarly literature and research. When possible, the Task Force relied on peer-reviewed publications, but books, chapters, and reports that do not typically receive a high level of peer review have also been cited when appropriate. These sources are from a diverse range of fields addressing mental health, including psychology, counseling, social work, and psychiatry. Some studies of TGNC people utilize small sample sizes, which limits the generalizability of results. Few studies of TGNC people utilize probability samples or randomized control groups (e.g., Conron et al., 2012; Dhejne et al., 2011). As a result, the Task Force relied primarily on studies using convenience samples, which limits the generalizability of results to the population as a whole, but can be adequate for describing issues and situations that arise within the pop-

Foundational Knowledge and Awareness

Guideline 1. Psychologists understand that gender is a nonbinary construct that allows for a range of gender identities and that a person's gender identity may not align with sex assigned at birth.

Rationale. Gender identity is defined as a person's deeply felt, inherent sense of being a girl, woman, or female; a boy, a man, or male; a blend of male or female; or an alternative gender (Bethea & McCollum, 2013; Institute of Medicine [IOM], 2011). In many cultures and religious traditions, gender has been perceived as a binary construct, with mutually exclusive categories of male or female, boy or girl, man or woman (Benjamin, 1966; Mollenkott, 2001; Tanis, 2003). These mutually exclusive categories include an assumption that gender identity is always in alignment with sex assigned at birth (Bethea & McCollum, 2013). For TGNC people, gender identity differs from sex assigned at birth to varying degrees, and may be experienced and expressed outside of the gender binary (Harrison, Grant, & Herman, 2012; Kuper, Nussbaum, & Mustanski, 2012).

Gender as a nonbinary construct has been described and studied for decades (Benjamin, 1966; Herdt, 1994; Kulick, 1998). There is historical evidence of recognition, societal acceptance, and sometimes reverence of diversity in gender identity and gender expression in several different cultures (Coleman et al., 1992; Feinberg, 1996; Miller

& Nichols, 2012; Schmidt, 2003). Many cultures in which gender nonconforming persons and groups were visible were diminished by westernization, colonialism, and systemic inequity (Nanda, 1999). In the 20th century, TGNC expression became medicalized (Hirschfeld, 1910/1991), and medical interventions to treat discordance between a person's sex assigned at birth, secondary sex characteristics, and gender identity became available (Meyerowitz, 2002).

As early as the 1950s, research found variability in how an individual described their³ gender, with some participants reporting a gender identity different from the culturally defined, mutually exclusive categories of "man" or "woman" (Benjamin, 1966). In several recent large online studies of the TGNC population in the United States, 30% to 40% of participants identified their gender identity as other than man or woman (Harrison et al., 2012; Kuper et al., 2012). Although some studies have cultivated a broader understanding of gender (Conron, Scout, & Austin, 2008), the majority of research has required a forced choice between man and woman, thus failing to represent or depict those with different gender identities (IOM, 2011). Research over the last two decades has demonstrated the existence of a wide spectrum of gender identity and gender expression (Bockting, 2008; Harrison et al., 2012; Kuper et al., 2012), which includes people who identify as either man or woman, neither man nor woman, a blend of man and woman, or a unique gender identity. A person's identification as TGNC can be healthy and self-affirming, and is not inherently pathological (Coleman et al., 2012). However, people may experience distress associated with discordance between their gender identity and their body or sex assigned at birth, as well as societal stigma and discrimination (Coleman et al., 2012).

Between the late 1960s and the early 1990s, health care to alleviate gender dysphoria largely reinforced a binary conceptualization of gender (APA TFGIGV, 2009; Bolin, 1994; Hastings, 1974). At that time, it was considered an ideal outcome for TGNC people to conform to an identity that aligned with either sex assigned at birth or, if not possible, with the "opposite" sex, with a heavy emphasis on blending into the cisgender population or "passing" (APA TFGIGV, 2009; Bolin, 1994; Hastings, 1974). Variance from these options could raise concern for health care providers about a TGNC person's ability to transition successfully. These concerns could act as a barrier to accessing surgery or hormone therapy because medical and mental health care provider endorsement was required before surgery or hormones could be accessed (Berger et al., 1979). Largely because of self-advocacy of TGNC individuals and communities in the 1990s, combined with advances in research and models of trans-affirmative care, there is greater recognition and acknowledgment of a spectrum of gender diversity and corresponding individualized, TGNCspecific health care (Bockting et al., 2006; Coleman et al.,

Application. A nonbinary understanding of gender is fundamental to the provision of affirmative care for TGNC people. Psychologists are encouraged to adapt or

modify their understanding of gender, broadening the range of variation viewed as healthy and normative. By understanding the spectrum of gender identities and gender expressions that exist, and that a person's gender identity may not be in full alignment with sex assigned at birth, psychologists can increase their capacity to assist TGNC people, their families, and their communities (Lev, 2004). Respecting and supporting TGNC people in authentically articulating their gender identity and gender expression, as well as their lived experience, can improve TGNC people's health, well-being, and quality of life (Witten, 2003).

Some TGNC people may have limited access to visible, positive TGNC role models. As a result, many TGNC people are isolated and must cope with the stigma of gender nonconformity without guidance or support, worsening the negative effect of stigma on mental health (Fredriksen-Goldsen et al., 2014; Singh, Hays, & Watson, 2011). Psychologists may assist TGNC people in challenging gender norms and stereotypes, and in exploring their unique gender identity and gender expression. TGNC people, partners, families, friends, and communities can benefit from education about the healthy variation of gender identity and gender expression, and the incorrect assumption that gender identity automatically aligns with sex assigned at birth.

Psychologists may model an acceptance of ambiguity as TGNC people develop and explore aspects of their gender, especially in childhood and adolescence. A non-judgmental stance toward gender nonconformity can help to counteract the pervasive stigma faced by many TGNC people and provide a safe environment to explore gender identity and make informed decisions about gender expression.

Guideline 2. Psychologists understand that gender identity and sexual orientation are distinct but interrelated constructs.

Rationale. The constructs of gender identity and sexual orientation are theoretically and clinically distinct, even though professionals and nonprofessionals frequently conflate them. Although some research suggests a potential link in the development of gender identity and sexual orientation, the mechanisms of such a relationship are unknown (Adelson & American Academy of Child and Adolescent Psychiatry [AACAP] Committee on Quality Issues [CQI], 2012; APA TFGIGV, 2009; A. H. Devor, 2004; Drescher & Byne, 2013). Sexual orientation is defined as a person's sexual and/or emotional attraction to another person (Shively & De Cecco, 1977), compared with gender identity, which is defined by a person's felt, inherent sense of gender. For most people, gender identity develops earlier than sexual orientation. Gender identity is often established in young toddlerhood (Adelson & AA-CAP CQI, 2012; Kohlberg, 1966), compared with aware-

³ The third person plural pronouns "they," "them," and "their" in some instances function in these guidelines as third-person singular pronouns to model a common technique used to avoid the use of gendered pronouns when speaking to or about TGNC people.

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ness of same-sex attraction, which often emerges in early adolescence (Adelson & AACAP CQI, 2012; D'Augelli & Hershberger, 1993; Herdt & Boxer, 1993; Ryan, 2009; Savin-Williams & Diamond, 2000). Although gender identity is usually established in childhood, individuals may become aware that their gender identity is not in full alignment with sex assigned at birth in childhood, adolescence, or adulthood. The developmental pathway of gender identity typically includes a progression through multiple stages of awareness, exploration, expression, and identity integration (Bockting & Coleman, 2007; A. H. Devor, 2004; Vanderburgh, 2007). Similarly, a person's sexual orientation may progress through multiple stages of awareness, exploration, and identity through adolescence and into adulthood (Bilodeau & Renn, 2005). Just as some people experience their sexual orientation as being fluid or variable (L. M. Diamond, 2013), some people also experience their gender identity as fluid (Lev, 2004).

The experience of questioning one's gender can create significant confusion for some TGNC people, especially for those who are unfamiliar with the range of gender identities that exist. To explain any discordance they may experience between their sex assigned at birth, related societal expectations, patterns of sexual and romantic attraction, and/or gender role nonconformity and gender identity, some TGNC people may assume that they must be gay, lesbian, bisexual, or queer (Bockting, Benner, & Coleman, 2009). Focusing solely on sexual orientation as the cause for discordance may obscure awareness of a TGNC identity. It can be very important to include sexual orientation and gender identity in the process of identity exploration as well as in the associated decisions about which options will work best for any particular person. In addition, many TGNC adults have disguised or rejected their experience of gender incongruence in childhood or adolescence to conform to societal expectations and minimize their fear of difference (Bockting & Coleman, 2007; Byne et al., 2012).

Because gender and patterns of attraction are used to identify a person's sexual orientation, the articulation of sexual orientation is made more complex when sex assigned at birth is not aligned with gender identity. A person's sexual orientation identity cannot be determined by simply examining external appearance or behavior, but must incorporate a person's identity and self-identification (Broido, 2000).

Application. Psychologists may assist people in differentiating gender identity and sexual orientation. As clients become aware of previously hidden or constrained aspects of their gender identity or sexuality, psychologists may provide acceptance, support, and understanding without making assumptions or imposing a specific sexual orientation or gender identity outcome (APA TFGIGV, 2009). Because of their roles in assessment, treatment, and prevention, psychologists are in a unique position to help TGNC people better understand and integrate the various aspects of their identities. Psychologists may assist TGNC people by introducing and normalizing differences in gender identity and expression. As a TGNC person finds a

comfortable way to actualize and express their gender identity, psychologists may notice that previously incongruent aspects of their sexual orientation may become more salient, better integrated, or increasingly egosyntonic (Bockting et al., 2009; H. Devor, 1993; Schleifer, 2006). This process may allow TGNC people the comfort and opportunity to explore attractions or aspects of their sexual orientation that previously had been repressed, hidden, or in conflict with their identity. TGNC people may experience a renewed exploration of their sexual orientation, a widened spectrum of attraction, or a shift in how they identify their sexual orientation in the context of a developing TGNC identity (Coleman, Bockting, & Gooren, 1993; Meier, Pardo, Labuski, & Babcock, 2013; Samons, 2008).

Psychologists may need to provide TGNC people with information about TGNC identities, offering language to describe the discordance and confusion TGNC people may be experiencing. To facilitate TGNC people's learning, psychologists may introduce some of the narratives written by TGNC people that reflect a range of outcomes and developmental processes in exploring and affirming gender identity (e.g., Bornstein & Bergman, 2010; Boylan, 2013; J. Green, 2004; Krieger, 2011; Lawrence, 2014). These resources may potentially aid TGNC people in distinguishing between issues of sexual orientation and gender identity and in locating themselves on the gender spectrum. Psychologists may also educate families and broader community systems (e.g., schools, medical systems) to better understand how gender identity and sexual orientation are different but related; this may be particularly useful when working with youth (Singh & Burnes, 2009; Whitman, 2013). Because gender identity and sexual orientation are often conflated, even by professionals, psychologists are encouraged to carefully examine resources that claim to provide affirmative services for lesbian, gay, bisexual, transgender, and queer (LGBTQ) people, and to confirm which are knowledgeable about and inclusive of the needs of TGNC people before offering referrals or recommendations to TGNC people and their families.

Guideline 3. Psychologists seek to understand how gender identity intersects with the other cultural identities of TGNC people.

Rationale. Gender identity and gender expression may have profound intersections with other aspects of identity (Collins, 2000; Warner, 2008). These aspects may include, but are not limited to, race/ethnicity, age, education, socioeconomic status, immigration status, occupation, disability status, HIV status, sexual orientation, relational status, and religion and/or spiritual affiliation. Whereas some of these aspects of identity may afford privilege, others may create stigma and hinder empowerment (Burnes & Chen, 2012; K. M. de Vries, 2015). In addition, TGNC people who transition may not be prepared for changes in privilege or societal treatment based on gender identity and gender expression. To illustrate, an African American trans man may gain male privilege, but may face racism and

societal stigma particular to African American men. An Asian American/Pacific Islander trans woman may experience the benefit of being perceived as a cisgender woman, but may also experience sexism, misogyny, and objectification particular to Asian American/Pacific Islander cisgender women.

The intersection of multiple identities within TGNC people's lives is complex and may obstruct or facilitate access to necessary support (A. Daley, Solomon, Newman, & Mishna, 2008). TGNC people with less privilege and/or multiple oppressed identities may experience greater stress and restricted access to resources. They may also develop resilience and strength in coping with disadvantages, or may locate community-based resources available to specific groups (e.g., for people living with HIV; Singh et al., 2011). Gender identity affirmation may conflict with religious beliefs or traditions (Bockting & Cesaretti, 2001). Finding an affirmative expression of their religious and spiritual beliefs and traditions, including positive relationships with religious leaders, can be an important resource for TGNC people (Glaser, 2008; Porter, Ronneberg, & Witten, 2013; Xavier, 2000).

Application. In practice, psychologists strive to recognize the salient multiple and intersecting identities of TGNC people that influence coping, discrimination, and resilience (Burnes & Chen, 2012). Improved rapport and therapeutic alliance are likely to develop when psychologists avoid overemphasizing gender identity and gender expression when not directly relevant to TGNC people's needs and concerns. Even when gender identity is the main focus of care, psychologists are encouraged to understand that a TGNC person's experience of gender may also be shaped by other important aspects of identity (e.g., age, race/ethnicity, sexual orientation), and that the salience of different aspects of identity may evolve as the person continues psychosocial development across the life span, regardless of whether they complete a social or medical transition.

At times, a TGNC person's intersection of identities may result in conflict, such as a person's struggle to integrate gender identity with religious and/or spiritual upbringing and beliefs (Kidd & Witten, 2008; Levy & Lo, 2013; Rodriguez & Follins, 2012). Psychologists may aid TGNC people in understanding and integrating identities that may be differently privileged within systems of power and systemic inequity (Burnes & Chen, 2012). Psychologists may also highlight and strengthen the development of TGNC people's competencies and resilience as they learn to manage the intersection of stigmatized identities (Singh, 2012).

Guideline 4. Psychologists are aware of how their attitudes about and knowledge of gender identity and gender expression may affect the quality of care they provide to TGNC people and their families.

Rationale. Psychologists, like other members of society, come to their personal understanding and acceptance of different aspects of human diversity through a

process of socialization. Psychologists' cultural biases, as well as the cultural differences between psychologists and their clients, have a clinical impact (Israel, Gorcheva, Burnes, & Walther, 2008; Vasquez, 2007). The assumptions, biases, and attitudes psychologists hold regarding TGNC people and gender identity and/or gender expression can affect the quality of services psychologists provide and their ability to develop an effective therapeutic alliance (Bess & Stabb, 2009; Rachlin, 2002). In addition, a lack of knowledge or training in providing affirmative care to TGNC people can limit a psychologist's effectiveness and perpetuate barriers to care (Bess & Stabb, 2009; Rachlin, 2002). Psychologists experienced with lesbian, gay, or bisexual (LGB) people may not be familiar with the unique needs of TGNC people (Israel, 2005; Israel et al., 2008). In community surveys, TGNC people have reported that many mental health care providers lack basic knowledge and skills relevant to care of TGNC people (Bradford, Xavier, Hendricks, Rives, & Honnold, 2007; Xavier, Bobbin, Singer, & Budd, 2005) and receive little training to prepare them to work with TGNC people (APA TFGIGV, 2009; Lurie, 2005). The National Transgender Discrimination Survey (Grant et al., 2011) reported that 50% of TGNC respondents shared that they had to educate their health care providers about TGNC care, 28% postponed seeking medical care due to antitrans bias, and 19% were refused care due to discrimination.

The APA ethics code (APA, 2010) specifies that psychologists practice in areas only within the boundaries of their competence (Standard 2.01), participate in proactive and consistent ways to enhance their competence (Standard 2.03), and base their work upon established scientific and professional knowledge (Standard 2.04). Competence in working with TGNC people can be developed through a range of activities, such as education, training, supervised experience, consultation, study, or professional experience.

Application. Psychologists may engage in practice with TGNC people in various ways; therefore, the depth and level of knowledge and competence required by a psychologist depends on the type and complexity of service offered to TGNC people. Services that psychologists provide to TGNC people require a basic understanding of the population and its needs, as well as the ability to respectfully interact in a trans-affirmative manner (L. Carroll, 2010).

APA emphasizes the use of evidence-based practice (APA Presidential Task Force on Evidence-Based Practice, 2006). Given how easily assumptions or stereotypes could influence treatment, evidence-based practice may be especially relevant to psychological practice with TGNC people. Until evidence-based practices are developed specifically for TGNC people, psychologists are encouraged to utilize existing evidence-based practices in the care they provide. APA also promotes collaboration with clients concerning clinical decisions, including issues related to costs, potential benefits, and the existing options and resources related to treatment (APA Presidential Task Force on Evidence-Based Practice, 2006). TGNC people could benefit from such collaboration and active engagement in decision

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making, given the historical disenfranchisement and disempowerment of TGNC people in health care.

In an effort to develop competence in working with TGNC people, psychologists are encouraged to examine their personal beliefs regarding gender and sexuality, gender stereotypes, and TGNC identities, in addition to identifying gaps in their own knowledge, understanding, and acceptance (American Counseling Association [ACA], 2010). This examination may include exploring one's own gender identity and gendered experiences related to privilege, power, or marginalization, as well as seeking consultation and training with psychologists who have expertise in working with TGNC people and communities.

Psychologists are further encouraged to develop competence in working with TGNC people and their families by seeking up-to-date basic knowledge and understanding of gender identity and expression, and learning how to interact with TGNC people and their families respectfully and without judgment. Competence in working with TGNC people may be achieved and maintained in formal and informal ways, ranging from exposure in the curriculum of training programs for future psychologists and continuing education at professional conferences, to affirmative involvement as allies in the TGNC community. Beyond acquiring general competence, psychologists who choose to specialize in working with TGNC people presenting with gender-identity-related concerns are strongly encouraged to obtain advanced training, consultation, and professional experience (ACA, 2010; Coleman et al., 2012).

Psychologists may gain knowledge about the TGNC community and become more familiar with the complex social issues that affect the lives of TGNC people through first-hand experiences (e.g., attending community meetings and conferences, reading narratives written by TGNC people). If psychologists have not yet developed competence in working with TGNC people, it is recommended that they refer TGNC people to other psychologists or providers who are knowledgeable and able to provide trans-affirmative care

Stigma, Discrimination, and Barriers to Care

Guideline 5. Psychologists recognize how stigma, prejudice, discrimination, and violence affect the health and well-being of TGNC people.

Rationale. Many TGNC people experience discrimination, ranging from subtle to severe, when accessing housing, health care, employment, education, public assistance, and other social services (Bazargan & Galvan, 2012; Bradford, Reisner, Honnold, & Xavier, 2013; Dispenza, Watson, Chung, & Brack, 2012; Grant et al., 2011). Discrimination can include assuming a person's assigned sex at birth is fully aligned with that person's gender identity, not using a person's preferred name or pronoun, asking TGNC people inappropriate questions about their bodies, or making the assumption that psychopathology exists given a specific gender identity or gender expression (Na-

dal, Rivera, & Corpus, 2010; Nadal, Skolnik, & Wong, 2012). Discrimination may also include refusing access to housing or employment or extreme acts of violence (e.g., sexual assault, murder). TGNC people who hold multiple marginalized identities are more vulnerable to discrimination and violence. TGNC women and people of color disproportionately experience severe forms of violence and discrimination, including police violence, and are less likely to receive help from law enforcement (Edelman, 2011; National Coalition of Anti-Violence Programs, 2011; Saffin, 2011).

TGNC people are at risk of experiencing antitrans prejudice and discrimination in educational settings. In a national representative sample of 7,898 LGBT youth in K-12 settings, 55.2% of participants reported verbal harassment, 22.7% reported physical harassment, and 11.4% reported physical assault based on their gender expression (Kosciw, Greytak, Palmer, & Boesen, 2014). In a national community survey of TGNC adults, 15% reported prematurely leaving educational settings ranging from kindergarten through college as a result of harassment (Grant et al., 2011). Many schools do not include gender identity and gender expression in their school nondiscrimination policies; this leaves TGNC youth without needed protections from bullying and aggression in schools (Singh & Jackson, 2012). TGNC youth in rural settings may be even more vulnerable to bullying and hostility in their school environments due to antitrans prejudice (Kosciw et al., 2014).

Inequities in educational settings and other forms of TGNC-related discrimination may contribute to the significant economic disparities TGNC people have reported. Grant and colleagues (2011) found that TGNC people were four times more likely to have a household income of less than \$10,000 compared with cisgender people, and almost half of a sample of TGNC older adults reported a household income at or below 200% of poverty (Fredriksen-Goldsen et al., 2014). TGNC people often face workplace discrimination both when seeking and maintaining employment (Brewster, Velez, Mennicke, & Tebbe, 2014; Dispenza et al., 2012; Mizock & Mueser, 2014). In a nonrepresentative national study of TGNC people, 90% reported having "directly experienced harassment or mistreatment at work and felt forced to take protective actions that negatively impacted their careers or their well-being, such as hiding who they were to avoid workplace repercussions" (Grant et al., 2011, p. 56). In addition, 78% of respondents reported experiencing some kind of direct mistreatment or discrimination at work (Grant et al., 2011). Employment discrimination may be related to stigma based on a TGNC person's appearance, discrepancies in identity documentation, or being unable to provide job references linked to that person's pretransition name or gender presentation (Bender-Baird, 2011).

Issues of employment discrimination and workplace harassment are particularly salient for TGNC military personnel and veterans. Currently, TGNC people cannot serve openly in the U.S. military. Military regulations cite "transsexualism" as a medical exclusion from service (Department of Defense, 2011; Elders & Steinman, 2014). When

enlisted, TGNC military personnel are faced with very difficult decisions related to coming out, transition, and seeking appropriate medical and mental health care, which may significantly impact or end their military careers. Not surprisingly, research documents very high rates of suicidal ideation and behavior among TGNC military and veteran populations (Blosnich et al., 2013; Matarazzo et al., 2014). Being open about their TGNC identity with health care providers can carry risk for TGNC military personnel (Out-Serve-Servicemembers Legal Defense Network, n.d.). Barriers to accessing health care noted by TGNC veterans include viewing the VA health care system as an extension of the military, perceiving the VA as an unwelcoming environment, and fearing providers' negative reactions to their identity (Sherman, Kauth, Shipherd, & Street, 2014; Shipherd, Mizock, Maguen, & Green, 2012). A recent study shows 28% of LGBT veterans perceived their VA as welcoming and one third as unwelcoming (Sherman et al., 2014). Multiple initiatives are underway throughout the VA system to improve the quality and sensitivity of services to LGBT veterans.

Given widespread workplace discrimination and possible dismissal following transition, TGNC people may engage in sex work or survival sex (e.g., trading sex for food), or sell drugs to generate income (Grant et al., 2011; Hwahng & Nuttbrock, 2007; Operario, Soma, & Underhill, 2008; Stanley, 2011). This increases the potential for negative interactions with the legal system, such as harassment by the police, bribery, extortion, and arrest (Edelman, 2011; Testa et al., 2012), as well as increased likelihood of mental health symptoms and greater health risks, such as higher incidence of sexually transmitted infections, including HIV (Nemoto, Operario, Keatley, & Villegas, 2004).

Incarcerated TGNC people report harassment, isolation, forced sex, and physical assault, both by prison personnel and other inmates (American Civil Liberties Union National Prison Project, 2005; Brotheim, 2013; C. Daley, 2005). In sex-segregated facilities, TGNC people may be subjected to involuntary solitary confinement (also called "administrative segregation"), which can lead to severe negative mental and physical health consequences and may block access to services (Gallagher, 2014; National Center for Transgender Equality, 2012). Another area of concern is for TGNC immigrants and refugees. TGNC people in detention centers may not be granted access to necessary care and experience significant rates of assault and violence in these facilities (Gruberg, 2013). TGNC people may seek asylum in the United States to escape danger as a direct result of lack of protections in their country of origin (APA Presidential Task Force on Immigration, 2012; Cerezo, Morales, Quintero, & Rothman, 2014; Morales, 2013).

TGNC people have difficulty accessing necessary health care (Fredriksen-Goldsen et al., 2014; Lambda Legal, 2012) and often feel unsafe sharing their gender identity or their experiences of antitrans prejudice and discrimination due to historical and current discrimination from health care providers (Grant et al., 2011; Lurie, 2005; Singh & McKleroy, 2011). Even when TGNC people have health insurance, plans may explicitly exclude coverage

related to gender transition (e.g., hormone therapy, surgery). TGNC people may also have difficulty accessing trans-affirmative primary health care if coverage for procedures is denied based on gender. For example, trans men may be excluded from necessary gynecological care based on the assumption that men do not need these services. These barriers often lead to a lack of preventive health care for TGNC people (Fredriksen-Goldsen et al., 2014; Lambda Legal, 2012). Although the landscape is beginning to change with the recent revision of Medicare policy (National Center for Transgender Equality, 2014) and changes to state laws (Transgender Law Center, n.d.), many TGNC people are still likely to have little to no access to TGNC-related health care as a result of the exclusions in their insurance.

Application. Awareness of and sensitivity to the effects of antitrans prejudice and discrimination can assist psychologists in assessing, treating, and advocating for their TGNC clients. When a TGNC person faces discrimination based on gender identity or gender expression, psychologists may facilitate emotional processing of these experiences and work with the person to identify supportive resources and possible courses of action. Specific needs of TGNC people might vary from developing self-advocacy strategies, to navigating public spaces, to seeking legal recourse for harassment and discrimination in social services and other systems. Additionally, TGNC people who have been traumatized by physical or emotional violence may need therapeutic support.

Psychologists may be able to assist TGNC people in accessing relevant social service systems. For example, psychologists may be able to assist in identifying health care providers and housing resources that are affirming and affordable, or locating affirming religious and spiritual communities (Glaser, 2008; Porter et al., 2013). Psychologists may also assist in furnishing documentation or official correspondence that affirms gender identity for the purpose of accessing appropriate public accommodations, such as bathroom use or housing (Lev, 2009; W. J. Meyer, 2009).

Additionally, psychologists may identify appropriate resources, information, and services to help TGNC people in addressing workplace discrimination, including strategies during a social and/or medical transition for identity disclosure at work. For those who are seeking employment, psychologists may help strategize about how and whether to share information about gender history. Psychologists may also work with employers to develop supportive policies for workplace gender transition or to develop training to help employees adjust to the transition of a coworker.

For TGNC military and veteran populations, psychologists may help to address the emotional impact of navigating TGNC identity development in the military system. Psychologists are encouraged to be aware that issues of confidentiality may be particularly sensitive with active duty or reserve status service members, as the consequences of being identified as TGNC may prevent the client's disclosure of gender identity in treatment.

In educational settings, psychologists may advocate for TGNC youth on a number of levels (APA & National

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Association of School Psychologists, 2014; Boulder Valley School District, 2012). Psychologists may consult with administrators, teachers, and school counselors to provide resources and trainings on antitrans prejudice and developing safer school environments for TGNC students (Singh & Burnes, 2009). Peer support from other TGNC people has been shown to buffer the negative effect of stigma on mental health (Bockting et al., 2013). As such, psychologists may consider and develop peer-based interventions to facilitate greater understanding and respectful treatment of TGNC youth by cisgender peers (Case & Meier, 2014). Psychologists may work with TGNC youth and their families to identify relevant resources, such as school policies that protect gender identity and gender expression (APA & National Association of School Psychologists, 2014; Gonzalez & McNulty, 2010), referrals to TGNC-affirmative organizations, and online resources, which may be especially helpful for TGNC youth in rural settings.

Guideline 6. Psychologists strive to recognize the influence of institutional barriers on the lives of TGNC people and to assist in developing TGNC-affirmative environments.

Rationale. Antitrans prejudice and the adherence of mainstream society to the gender binary adversely affect TGNC people within their families, schools, health care, legal systems, workplaces, religious traditions, and communities (American Civil Liberties Union National Prison Project, 2005; Bradford et al., 2013; Brewster et al., 2014; Levy & Lo, 2013; McGuire, Anderson, & Toomey, 2010). TGNC people face challenges accessing gender-inclusive restrooms, which may result in discomfort when being forced to use a men's or women's restroom (Transgender Law Center, 2005). In addition to the emotional distress the forced binary choice that public restrooms may create for some, TGNC people are frequently concerned with others' reactions to their presence in public restrooms, including potential discrimination, harassment, and violence (Herman, 2013).

Many TGNC people may be distrustful of care providers due to previous experiences of being pathologized (Benson, 2013). Experiences of discrimination and prejudice with health care providers may be complicated by power differentials within the therapeutic relationship that may greatly affect or complicate the care that TGNC people experience. TGNC people have routinely been asked to obtain an endorsement letter from a psychologist attesting to the stability of their gender identity as a prerequisite to access an endocrinologist, surgeon, or legal institution (e.g., driver's license bureau; Lev, 2009). The need for such required documentation from a psychologist may influence rapport, resulting in TGNC people fearing prejudicial treatment in which this documentation is withheld or delayed by the treating provider (Bouman et al., 2014). Whether a TGNC person has personally experienced interactions with providers as disempowering or has learned from community members to expect such a dynamic, psychologists are encouraged to be prepared for TGNC people to be very cautious when entering into a therapeutic relationship. When TGNC people feel validated and empowered within the environment in which a psychologist practices, the therapeutic relationship will benefit and the person may be more willing to explore their authentic selves and share uncertainties and ambiguities that are a common part of TGNC identity development.

Application. Because many TGNC people experience antitrans prejudice or discrimination, psychologists are encouraged to ensure that their work settings are welcoming and respectful of TGNC people, and to be mindful of what TGNC people may perceive as unwelcoming. To do so, psychologists may educate themselves about the many ways that cisgender privilege and antitrans prejudice may be expressed. Psychologists may also have specific conversations with TGNC people about their experiences of the mental health system and implement feedback to foster TGNC-affirmative environments. As a result, when TGNC people access various treatment settings and public spaces, they may experience less harm, disempowerment, or pathologization, and thus will be more likely to avail themselves of resources and support.

Psychologists are encouraged to be proactive in considering how overt or subtle cues in their workplaces and other environments may affect the comfort and safety of TGNC people. To increase the comfort of TGNC people, psychologists are encouraged to display TGNC-affirmative resources in waiting areas and to avoid the display of items that reflect antitrans attitudes (Lev, 2009). Psychologists are encouraged to examine how their language (e.g., use of incorrect pronouns and names) may reinforce the gender binary in overt or subtle and unintentional ways (Smith, Shin, & Officer, 2012). It may be helpful for psychologists to provide training for support staff on how to respectfully interact with TGNC people. A psychologist may consider making changes to paperwork, forms, or outreach materials to ensure that these materials are more inclusive of TGNC people (Spade, 2011b). For example, demographic questionnaires can communicate respect through the use of inclusive language and the inclusion of a range of gender identities. In addition, psychologists may also work within their institutions to advocate for restrooms that are inclusive and accessible for people of all gender identities and/or gender expressions.

When working with TGNC people in a variety of care and institutional settings (e.g., inpatient medical and psychiatric hospitals, substance abuse treatment settings, nursing homes, foster care, religious communities, military and VA health care settings, and prisons), psychologists may become liaisons and advocates for TGNC people's mental health needs and for respectful treatment that addresses their gender identity in an affirming manner. In playing this role, psychologists may find guidance and best practices that have been published for particular institutional contexts to be helpful (e.g., Department of Veterans Affairs, Veterans' Health Administration, 2013; Glezer, McNiel, & Binder, 2013; Merksamer, 2011).

Guideline 7: Psychologists understand the need to promote social change that reduces the negative effects of stigma on the health and well-being of TGNC people.

Rationale. The lack of public policy that addresses the needs of TGNC people creates significant hardships for them (Taylor, 2007). Although there have been major advances in legal protections for TGNC people in recent years (Buzuvis, 2013; Harvard Law Review Association, 2013), many TGNC people are still not afforded protections from discrimination on the basis of gender identity or expression (National LGBTQ Task Force, 2013; Taylor, 2007). For instance, in many states, TGNC people do not have employment or housing protections and may be fired or lose their housing based on their gender identity. Many policies that protect the rights of cisgender people, including LGB people, do not protect the rights of TGNC people (Currah, & Minter, 2000; Spade, 2011a).

TGNC people can experience challenges obtaining gender-affirming identity documentation (e.g., birth certificate, passport, social security card, driver's license). For TGNC people experiencing poverty or economic hardship, requirements for obtaining this documentation may be impossible to meet, in part due to the difficulty of securing employment without identity documentation that aligns with their gender identity and gender expression (Sheridan, 2009). Additionally, systemic barriers related to binary gender identification systems prevent some TGNC people from changing their documents, including those who are incarcerated, undocumented immigrants, and people who live in jurisdictions that explicitly forbid such changes (Spade, 2006). Documentation requirements can also assume a universal TGNC experience that marginalizes some TGNC people, especially those who do not undergo a medical transition. This may affect a TGNC person's social and psychological well-being and interfere with accessing employment, education, housing and shelter, health care, public benefits, and basic life management resources (e.g., opening a bank account).

Application. Psychologists are encouraged to inform public policy to reduce negative systemic impact on TGNC people and to promote positive social change. Psychologists are encouraged to identify and improve systems that permit violence; educational, employment, and housing discrimination; lack of access to health care; unequal access to other vital resources; and other instances of systemic inequity that TGNC people experience (ACA, 2010). Many TGNC people experience stressors from constant barriers, inequitable treatment, and forced release of sensitive and private information about their bodies and their lives (Hendricks & Testa, 2012). To obtain proper identity documentation, TGNC people may be required to provide court orders, proof of having had surgery, and documentation of psychotherapy or a psychiatric diagnosis. Psychologists may assist TGNC people by normalizing their reactions of fatigue and traumatization while interacting with legal systems and requirements; TGNC people may also benefit from guidance about alternate avenues of

recourse, self-advocacy, or appeal. When TGNC people feel that it is unsafe to advocate for themselves, psychologists may work with their clients to access appropriate resources in the community.

Psychologists are encouraged to be sensitive to the challenges of attaining gender-affirming identity documentation and how the receipt or denial of such documentation may affect social and psychological well-being, the person's ability to obtain education and employment, find safe housing, access public benefits, obtain student loans, and access health insurance. It may be of significant assistance for psychologists to understand and offer information about the process of a legal name change, gender marker change on identification, or the process for accessing other genderaffirming documents. Psychologists may consult the National Center for Transgender Equality, the Sylvia Rivera Law Project, or the Transgender Law Center for additional information on identity documentation for TGNC people.

Psychologists may choose to become involved with an organization that seeks to revise law and public policy to better protect the rights and dignities of TGNC people. Psychologists may participate at the local, state, or national level to support TGNC-affirmative health care accessibility, human rights in sex-segregated facilities, or policy change regarding gender-affirming identity documentation. Psychologists working in institutional settings may also expand their roles to work as collaborative advocates for TGNC people (Gonzalez & McNulty, 2010). Psychologists are encouraged to provide written affirmations supporting TGNC people and their gender identity so that they may access necessary services (e.g., hormone therapy).

Life Span Development

Guideline 8. Psychologists working with gender-questioning ⁴ and TGNC youth understand the different developmental needs of children and adolescents, and that not all youth will persist in a TGNC identity into adulthood.

Rationale. Many children develop stability (constancy across time) in their gender identity between Ages 3 to 4 (Kohlberg, 1966), although gender consistency (recognition that gender remains the same across situations) often does not occur until Ages 4 to 7 (Siegal & Robinson, 1987). Children who demonstrate gender nonconformity in preschool and early elementary years may not follow this trajectory (Zucker & Bradley, 1995). Existing research suggests that between 12% and 50% of children diagnosed with gender dysphoria may persist in their identification with a gender different than sex assigned at birth into late adolescence and young adulthood (Drummond, Bradley,

⁴ Gender-questioning youth are differentiated from TGNC youth in this section of the guidelines. Gender-questioning youth may be questioning or exploring their gender identity but have not yet developed a TGNC identity. As such, they may not be eligible for some services that would be offered to TGNC youth. Gender-questioning youth are included here because gender questioning may lead to a TGNC identity.

Peterson-Badaali, & Zucker, 2008; Steensma, McGuire, Kreukels, Beekman, & Cohen-Kettenis, 2013; Wallien & Cohen-Kettenis, 2008). However, several research studies categorized 30% to 62% of youth who did not return to the clinic for medical intervention after initial assessment, and whose gender identity may be unknown, as "desisters" who no longer identified with a gender different than sex assigned at birth (Steensma et al., 2013; Wallien & Cohen-Kettenis, 2008; Zucker, 2008a). As a result, this research runs a strong risk of inflating estimates of the number of youth who do not persist with a TGNC identity. Research has suggested that children who identify more intensely with a gender different than sex assigned at birth are more likely to persist in this gender identification into adolescence (Steensma et al., 2013), and that when gender dysphoria persists through childhood and intensifies into adolescence, the likelihood of long-term TGNC identification increases (A. L. de Vries, Steensma, Doreleijers, & Cohen-Kettenis, 2011; Steensma et al., 2013; Wallien & Cohen-Kettenis, 2008; Zucker, 2008b). Gender-questioning children who do not persist may be more likely to later identify as gay or lesbian than non-gender-questioning children (Bailey & Zucker, 1995; Drescher, 2014; Wallien & Cohen-Kettenis, 2008).

A clear distinction between care of TGNC and genderquestioning children and adolescents exists in the literature. Due to the evidence that not all children persist in a TGNC identity into adolescence or adulthood, and because no approach to working with TGNC children has been adequately, empirically validated, consensus does not exist regarding best practice with prepubertal children. Lack of consensus about the preferred approach to treatment may be due in part to divergent ideas regarding what constitutes optimal treatment outcomes for TGNC and gender-questioning youth (Hembree et al., 2009). Two distinct approaches exist to address gender identity concerns in children (Hill, Menvielle, Sica, & Johnson, 2010; Wallace & Russell, 2013), with some authors subdividing one of the approaches to suggest three (Byne et al., 2012; Drescher, 2014; Stein, 2012).

One approach encourages an affirmation and acceptance of children's expressed gender identity. This may include assisting children to socially transition and to begin medical transition when their bodies have physically developed, or allowing a child's gender identity to unfold without expectation of a specific outcome (A. L. de Vries & Cohen-Kettenis, 2012; Edwards-Leeper & Spack, 2012; Ehrensaft, 2012; Hidalgo et al., 2013; Tishelman et al., 2015). Clinicians using this approach believe that an open exploration and affirmation will assist children to develop coping strategies and emotional tools to integrate a positive TGNC identity should gender questioning persist (Edwards-Leeper & Spack, 2012).

In the second approach, children are encouraged to embrace their given bodies and to align with their assigned gender roles. This includes endorsing and supporting behaviors and attitudes that align with the child's sex assigned at birth prior to the onset of puberty (Zucker, 2008a; Zucker, Wood, Singh, & Bradley, 2012). Clinicians using

this approach believe that undergoing multiple medical interventions and living as a TGNC person in a world that stigmatizes gender nonconformity is a less desirable outcome than one in which children may be assisted to happily align with their sex assigned at birth (Zucker et al., 2012). Consensus does not exist regarding whether this approach may provide benefit (Zucker, 2008a; Zucker et al., 2012) or may cause harm or lead to psychosocial adversities (Hill et al., 2010; Pyne, 2014; Travers et al., 2012; Wallace & Russell, 2013). When addressing psychological interventions for children and adolescents, the World Professional Association for Transgender Health Standards of Care identify interventions "aimed at trying to change gender identity and expression to become more congruent with sex assigned at birth" as unethical (Coleman et al., 2012, p. 175). It is hoped that future research will offer improved guidance in this area of practice (Adelson & AACAP CQI, 2012; Malpas, 2011).

Much greater consensus exists regarding practice with adolescents. Adolescents presenting with gender identity concerns bring their own set of unique challenges. This may include having a late-onset (i.e., postpubertal) presentation of gender nonconforming identification, with no history of gender role nonconformity or gender questioning in childhood (Edwards-Leeper & Spack, 2012). Complicating their clinical presentation, many gender-questioning adolescents also present with co-occurring psychological concerns, such as suicidal ideation, self-injurious behaviors (Liu & Mustanski, 2012; Mustanski, Garofalo, & Emerson, 2010), drug and alcohol use (Garofalo et al., 2006), and autism spectrum disorders (A. L. de Vries, Noens, Cohen-Kettenis, van Berckelaer-Onnes, & Doreleijers, 2010; Jones et al., 2012). Additionally, adolescents can become intensely focused on their immediate desires, resulting in outward displays of frustration and resentment when faced with any delay in receiving the medical treatment from which they feel they would benefit and to which they feel entitled (Angello, 2013; Edwards-Leeper & Spack, 2012). This intense focus on immediate needs may create challenges in assuring that adolescents are cognitively and emotionally able to make life-altering decisions to change their name or gender marker, begin hormone therapy (which may affect fertility), or pursue surgery.

Nonetheless, there is greater consensus that treatment approaches for adolescents affirm an adolescents' gender identity (Coleman et al., 2012). Treatment options for adolescents extend beyond social approaches to include medical approaches. One particular medical intervention involves the use of puberty-suppressing medication or "blockers" (GnRH analogue), which is a reversible medical intervention used to delay puberty for appropriately screened adolescents with gender dysphoria (Coleman et al., 2012; A. L. C. de Vries et al., 2014; Edwards-Leeper, & Spack, 2012). Because of their age, other medical interventions may also become available to adolescents, and psychologists are frequently consulted to provide an assessment of whether such procedures would be advisable (Coleman et al., 2012).

Application. Psychologists working with TGNC and gender-questioning youth are encouraged to regularly review the most current literature in this area, recognizing the limited available research regarding the potential benefits and risks of different treatment approaches for children and for adolescents. Psychologists are encouraged to offer parents and guardians clear information about available treatment approaches, regardless of the specific approach chosen by the psychologist. Psychologists are encouraged to provide psychological service to TGNC and gender-questioning children and adolescents that draws from empirically validated literature when available, recognizing the influence psychologists' values and beliefs may have on the treatment approaches they select (Ehrbar & Gorton, 2010). Psychologists are also encouraged to remain aware that what one youth and/or parent may be seeking in a therapeutic relationship may not coincide with a clinician's approach (Brill & Pepper, 2008). In cases in which a youth and/or parent identify different preferred treatment outcomes than a clinician, it may not be clinically appropriate for the clinician to continue working with the youth and family, and alternative options, including referral, might be considered. Psychologists may also find themselves navigating family systems in which youth and their caregivers are seeking different treatment outcomes (Edwards-Leeper & Spack, 2012). Psychologists are encouraged to carefully reflect on their personal values and beliefs about gender identity development in conjunction with the available research, and to keep the best interest of the child or adolescent at the forefront of their clinical decisions at all times.

Because gender nonconformity may be transient for younger children in particular, the psychologist's role may be to help support children and their families through the process of exploration and self-identification (Ehrensaft, 2012). Additionally, psychologists may provide parents with information about possible long-term trajectories children may take in regard to their gender identity, along with the available medical interventions for adolescents whose TGNC identification persists (Edwards-Leeper & Spack, 2012)

When working with adolescents, psychologists are encouraged to recognize that some TGNC adolescents will not have a strong history of childhood gender role nonconformity or gender dysphoria either by self-report or family observation (Edwards-Leeper & Spack, 2012). Some of these adolescents may have withheld their feelings of gender nonconformity out of a fear of rejection, confusion, conflating gender identity and sexual orientation, or a lack of awareness of the option to identify as TGNC. Parents of these adolescents may need additional assistance in understanding and supporting their youth, given that late-onset gender dysphoria and TGNC identification may come as a significant surprise. Moving more slowly and cautiously in these cases is often advisable (Edwards-Leeper & Spack, 2012). Given the possibility of adolescents' intense focus on immediate desires and strong reactions to perceived delays or barriers, psychologists are encouraged to validate these concerns and the desire to move through the process

quickly while also remaining thoughtful and deliberate in treatment. Adolescents and their families may need support in tolerating ambiguity and uncertainty with regard to gender identity and its development (Brill & Pepper, 2008). It is encouraged that care should be taken not to foreclose this process.

For adolescents who exhibit a long history of gender nonconformity, psychologists may inform parents that the adolescent's self-affirmed gender identity is most likely stable (A. L. de Vries et al., 2011). The clinical needs of these adolescents may be different than those who are in the initial phases of exploring or questioning their gender identity. Psychologists are encouraged to complete a comprehensive evaluation and ensure the adolescent's and family's readiness to progress while also avoiding unnecessary delay for those who are ready to move forward.

Psychologists working with TGNC and gender-questioning youth are encouraged to become familiar with medical treatment options for adolescents (e.g., puberty-suppressing medication, hormone therapy) and work collaboratively with medical providers to provide appropriate care to clients. Because the ongoing involvement of a knowledgeable mental health provider is encouraged due to the psychosocial implications, and is often also a required part of the medical treatment regimen that may be offered to TGNC adolescents (Coleman et al., 2012; Hembree et al., 2009), psychologists often play an essential role in assisting in this process.

Psychologists may encourage parents and caregivers to involve youth in developmentally appropriate decision making about their education, health care, and peer networks, as these relate to children's and adolescents' gender identity and gender expression (Ryan, Russell, Huebner, Diaz, & Sanchez, 2010). Psychologists are also encouraged to educate themselves about the advantages and disadvantages of social transition during childhood and adolescence, and to discuss these factors with both their young clients and clients' parents. Emphasizing to parents the importance of allowing their child the freedom to return to a gender identity that aligns with sex assigned at birth or another gender identity at any point cannot be overstated, particularly given the research that suggests that not all young gender nonconforming children will ultimately express a gender identity different from that assigned at birth (Wallien, & Cohen-Kettenis, 2008; Zucker & Bradley, 1995). Psychologists are encouraged to acknowledge and explore the fear and burden of responsibility that parents and caregivers may feel as they make decisions about the health of their child or adolescent (Grossman, D'Augelli, Howell, & Hubbard, 2006). Parents and caregivers may benefit from a supportive environment to discuss feelings of isolation, explore loss and grief they may experience, vent anger and frustration at systems that disrespect or discriminate against them and their youth, and learn how to communicate with others about their child's or adolescent's gender identity or gender expression (Brill & Pepper, 2008).

Guideline 9. Psychologists strive to understand both the particular challenges that TGNC elders experience and the resilience they can develop.

Rationale. Little research has been conducted about TGNC elders, leaving much to be discovered about this life stage for TGNC people (Auldridge, Tamar-Mattis, Kennedy, Ames, & Tobin, 2012). Socialization into gender role behaviors and expectations based on sex assigned at birth, as well as the extent to which TGNC people adhere to these societal standards, is influenced by the chronological age at which a person self-identifies as TGNC, the age at which a person comes out or socially and/or medically transitions (Birren & Schaie, 2006; Bockting & Coleman, 2007; Cavanaugh & Blanchard-Fields, 2010; Nuttbrock et al., 2010; Wahl, Iwarsson, & Oswald, 2012), and a person's generational cohort (e.g., 1950 vs. 2010; Fredriksen-Goldsen et al., 2011).

Even decades after a medical or social transition, TGNC elders may still subscribe to the predominant gender role expectations that existed at the time of their transition (Knochel, Croghan, Moore, & Quam, 2011). Prior to the 1980s, TGNC people who transitioned were strongly encouraged by providers to pass in society as cisgender and heterosexual and to avoid associating with other TGNC people (Benjamin, 1966; R. Green & Money, 1969; Hastings, 1974; Hastings & Markland, 1978). Even TGNC elders who were comfortable telling others about their TGNC identity when they were younger may choose not to reveal their identity at a later stage of life (Ekins & King, 2005; Ippolito & Witten, 2014). Elders' unwillingness to disclose their TGNC identity can result from feelings of physical vulnerability or increased reliance on others who may discriminate against them or treat them poorly as a result of their gender identity (Bockting & Coleman, 2007), especially if the elder resides in an institutionalized setting (i.e., nursing home, assisted living facility) and relies on others for many daily needs (Auldridge et al., 2012). TGNC elders are also at a heightened risk for depression, suicidal ideation, and loneliness compared with LGB elders (Auldridge et al., 2012; Fredriksen-Goldsen et al., 2011).

A Transgender Law Center survey found that TGNC and LGB elders had less financial well-being than their younger cohorts, despite having a higher than average educational level for their age group compared with the general population (Hartzell, Frazer, Wertz, & Davis, 2009). Survey research has also revealed that TGNC elders experience underemployment and gaps in employment, often due to discrimination (Auldridge et al., 2012; Beemyn & Rankin, 2011; Factor & Rothblum, 2007). In the past, some TGNC people with established careers may have been encouraged by service providers to find new careers or jobs to avoid undergoing a gender transition at work or being identified as TGNC, potentially leading to a significant loss of income and occupational identity (Cook-Daniels, 2006). Obstacles to employment can increase economic disparities that result in increased needs for supportive housing and other social services (National Center for

Transgender Equality, 2012; Services and Advocacy for GLBT Elders & National Center for Transgender Equality, 2012).

TGNC elders may face obstacles to seeking or accessing resources that support their physical, financial, or emotional well-being. For instance, they may be concerned about applying for social security benefits, fearing that their TGNC identity may become known (Hartzell et al., 2009). A TGNC elder may avoid medical care, increasing the likelihood of later needing a higher level of medical care (e.g., home-based care, assisted living, or nursing home) than their same-age cisgender peers (Hartzell et al., 2009; Ippolito & Witten, 2014; Mikalson et al., 2012). Nursing homes and assisted living facilities are rarely sensitive to the unique medical needs of TGNC elders (National Senior Citizens Law Center, 2011). Some TGNC individuals who enter congregate housing, assisted living, or long-term care settings may feel the need to reverse their transition to align with sex assigned at birth to avoid discrimination and persecution by other residents and staff (Ippolito & Witten, 2014).

Older age may both facilitate and complicate medical treatment related to gender transition. TGNC people who begin hormone therapy later in life may have a smoother transition due to waning hormone levels that are a natural part of aging (Witten & Eyler, 2012). Age may also influence the decisions TGNC elders make regarding sex-affirmation surgeries, especially if physical conditions exist that could significantly increase risks associated with surgery or recovery.

Much has been written about the resilience of elders who have endured trauma (Fuhrmann & Shevlowitz, 2006; Hardy, Concato, & Gill, 2004; Mlinac, Sheeran, Blissmer, Lees, & Martins, 2011; Rodin & Stewart, 2012). Although some TGNC elders have experienced significant psychological trauma related to their gender identity, some also have developed resilience and effective ways of coping with adversity (Fruhauf & Orel, 2015). Despite the limited availability of LGBTQ-affirmative religious organizations in many local communities, TGNC elders make greater use of these resources than their cisgender peers (Porter et al., 2013).

Application. Psychologists are encouraged to seek information about the biopsychosocial needs of TGNC elders to inform case conceptualization and treatment planning to address psychological, social, and medical concerns. Many TGNC elders are socially isolated. Isolation can occur as a result of a loss of social networks through death or through disclosure of a TGNC identity. Psychologists may assist TGNC elders in establishing new social networks that support and value their TGNC identity, while also working to strengthen existing family and friend networks after a TGNC identity has been disclosed. TGNC elders may find special value in relationships with others in their generational cohort or those who may have similar coming-out experiences. Psychologists may encourage TGNC elders to identify ways they can mentor and improve the resilience of younger TGNC generations, creating a sense of generativity (Erikson, 1968) and contribu-

tion while building new supportive relationships. Psychologists working with TGNC elders may help them recognize the sources of their resilience and encourage them to connect with and be active in their communities (Fuhrmann & Craffey, 2014).

For TGNC elders who have chosen not to disclose their gender identity, psychologists may provide support to address shame, guilt, or internalized antitrans prejudice, and validate each person's freedom to choose their pattern of disclosure. Clinicians may also provide validation and empathy when TGNC elders have chosen a model of transition that avoids any disclosure of gender identity and is heavily focused on passing as cisgender.

TGNC elders who choose to undergo a medical or social transition in older adulthood may experience antitrans prejudice from people who question the value of transition at an older age or who believe that these elders are not truly invested in their transition or in a TGNC identity given the length of time they have waited (Auldridge et al., 2012). Some TGNC elders may also grieve lost time and missed opportunities. Psychologists may validate elders' choices to come out, transition, or evolve their gender identity or gender expression at any age, recognizing that such choices may have been much less accessible or viable at earlier stages of TGNC elders' lives.

Psychologists may assist congregate housing, assisted living, or long-term care settings to best meet TGNC elders' needs through respectful communication and affirmation of each person's gender identity and gender expression. Psychologists may work with TGNC people in hospice care systems to develop an end-of-life plan that respects the person's wishes about disclosure of gender identity during and after death.

Assessment, Therapy, and Intervention

Guideline 10. Psychologists strive to understand how mental health concerns may or may not be related to a TGNC person's gender identity and the psychological effects of minority stress.

Rationale. TGNC people may seek assistance from psychologists in addressing gender-related concerns, other mental health issues, or both. Mental health problems experienced by a TGNC person may or may not be related to that person's gender identity and/or may complicate assessment and intervention of gender-related concerns. In some cases, there may not be a relationship between a person's gender identity and a co-occurring condition (e.g., depression, PTSD, substance abuse). In other cases, having a TGNC identity may lead or contribute to a co-occurring mental health condition, either directly by way of gender dysphoria, or indirectly by way of minority stress and oppression (Hendricks & Testa, 2012; I. H. Meyer, 1995, 2003). In extremely rare cases, a co-occurring condition can mimic gender dysphoria (i.e., a psychotic process that distorts the perception of one's gender; Baltieri & De

Andrade, 2009; Hepp, Kraemer, Schnyder, Miller, & Delsignore, 2004).

Regardless of the presence or absence of an etiological link, gender identity may affect how a TGNC person experiences a co-occurring mental health condition, and/or a co-occurring mental health condition may complicate the person's gender expression or gender identity. For example, an eating disorder may be influenced by a TGNC person's gender expression (e.g., rigid eating patterns used to manage body shape or menstruation may be related to gender identity or gender dysphoria; Ålgars, Alanko, Santtila, & Sandnabba, 2012; Murray, Boon, & Touyz, 2013). In addition, the presence of autism spectrum disorder may complicate a TGNC person's articulation and exploration of gender identity (Jones et al., 2012). In cases in which gender dysphoria is contributing to other mental health concerns, treatment of gender dysphoria may be helpful in alleviating those concerns as well (Keo-Meier et al., 2015).

A relationship also exists between mental health conditions and the psychological sequelae of minority stress that TGNC people can experience. Given that TGNC people experience physical and sexual violence (Clements-Nolle et al., 2006; Kenagy & Bostwick, 2005; Lombardi, Wilchins, Priesing, & Malouf, 2001; Xavier et al., 2005), general harassment and discrimination (Beemyn & Rankin, 2011; Factor & Rothblum, 2007), and employment and housing discrimination (Bradford et al., 2007), they are likely to experience significant levels of minority stress. Studies have demonstrated the disproportionately high levels of negative psychological sequelae related to minority stress, including suicidal ideation and suicide attempts (Center for Substance Abuse Treatment, 2012; Clements-Nolle et al., 2006; Cochran & Cauce, 2006; Nuttbrock et al., 2010; Xavier et al., 2005) and completed suicides (Dhejne et al., 2011; van Kesteren, Asscheman, Megens, & Gooren, 1997). Recent studies have begun to demonstrate an association between sources of external stress and psychological distress (Bockting et al., 2013; Nuttbrock et al., 2010), including suicidal ideation and attempts and selfinjurious behavior (dickey, Reisner, & Juntunen, 2015; Goldblum et al., 2012; Testa et al., 2012).

The minority stress model accounts for both the negative mental health effects of stigma-related stress and the processes by which members of the minority group may develop resilience and resistance to the negative effects of stress (I. H. Meyer, 1995, 2003). Although the minority stress model was developed as a theory of the relationship between sexual orientation and mental disorders, the model has been adapted to TGNC populations (Hendricks & Testa, 2012).

Application. Because of the increased risk of stress-related mental health conditions, psychologists are encouraged to conduct a careful diagnostic assessment, including a differential diagnosis, when working with TGNC people (Coleman et al., 2012). Taking into account the intricate interplay between the effects of mental health symptoms and gender identity and gender expression, psychologists are encouraged to neither ignore mental health problems a TGNC person is experiencing, nor erroneously

assume that those mental health problems are a result of the person's gender identity or gender expression. Psychologists are strongly encouraged to be cautious before determining that gender nonconformity or dysphoria is due to an underlying psychotic process, as this type of causal relationship is rare.

When TGNC people seek to access transition-related health care, a psychosocial assessment is often part of this process (Coleman et al., 2012). A comprehensive and balanced assessment typically includes not only information about a person's past experiences of antitrans prejudice or discrimination, internalized messages related to these experiences, and anticipation of future victimization or rejection (Coolhart, Provancher, Hager, & Wang, 2008), but also coping strategies and sources of resilience (Hendricks & Testa, 2012; Singh et al., 2011). Gathering information about negative life events directly related to a TGNC person's gender identity and gender expression may assist psychologists in understanding the sequelae of stress and discrimination, distinguishing them from concurrent and potentially unrelated mental health problems. Similarly, when a TGNC person has a primary presenting concern that is not gender focused, a comprehensive assessment takes into account that person's experience relative to gender identity and gender expression, including any discrimination, just as it would include assessing other potential trauma history, medical concerns, previous experience with helping professionals, important future goals, and important aspects of identity. Strategies a TGNC person uses to navigate antitrans discrimination could be sources of strength to deal with life challenges or sources of distress that increase challenges and barriers.

Psychologists are encouraged to help TGNC people understand the pervasive influence of minority stress and discrimination that may exist in their lives, potentially including internalized negative attitudes about themselves and their TGNC identity (Hendricks & Testa, 2012). With this support, clients can better understand the origins of their mental health symptoms and normalize their reactions when faced with TGNC-related inequities and discrimination. Minority stress models also identify potentially important sources of resilience. TGNC people can develop resilience when they connect with other TGNC people who provide information on how to navigate antitrans prejudice and increase access to necessary care and resources (Singh et al., 2011). TGNC people may need help developing social support systems to nurture their resilience and bolster their ability to cope with the adverse effects of antitrans prejudice and/or discrimination (Singh & McKleroy, 2011).

Feminizing or masculinizing hormone therapy can positively or negatively affect existing mood disorders (Coleman et al., 2012). Psychologists may also help TGNC people who are in the initial stages of hormone therapy adjust to normal changes in how they experience emotions. For example, trans women who begin estrogens and antiandrogens may experience a broader range of emotions than they are accustomed to, or trans men beginning testosterone might be faced with adjusting to a higher libido

and feeling more emotionally reactive in stressful situations. These changes can be normalized as similar to the emotional adjustments that cisgender women and men experience during puberty. Some TGNC people will be able to adapt existing coping strategies, whereas others may need help developing additional skills (e.g., emotional regulation or assertiveness). Readers are encouraged to refer to the World Professional Association for Transgender Health Standards of Care for discussion of the possible effects of hormone therapy on a TGNC person's mood, affect, and behavior (Coleman et al., 2012).

Guideline 11. Psychologists recognize that TGNC people are more likely to experience positive life outcomes when they receive social support or trans-affirmative care.

Rationale. Research has primarily shown positive treatment outcomes when TGNC adults and adolescents receive TGNC-affirmative medical and psychological services (i.e., psychotherapy, hormones, surgery; Byne et al., 2012; R. Carroll, 1999; Cohen-Kettenis, Delemarre-van de Waal, & Gooren, 2008; Davis & Meier, 2014; De Cuypere et al., 2006; Gooren, Giltay, & Bunck, 2008; Kuhn et al., 2009), although sample sizes are frequently small with no population-based studies. In a meta-analysis of the hormone therapy treatment literature with TGNC adults and adolescents, researchers reported that 80% of participants receiving trans-affirmative care experienced an improved quality of life, decreased gender dysphoria, and a reduction in negative psychological symptoms (Murad et al., 2010).

In addition, TGNC people who receive social support about their gender identity and gender expression have improved outcomes and quality of life (Brill & Pepper, 2008; Pinto, Melendez, & Spector, 2008). Several studies indicate that family acceptance of TGNC adolescents and adults is associated with decreased rates of negative outcomes, such as depression, suicide, and HIV risk behaviors and infection (Bockting et al., 2013; Dhejne et al., 2011; Grant et al., 2011; Liu & Mustanski, 2012; Ryan, 2009). Family support is also a strong protective factor for TGNC adults and adolescents (Bockting et al., 2013; Moody & Smith, 2013; Ryan et al., 2010). TGNC people, however, frequently experience blatant or subtle antitrans prejudice, discrimination, and even violence within their families (Bradford et al., 2007). Such family rejection is associated with higher rates of HIV infection, suicide, incarceration, and homelessness for TGNC adults and adolescents (Grant et al., 2011; Liu & Mustanski, 2012). Family rejection and lower levels of social support are significantly correlated with depression (Clements-Nolle et al., 2006; Ryan, 2009). Many TGNC people seek support through peer relationships, chosen families, and communities in which they may be more likely to experience acceptance (Gonzalez & Mc-Nulty, 2010; Nuttbrock et al., 2009). Peer support from other TGNC people has been found to be a moderator between antitrans discrimination and mental health, with higher levels of peer support associated with better mental health (Bockting et al., 2013). For some TGNC people, support from religious and spiritual communities provides

an important source of resilience (Glaser, 2008; Kidd & Witten, 2008; Porter et al., 2013).

Application. Given the strong evidence for the positive influence of affirmative care, psychologists are encouraged to facilitate access to and provide trans-affirmative care to TGNC people. Whether through the provision of assessment and psychotherapy, or through assisting clients to access hormone therapy or surgery, psychologists may play a critical role in empowering and validating TGNC adults' and adolescents' experiences and increasing TGNC people's positive life outcomes (Bess & Stabb, 2009; Rachlin, 2002).

Psychologists are also encouraged to be aware of the importance of affirmative social support and assist TGNC adults and adolescents in building social support networks in which their gender identity is accepted and affirmed. Psychologists may assist TGNC people in negotiating family dynamics that may arise in the course of exploring and establishing gender identity. Depending on the context of psychological practice, these issues might be addressed in individual work with TGNC clients, conjoint sessions including members of their support system, family therapy, or group therapy. Psychologists may help TGNC people decide how and when to reveal their gender identity at work or school, in religious communities, and to friends and contacts in other settings. TGNC people who decide not to come out in all aspects of their lives can still benefit from TGNC-affirmative in-person or online peer support

Clients may ask psychologists to assist family members in exploring feelings about their loved one's gender identity and gender expression. Published models of family adjustment (Emerson & Rosenfeld, 1996) may be useful to help normalize family members' reactions upon learning that they have a TGNC family member, and to reduce feelings of isolation. When working with family members or significant others, it may be helpful to normalize feelings of loss or fear of what may happen to current relationships as TGNC people disclose their gender identity and expression to others. Psychologists may help significant others adjust to changing relationships and consider how to talk to extended family, friends, and other community members about TGNC loved ones. Providing significant others with referrals to TGNC-affirmative providers, educational resources, and support groups can have a profound impact on their understanding of gender identity and their communication with TGNC loved ones. Psychologists working with couples and families may also help TGNC people identify ways to include significant others in their social or medical transition.

Psychologists working with TGNC people in rural settings may provide clients with resources to connect with other TGNC people online or provide information about in-person support groups in which they can explore the unique challenges of being TGNC in these geographic areas (Walinsky & Whitcomb, 2010). Psychologists serving TGNC military and veteran populations are encouraged to be sensitive to the barriers these individuals face, especially for people who are on active duty in the U.S. military

(OutServe-Servicemembers Legal Defense Network, n.d.). Psychologists may help TGNC military members and veterans establish specific systems of support that create a safe and affirming space to reduce isolation and to create a network of peers with a shared military experience. Psychologists who work with veterans are encouraged to educate themselves on recent changes to VA policy that support equal access to VA medical and mental health services (Department of Veterans Affairs, Veterans' Health Administration, 2013).

Guideline 12. Psychologists strive to understand the effects that changes in gender identity and gender expression have on the romantic and sexual relationships of TGNC people.

Rationale. Relationships involving TGNC people can be healthy and successful (Kins, Hoebeke, Heylens, Rubens, & De Cuyprere, 2008; Meier, Sharp, Michonski, Babcock, & Fitzgerald, 2013) as well as challenging (Brown, 2007; Iantaffi & Bockting, 2011). A study of successful relationships between TGNC men and cisgender women found that these couples attributed the success of their relationship to respect, honesty, trust, love, understanding, and open communication (Kins et al., 2008). Just as relationships between cisgender people can involve abuse, so can relationships between TGNC people and their partners (Brown, 2007), with some violent partners threatening to disclose a TGNC person's identity to exact control in the relationship (FORGE, n.d.).

In the early decades of medical and social transition for TGNC people, only those whose sexual orientations would be heterosexual posttransition (e.g., trans woman with a cisgender man) were deemed eligible for medical and social transition (Meyerowitz, 2002). This restriction prescribed only certain relationship partners (American Psychiatric Association, 1980; Benjamin, 1966; Chivers & Bailey, 2000), denied access to surgery for trans men identifying as gay or bisexual (Coleman & Bockting, 1988), or trans women identifying as lesbian or bisexual, and even required that TGNC people's existing legal marriages be dissolved before they could gain access to transition care (Lev, 2004).

Disclosure of a TGNC identity can have an important impact on the relationship between TGNC people and their partners. Disclosure of TGNC status earlier in the relationship tends to be associated with better relationship outcomes, whereas disclosure of TGNC status many years into an existing relationship may be perceived as a betrayal (Erhardt, 2007). When a TGNC person comes out in the context of an existing relationship, it can also be helpful if both partners are involved in decision making about the use of shared resources (i.e., how to balance the financial costs of transition with other family needs) and how to share this news with shared supports (i.e., friends and family). Sometimes relationship roles are renegotiated in the context of a TGNC person coming out to their partner (Samons, 2008). Assumptions about what it means to be a "husband" or a "wife" can shift if the gender identity of one's spouse shifts

(Erhardt, 2007). Depending on when gender issues are disclosed and how much of a change this creates in the relationship, partners may grieve the loss of aspects of their partner and the way the relationship used to be (Lev, 2004).

Although increasing alignment between gender identity and gender expression, whether it be through dress, behavior, or through medical interventions (i.e., hormones, surgery), does not necessarily affect to whom a TGNC person is attracted (Coleman et al., 1993), TGNC people may become more open to exploring their sexual orientation, may redefine sexual orientation as they move through transition, or both (Daskalos, 1998; H. Devor, 1993; Schleifer, 2006). Through increased comfort with their body and gender identity, TGNC people may explore aspects of their sexual orientation that were previously hidden or that felt discordant with their sex assigned at birth. Following a medical and/or social transition, a TGNC person's sexual orientation may remain constant or shift, either temporarily or permanently (e.g., renewed exploration of sexual orientation in the context of TGNC identity, shift in attraction or choice of sexual partners, widened spectrum of attraction, shift in sexual orientation identity; Meier, Sharp et al., 2013; Samons, 2008). For example, a trans man previously identified as a lesbian may later be attracted to men (Coleman et al., 1993; dickey, Burnes, & Singh, 2012), and a trans woman attracted to women pretransition may remain attracted to women posttransition (Lev, 2004).

Some TGNC people and their partners may fear the loss of mutual sexual attraction and other potential effects of shifting gender identities in the relationship. Lesbianidentified partners of trans men may struggle with the idea that being in a relationship with a man may cause others to perceive them as a heterosexual couple (Califia, 1997). Similarly, women in heterosexual relationships who later learn that their partners are trans women may be unfamiliar with navigating stigma associated with sexual minority status when viewed as a lesbian couple (Erhardt, 2007). Additionally, partners may find they are not attracted to a partner after transition. As an example, a lesbian whose partner transitions to a male identity may find that she is no longer attracted to this person because she is not sexually attracted to men. Partners of TGNC people may also experience grief and loss as their partners engage in social and/or medical transitions.

Application. Psychologists may help foster resilience in relationships by addressing issues specific to partners of TGNC people. Psychologists may provide support to partners of TGNC people who are having difficulty with their partner's evolving gender identity or transition, or are experiencing others having difficulty with the partner's transition. Partner peer support groups may be especially helpful in navigating internalized antitrans prejudice, shame, resentment, and relationship concerns related to a partner's gender transition. Meeting or knowing other TGNC people, other partners of TGNC people, and couples who have successfully navigated transition may also help TGNC people and their partners and serve as a protective factor (Brown, 2007). When TGNC status is disclosed during an existing relationship, psychologists may help

couples explore which relationship dynamics they want to preserve and which they might like to change.

In working with psychologists, TGNC people may explore a range of issues in their relationships and sexuality (dickey et al., 2012), including when and how to come out to current or potential romantic and sexual partners, communicating their sexual desires, renegotiating intimacy that may be lost during the TGNC partner's transition, adapting to bodily changes caused by hormone use or surgery, and exploring boundaries regarding touch, affection, and safer sex practices (Iantaffi & Bockting, 2011; Sevelius, 2009). TGNC people may experience increased sexual self-efficacy through transition. Although psychologists may aid partners in understanding a TGNC person's transition decisions, TGNC people may also benefit from help in cultivating awareness of the ways in which these decisions influence the lives of loved ones.

Guideline 13. Psychologists seek to understand how parenting and family formation among TGNC people take a variety of forms.

Rationale. Psychologists work with TGNC people across the life span to address parenting and family issues (Kenagy & Hsieh, 2005). There is evidence that many TGNC people have and want children (Wierckx et al., 2012). Some TGNC people conceive a child through sexual intercourse, whereas others may foster, adopt, pursue surrogacy, or employ assisted reproductive technologies, such as sperm or egg donation, to build or expand a family (De Sutter, Kira, Verschoor, & Hotimsky, 2002). Based on a small body of research to date, there is no indication that children of TGNC parents suffer long-term negative impacts directly related to parental gender change (R. Green, 1978, 1988; White & Ettner, 2004). TGNC people may find it both challenging to find medical providers who are willing to offer them reproductive treatment and to afford the cost (Coleman et al., 2012). Similarly, adoption can be quite costly, and some TGNC people may find it challenging to find foster care or adoption agencies that will work with them in a nondiscriminatory manner. Current or past use of hormone therapy may limit fertility and restrict a TGNC person's reproductive options (Darnery, 2008; Wierckx et al., 2012). Other TGNC people may have children or families before coming out as TGNC or beginning a gender transition.

TGNC people may present with a range of parenting and family-building concerns. Some will seek support to address issues within preexisting family systems, some will explore the creation or expansion of a family, and some will need to make decisions regarding potential fertility issues related to hormone therapy, pubertal suppression, or surgical transition. The medical and/or social transition of a TGNC parent may shift family dynamics, creating challenges and opportunities for partners, children, and other family members. One study of therapists' reflections on their experiences with TGNC clients suggested that family constellation and the parental relationship was more significant for children than the parent's social and/or medical

transition itself (White & Ettner, 2004). Although research has not documented that the transitions of TGNC people have an effect on their parenting abilities, preexisting partnerships or marriages may not survive the disclosure of a TGNC identity or a subsequent transition (dickey et al., 2012). This may result in divorce or separation, which may affect the children in the family. A positive relationship between parents, regardless of marital status, has been suggested to be an important protective factor for children (Amato, 2001; White & Ettner, 2007). This seems to be the case especially when children are reminded of the parent's love and assured of the parent's continued presence in their life (White & Ettner, 2007). Based on a small body of literature available, it is generally the case that younger children are best able to incorporate the transition of a parent, followed by adult children, with adolescents generally having the most difficulty (White & Ettner, 2007). If separated or divorced from their partners or spouses, TGNC parents may be at risk for loss of custody or visitation rights because some courts presume that there is a nexus between their gender identity or gender expression and parental fitness (Flynn, 2006). This type of prejudice is especially common for TGNC people of color (Grant et al., 2011).

Application. Psychologists are encouraged to attend to the parenting and family-building concerns of TGNC people. When working with TGNC people who have previous parenting experience, psychologists may help TGNC people identify how being a parent may influence decisions to come out as TGNC or to begin a transition (Freeman, Tasker, & Di Ceglie, 2002; Grant et al., 2011; Wierckx et al., 2012). Some TGNC people may choose to delay disclosure until their children have grown and left home (Bethea & McCollum, 2013). Clinical guidelines jointly developed by a Vancouver, British Columbia, TGNC community organization and a health care provider organization encourage psychologists and other mental health providers working with TGNC people to plan for disclosure to a partner, previous partner, or children, and to pay particular attention to resources that assist TGNC people to discuss their identity with children of various ages in developmentally appropriate ways (Bockting et al., 2006). Lev (2004) uses a developmental stage framework for the process that family members are likely to go through in coming to terms with a TGNC family member's identity that some psychologists may find helpful. Awareness of peer support networks for spouses and children of TGNC people can also be helpful (e.g., PFLAG, TransYouth Family Allies). Psychologists may provide family counseling to assist a family in managing disclosure, improve family functioning, and maintain family involvement of the TGNC person, as well as aiding the TGNC person in attending to the ways that their transition process has affected their family members (Samons, 2008). Helping parents to continue to work together to focus on the needs of their children and to maintain family bonds is likely to lead to the best results for the children (White & Ettner, 2007).

For TGNC people with existing families, psychologists may support TGNC people in seeking legal counsel regarding parental rights in adoption or custody. Depending on the situation, this may be desirable even if the TGNC parent is biologically related to the child (Minter & Wald, 2012). Although being TGNC is not a legal impediment to adoption in the United States, there is the potential for overt and covert discrimination and barriers, given the widespread prejudice against TGNC people. The question of whether to disclose TGNC status on an adoption application is a personal one, and a prospective TGNC parent would benefit from consulting a lawyer for legal advice, including what the laws in their jurisdiction say about disclosure. Given the extensive background investigation frequently conducted, it may be difficult to avoid disclosure. Many lawyers favor disclosure to avoid any potential legal challenges during the adoption process (Minter & Wald, 2012).

In discussing family-building options with TGNC people, psychologists are encouraged to remain aware that some of these options require medical intervention and are not available everywhere, in addition to being quite costly (Coleman et al., 2012). Psychologists may work with clients to manage feelings of loss, grief, anger, and resentment that may arise if TGNC people are unable to access or afford the services they need for building a family (Bockting et al., 2006; De Sutter et al., 2002).

When TGNC people consider beginning hormone therapy, psychologists may engage them in a conversation about the possibly permanent effects on fertility to better prepare TGNC people to make a fully informed decision. This may be of special importance with TGNC adolescents and young adults who often feel that family planning or loss of fertility is not a significant concern in their current daily lives, and therefore disregard the long-term reproductive implications of hormone therapy or surgery (Coleman et al., 2012). Psychologists are encouraged to discuss contraception and safer sex practices with TGNC people, given that they may still have the ability to conceive even when undergoing hormone therapy (Bockting, Robinson, & Rosser, 1998). Psychologists may play a critical role in educating TGNC adolescents and young adults and their parents about the long-term effects of medical interventions on fertility and assist them in offering informed consent prior to pursuing such interventions. Although hormone therapy may limit fertility (Coleman et al., 2012), psychologists may encourage TGNC people to refrain from relying on hormone therapy as the sole means of birth control, even when a person has amenorrhea (Gorton & Grubb, 2014). Education on safer sex practices may also be important, as some segments of the TGNC community (e.g., trans women and people of color) are especially vulnerable to sexually transmitted infections and have been shown to have high prevalence and incidence rates of HIV infection (Kellogg, Clements-Nolle, Dilley, Katz, & McFarland, 2001; Nemoto, Operario, Keatley, Han, & Soma, 2004).

Depending on the timing and type of options selected, psychologists may explore the physical, social, and emotional implications should TGNC people choose to delay or

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stop hormone therapy, undergo fertility treatment, or become pregnant. Psychological effects of stopping hormone therapy may include depression, mood swings, and reactions to the loss of physical masculinization or feminization facilitated by hormone therapy (Coleman et al., 2012). TGNC people who choose to halt hormone therapy during attempts to conceive or during a pregnancy may need additional psychological support. For example, TGNC people and their families may need help in managing the additional antitrans prejudice and scrutiny that may result when a TGNC person with stereotypically masculine features becomes visibly pregnant. Psychologists may also assist TGNC people in addressing their loss when they cannot engage in reproductive activities that are consistent with their gender identity, or when they encounter barriers to conceiving, adopting, or fostering children not typically faced by other people (Vanderburgh, 2007). Psychologists are encouraged to assess the degree to which reproductive health services are TGNC-affirmative prior to referring TGNC people to them. Psychologists are also encouraged to provide TGNC-affirmative information to reproductive health service personnel when there is a lack of transaffirmative knowledge.

Guideline 14. Psychologists recognize the potential benefits of an interdisciplinary approach when providing care to TGNC people and strive to work collaboratively with other providers.

Rationale. Collaboration across disciplines can be crucial when working with TGNC people because of the potential interplay of biological, psychological, and social factors in diagnosis and treatment (Hendricks & Testa, 2012). The challenges of living with a stigmatized identity and the need of many TGNC people to transition, socially and/or medically, may call for the involvement of health professionals from various disciplines, including psychologists, psychiatrists, social workers, primary health care providers, endocrinologists, nurses, pharmacists, surgeons, gynecologists, urologists, electrologists, speech therapists, physical therapists, pastoral counselors and chaplains, and career or educational counselors. Communication, cooperation, and collaboration will ensure optimal coordination and quality of care. Just as psychologists often refer TGNC people to medical providers for assessment and treatment of medical issues, medical providers may rely on psychologists to assess readiness and assist TGNC clients to prepare for the psychological and social aspects of transition before, during, and after medical interventions (Coleman et al., 2012; Hembree et al., 2009; Lev, 2009). Outcome research to date supports the value and effectiveness of an interdisciplinary, collaborative approach to TGNC-specific care (see Coleman et al., 2012 for a review).

Application. Psychologists' collaboration with colleagues in medical and associated health disciplines involved in TGNC clients' care (e.g., hormonal and surgical treatment, primary health care; Coleman et al., 2012; Lev, 2009) may take many forms and should occur in a timely manner that does not complicate access to needed

services (e.g., considerations of wait time). For example, a psychologist working with a trans man who has a diagnosis of bipolar disorder may need to coordinate with his primary care provider and psychiatrist to adjust his hormone levels and psychiatric medications, given that testosterone can have an activating effect, in addition to treating gender dysphoria. At a basic level, collaboration may entail the creation of required documentation that TGNC people present to surgeons or medical providers to access genderaffirming medical interventions (e.g., surgery, hormone therapy; Coleman et al., 2012). Psychologists may offer support, information, and education to interdisciplinary colleagues who are unfamiliar with issues of gender identity and gender expression to assist TGNC people in obtaining TGNC-affirmative care (Holman & Goldberg, 2006; Lev, 2009). For example, a psychologist who is assisting a trans woman with obtaining gender-affirming surgery may, with her consent, contact her new gynecologist in preparation for her first medical visit. This contact could include sharing general information about her gender history and discussing how both providers could most affirmatively support appropriate health checks to ensure her best physical health (Holman & Goldberg, 2006).

Psychologists in interdisciplinary settings could also collaborate with medical professionals prescribing hormone therapy by educating TGNC people and ensuring TGNC people are able to make fully informed decisions prior to starting hormone treatment (Coleman et al., 2012; Deutsch, 2012; Lev, 2009). Psychologists working with children and adolescents play a particularly important role on the interdisciplinary team due to considerations of cognitive and social development, family dynamics, and degree of parental support. This role is especially crucial when providing psychological evaluation to determine the appropriateness and timeliness of a medical intervention. When psychologists are not part of an interdisciplinary setting, especially in isolated or rural communities, they can identify interdisciplinary colleagues with whom they may collaborate and/or refer (Walinsky & Whitcomb, 2010). For example, a rural psychologist could identify a trans-affirmative pediatrician in a surrounding area and collaborate with the pediatrician to work with parents raising concerns about their TGNC and questioning children and adolescents.

In addition to working collaboratively with other providers, psychologists who obtain additional training to specialize in work with TGNC people may also serve as consultants in the field (e.g., providing additional support to providers working with TGNC people or assisting school and workplaces with diversity training). Psychologists who have expertise in working with TGNC people may play a consultative role with providers in inpatient settings seeking to provide affirmative care to TGNC clients. Psychologists may also collaborate with social service colleagues to provide TGNC people with affirmative referrals related to housing, financial support, vocational/educational counseling and training, TGNC-affirming religious or spiritual communities, peer support, and other community resources (Gehi & Arkles, 2007). This collaboration might also in-

clude assuring that TGNC people who are minors in the care of the state have access to culturally appropriate care.

Research, Education, and Training

Guideline 15. Psychologists respect the welfare and rights of TGNC participants in research and strive to represent results accurately and avoid misuse or misrepresentation of findings.

Rationale. Historically, in a set of demographic questions, psychological research has included one item on either sex or gender, with two response options-male and female. This approach wastes an opportunity to increase knowledge about TGNC people for whom neither option may fit their identity, and runs the risk of alienating TGNC research participants (IOM, 2011). For example, there is little knowledge about HIV prevalence, risks, and prevention needs of TGNC people because most of the research on HIV has not included demographic questions to identify TGNC participants within their samples. Instead, TGNC people have been historically subsumed within larger demographic categories (e.g., men who have sex with men, women of color), rendering the impact of the HIV epidemic on the TGNC population invisible (Herbst et al., 2008). Scholars have noted that this invisibility fails to draw attention to the needs of TGNC populations that experience the greatest health disparities, including TGNC people who are of color, immigrants, low income, homeless, veterans, incarcerated, live in rural areas, or have disabilities (Bauer et al., 2009; Hanssmann, Morrison, Russian, Shiu-Thornton, & Bowen, 2010; Shipherd et al., 2012; Walinsky & Whitcomb, 2010).

There is a great need for more research to inform practice, including affirmative treatment approaches with TGNC people. Although sufficient evidence exists to support current standards of care (Byne et al., 2012; Coleman et al., 2012), much is yet to be learned to optimize quality of care and outcome for TGNC clients, especially as it relates to the treatment of children (IOM, 2011; Mikalson et al., 2012). In addition, some research with TGNC populations has been misused and misinterpreted, negatively affecting TGNC people's access to health services to address issues of gender identity and gender expression (Namaste, 2000). This has resulted in justifiable skepticism and suspicion in the TGNC community when invited to participate in research initiatives. In accordance with the APA ethics code (APA, 2010), psychologists conduct research and distribute research findings with integrity and respect for their research participants. As TGNC research increases, some TGNC communities may experience being oversampled in particular geographic areas and/or TGNC people of color may not be well-represented in TGNC studies (Hwahng & Lin, 2009; Namaste, 2000).

Application. All psychologists conducting research, even when not specific to TGNC populations, are encouraged to provide a range of options for capturing demographic information about TGNC people so that TGNC people may be included and accurately represented

(Conron et al., 2008; Deutsch et al., 2013). One group of experts has recommended that population research, and especially government-sponsored surveillance research, use a two-step method, first asking for sex assigned at birth, and then following with a question about gender identity (GenIUSS, 2013). For research focused on TGNC people, including questions that assess both sex assigned at birth and current gender identity allows the disaggregation of subgroups within the TGNC population and has the potential to increase knowledge of differences within the population. In addition, findings about one subgroup of TGNC people may not apply to other subgroups. For example, results from a study of trans women of color with a history of sex work who live in urban areas (Nemoto, Operario, Keatley, & Villegas, 2004) may not generalize to all TGNC women of color or to the larger TGNC population (Bauer, Travers, Scanlon, & Coleman, 2012; Operario et al., 2008).

In conducting research with TGNC people, psychologists will confront the challenges associated with studying a relatively small, geographically dispersed, diverse, stigmatized, hidden, and hard-to-reach population (IOM, 2011). Because TGNC individuals are often hard to reach (IOM, 2011) and TGNC research is rapidly evolving, it is important to consider the strengths and limitations of the methods that have been or may be used to study the TGNC population, and to interpret and represent findings accordingly. Some researchers have strongly recommended collaborative research models (e.g., participatory action research) in which TGNC community members are integrally involved in these research activities (Clements-Nolle & Bachrach, 2003; Singh, Richmond, & Burnes, 2013). Psychologists who seek to educate the public by communicating research findings in the popular media will also confront challenges, because most journalists have limited knowledge about the scientific method and there is potential for the media to misinterpret, exploit, or sensationalize findings (Garber, 1992; Namaste, 2000).

Guideline 16. Psychologists Seek to Prepare Trainees in Psychology to Work Competently With TGNC People.

Rationale. The Ethical Principles of Psychologists and Code of Conduct (APA, 2010) include gender identity as one factor for which psychologists may need to obtain training, experience, consultation, or supervision in order to ensure their competence (APA, 2010). In addition, when APA-accredited programs are required to demonstrate a commitment to cultural and individual diversity, gender identity is specifically included (APA, 2015). Yet surveys of TGNC people suggest that many mental health care providers lack even basic knowledge and skills required to offer trans-affirmative care (Bradford et al., 2007; O'Hara, Dispenza, Brack, & Blood, 2013; Xavier et al., 2005). The APA Task Force on Gender Identity and Gender Variance (2009) projected that many, if not most, psychologists and graduate psychology students will at some point encounter TGNC people among their clients, colleagues, and trainees. Yet professional education and training in psychology includes little or no preparation for

working with TGNC people (Anton, 2009; APA TFGIGV, 2009), and continuing professional education available to practicing mental health clinicians is also scant (Lurie, 2005). Only 52% percent of psychologists and graduate students who responded to a survey conducted by an APA Task Force reported having had the opportunity to learn about TGNC issues in school; of those respondents, only 27% reported feeling adequately familiar with gender concerns (n = 294; APA TFGIGV, 2009).

Training on gender identity in professional psychology has frequently been subsumed under discussions of sexual orientation or in classes on human sexuality. Some scholars have suggested that psychologists and students may mistakenly believe that they have obtained adequate knowledge and awareness about TGNC people through training focused on LGB populations (Harper & Schneider, 2003). However, Israel and colleagues have found important differences between the therapeutic needs of TGNC people and those of LGB people in the perceptions of both clients and providers (Israel et al., 2008; Israel, Walther, Gorcheva, & Perry, 2011). Nadal and colleagues have suggested that the absence of distinct, accurate information about TGNC populations in psychology training not only perpetuates misunderstanding and marginalization of TGNC people by psychologists but also contributes to continued marginalization of TGNC people in society as a whole (Nadal et al., 2010, 2012).

Application. Psychologists strive to continue their education on issues of gender identity and gender expression with TGNC people as a foundational component of affirmative psychological practice. In addition to these guidelines, which educators may use as a resource in developing curricula and training experiences, ACA (2010) has also adopted a set of competencies that may be a helpful resource for educators. In addition to including TGNC people and their issues in foundational education in health service psychology (e.g., personality development, multiculturalism, research methods), some psychology programs may also provide coursework and training for students interested in developing more advanced expertise on issues of gender identity and gender expression.

Because of the high level of societal ignorance and stigma associated with TGNC people, ensuring that psychological education, training, and supervision is affirmative, and does not sensationalize (Namaste, 2000), exploit, or pathologize TGNC people (Lev, 2004), will require care on the part of educators. Students will benefit from support from their educators in developing a professional, nonjudgmental attitude toward people who may have a different experience of gender identity and gender expression from their own. A number of training resources have been published that may be helpful to psychologists in integrating information about TGNC people into the training they offer (e.g., Catalano, McCarthy, & Shlasko, 2007; Stryker, 2008; Wentling, Schilt, Windsor, & Lucal, 2008). Because most psychologists have had little or no training on TGNC populations and do not perceive themselves as having sufficient understanding of issues related to gender identity and gender expression (APA TFGIGV, 2009), psychologists with relevant expertise are encouraged to develop and distribute continuing education and training to help to address these gaps. Psychologists providing education can incorporate activities that increase awareness of cisgender privilege, antitrans prejudice and discrimination, host a panel of TGNC people to offer personal perspectives, or include narratives of TGNC people in course readings (ACA, 2010). When engaging these approaches, it is important to include a wide variety of TGNC experiences to reflect the inherent diversity within the TGNC community.

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Appendix A Definitions

Terminology within the health care field and transgender and gender nonconforming (TGNC) communities is constantly evolving (Coleman et al., 2012). The evolution of terminology has been especially rapid in the last decade, as the profession's awareness of gender diversity has increased, as more literature and research in this area has been published, and as voices of the TGNC community have strengthened. Some terms or definitions are not universally accepted, and there is some disagreement among professionals and communities as to the "correct" words or definitions, depending on theoretical orientation, geographic region, generation, or culture, with some terms seen as affirming and others as outdated or demeaning. American Psychological Association (APA) Task Force for Guidelines for Psychological Practice with Transgender and Gender Nonconforming People developed the definitions below by reviewing existing

definitions put forward by professional organizations (e.g., APA Task Force on Gender Identity and Gender Variance, 2009; the Institute of Medicine, 2011; and the World Professional Association for Transgender Health [Coleman et al., 2012]), health care agencies serving TGNC clients (e.g., Fenway Health Center), TGNC community resources (Gender Equity Resource Center, National Center for Transgender Equality), and professional literature. Psychologists are encouraged to refresh their knowledge and familiarity with evolving terminology on a regular basis as changes emerge in the community and/or the professional literature. The definitions below include terms frequently used within the *Guidelines*, by the TGNC community, and within professional literature.

Ally: a cisgender person who supports and advocates for TGNC people and/or communities.

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Antitrans prejudice (transprejudice, transnegativity, transphobia): prejudicial attitudes that may result in the devaluing, dislike, and hatred of people whose gender identity and/or gender expression do not conform to their sex assigned at birth. Antitrans prejudice may lead to discriminatory behaviors in such areas as employment and public accommodations, and may lead to harassment and violence. When TGNC people hold these negative attitudes about themselves and their gender identity, it is called internalized transphobia (a construct analogous to internalized homophobia). Transmisogyny describes a simultaneous experience of sexism and antitrans prejudice with particularly adverse effects on trans women.

Cisgender: an adjective used to describe a person whose gender identity and gender expression align with sex assigned at birth; a person who is not TGNC.

Cisgenderism: a systemic bias based on the ideology that gender expression and gender identities are determined by sex assigned at birth rather than self-identified gender identity. Cisgenderism may lead to prejudicial attitudes and discriminatory behaviors toward TGNC people or to forms of behavior or gender expression that lie outside of the traditional gender binary.

Coming out: a process by which individuals affirm and actualize a stigmatized identity. Coming out as TGNC can include disclosing a gender identity or gender history that does not align with sex assigned at birth or current gender expression. Coming out is an individual process and is partially influenced by one's age and other generational influences.

Cross dressing: wearing clothing, accessories, and/or make-up, and/or adopting a gender expression not associated with a person's assigned sex at birth according to cultural and environmental standards (Bullough & Bullough, 1993). Cross-dressing is not always reflective of gender identity or sexual orientation. People who cross-dress may or may not identify with the larger TGNC community.

Disorders of sex development (DSD, Intersex): term used to describe a variety of medical conditions associated with atypical development of an individual's physical sex characteristics (Hughes, Houk, Ahmed, & Lee, 2006). These conditions may involve differences of a person's internal and/or external reproductive organs, sex chromosomes, and/or sex-related hormones that may complicate sex assignment at birth. DSD conditions may be considered variations in biological diversity rather than disorders (M. Diamond, 2009); therefore some prefer the terms *intersex*, *intersexuality*, or *differences in sex development* rather than "disorders of sex development" (Coleman et al., 2012).

Drag: the act of adopting a gender expression, often as part of a performance. Drag may be enacted as a political

comment on gender, as parody, or as entertainment, and is not necessarily reflective of gender identity.

Female-to-male (FTM): individuals assigned a female sex at birth who have changed, are changing, or wish to change their body and/or gender identity to a more masculine body or gender identity. FTM persons are also often referred to as *transgender men*, *transmen*, or *transmen*.

Gatekeeping: the role of psychologists and other mental health professionals of evaluating a TGNC person's eligibility and readiness for hormone therapy or surgery according to the Standards of Care set forth by the World Professional Association for Transgender Health (Coleman et al., 2012). In the past, this role has been perceived as limiting a TGNC adult's autonomy and contributing to mistrust between psychologists and TGNC clients. Current approaches are sensitive to this history and are more affirming of a TGNC adult's autonomy in making decisions with regard to medical transition (American Counseling Association, 2010; Coleman et al., 2012; Singh & Burnes, 2010).

Gender-affirming surgery (sex reassignment surgery or gender reassignment surgery): surgery to change primary and/or secondary sex characteristics to better align a person's physical appearance with their gender identity. Gender-affirming surgery can be an important part of medically necessary treatment to alleviate gender dysphoria and may include mastectomy, hysterectomy, metoidioplasty, phalloplasty, breast augmentation, orchiectomy, vaginoplasty, facial feminization surgery, and/or other surgical procedures.

Gender binary: the classification of gender into two discrete categories of boy/man and girl/woman.

Gender dysphoria: discomfort or distress related to incongruence between a person's gender identity, sex assigned at birth, gender identity, and/or primary and secondary sex characteristics (Knudson, De Cuypere, & Bockting, 2010). In 2013, the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5*; American Psychiatric Association, 2013) adopted the term *gender dysphoria* as a diagnosis characterized by "a marked incongruence between" a person's gender assigned at birth and gender identity (American Psychiatric Association, 2013, p. 453). Gender dysphoria replaced the diagnosis of gender identity disorder (GID) in the previous version of the *DSM* (American Psychiatric Association, 2000).

Gender expression: the presentation of an individual, including physical appearance, clothing choice and accessories, and behaviors that express aspects of gender identity or role. Gender expression may or may not conform to a person's gender identity.

Gender identity: a person's deeply felt, inherent sense of being a boy, a man, or male; a girl, a woman, or female; or an alternative gender (e.g., genderqueer, gender nonconforming, gender neutral) that may or may not correspond to a person's sex assigned at birth or to a person's primary or secondary sex characteristics. Because gender identity is internal, a person's gender identity is not necessarily visible to others. "Affirmed gender identity" refers to a person's gender identity after coming out as TGNC or undergoing a social and/or medical transition process.

Gender marker: an indicator (M, F) of a person's sex or gender found on identification (e.g., driver's license, passport) and other legal documents (e.g., birth certificate, academic transcripts).

Gender nonconforming (GNC): an adjective used as an umbrella term to describe people whose gender expression or gender identity differs from gender norms associated with their assigned birth sex. Subpopulations of the TGNC community can develop specialized language to represent their experience and culture, such as the term "masculine of center" (MOC; Cole & Han, 2011) that is used in communities of color to describe one's GNC identity.

Gender questioning: an adjective to describe people who may be questioning or exploring their gender identity and whose gender identity may not align with their sex assigned at birth.

Genderqueer: a term to describe a person whose gender identity does not align with a binary understanding of gender (i.e., a person who does not identify fully as either a man or a woman). People who identify as genderqueer may redefine gender or decline to define themselves as gendered altogether. For example, people who identify as genderqueer may think of themselves as both man and woman (bigender, pangender, androgyne); neither man nor woman (genderless, gender neutral, neutrois, agender); moving between genders (genderfluid); or embodying a third gender.

Gender role: refers to a pattern of appearance, personality, and behavior that, in a given culture, is associated with being a boy/man/male or being a girl/woman/female. The appearance, personality, and behavior characteristics may or may not conform to what is expected based on a person's sex assigned at birth according to cultural and environmental standards. Gender role may also refer to the *social* role in which one is living (e.g., as a woman, a man, or another gender), with some role characteristics conforming and others not conforming to what is associated with girls/women or boys/men in a given culture and time.

Hormone therapy (gender-affirming hormone therapy, hormone replacement therapy): the use of hormones to masculinize or feminize a person's body to better

align that person's physical characteristics with their gender identity. People wishing to feminize their body receive antiandrogens and/or estrogens; people wishing to masculinize their body receive testosterone. Hormone therapy may be an important part of medically necessary treatment to alleviate gender dysphoria.

Male-to-female (MTF): individuals whose assigned sex at birth was male and who have changed, are changing, or wish to change their body and/or gender role to a more feminized body or gender role. MTF persons are also often referred to as *transgender women*, *transwomen*, or *transwomen*.

Passing: the ability to blend in with cisgender people without being recognized as transgender based on appearance or gender role and expression; being perceived as cisgender. Passing may or may not be a goal for all TGNC people.

Puberty suppression (puberty blocking, puberty delaying therapy): a treatment that can be used to temporarily suppress the development of secondary sex characteristics that occur during puberty in youth, typically using gonadotropin-releasing hormone (GnRH) analogues. Puberty suppression may be an important part of medically necessary treatment to alleviate gender dysphoria. Puberty suppression can provide adolescents time to determine whether they desire less reversible medical intervention and can serve as a diagnostic tool to determine if further medical intervention is warranted.

Sex (sex assigned at birth): sex is typically assigned at birth (or before during ultrasound) based on the appearance of external genitalia. When the external genitalia are ambiguous, other indicators (e.g., internal genitalia, chromosomal and hormonal sex) are considered to assign a sex, with the aim of assigning a sex that is most likely to be congruent with the child's gender identity (MacLaughlin & Donahoe, 2004). For most people, gender identity is congruent with sex assigned at birth (see *cisgender*); for TGNC individuals, gender identity differs in varying degrees from sex assigned at birth.

Sexual orientation: a component of identity that includes a person's sexual and emotional attraction to another person and the behavior and/or social affiliation that may result from this attraction. A person may be attracted to men, women, both, neither, or to people who are genderqueer, androgynous, or have other gender identities. Individuals may identify as lesbian, gay, heterosexual, bisexual, queer, pansexual, or asexual, among others.

Stealth (going stealth): a phrase used by some TGNC people across the life span (e.g., children, adolescents) who choose to make a transition in a new environment (e.g., school) in their affirmed gender without openly sharing their identity as a TGNC person.

TGNC: an abbreviation used to refer to people who are transgender or gender nonconforming.

Trans: common short-hand for the terms transgender, transsexual, and/or gender nonconforming. Although the term "trans" is commonly accepted, not all transsexual or gender nonconforming people identify as trans.

Trans-affirmative: being respectful, aware and supportive of the needs of TGNC people.

Transgender: an adjective that is an umbrella term used to describe the full range of people whose gender identity and/or gender role do not conform to what is typically associated with their sex assigned at birth. Although the term "transgender" is commonly accepted, not all TGNC people self-identify as transgender.

Transgender man, trans man, or transman: a person whose sex assigned at birth was female, but who identifies as a man (see FTM).

Transgender woman, trans woman, or transwoman: a person whose sex assigned at birth was male, but who identifies as a woman (see MTF).

Transition: a process some TGNC people progress through when they shift toward a gender role that differs from the one associated with their sex assigned at birth. The length, scope, and process of transition are unique to

each person's life situation. For many people, this involves developing a gender role and expression that is more aligned with their gender identity. A transition typically occurs over a period of time; TGNC people may proceed through a social transition (e.g., changes in gender expression, gender role, name, pronoun, and gender marker) and/or a medical transition (e.g., hormone therapy, surgery, and/or other interventions).

Transsexual: term to describe TGNC people who have changed or are changing their bodies through medical interventions (e.g., hormones, surgery) to better align their bodies with a gender identity that is different than their sex assigned at birth. Not all people who identify as transsexual consider themselves to be TGNC. For example, some transsexual individuals identify as female or male, without identifying as TGNC. Transsexualism is used as a medical diagnosis in the World Health Organization's (2015) International Classification of Diseases version 10.

Two-spirit: term used by some Native American cultures to describe people who identify with both male and female gender roles; this can include both gender identity and sexual orientation. Two-spirit people are often respected and carry unique spiritual roles for their community.

Appendix B

Guidelines for Psychological Practice With Transgender and Gender Nonconforming People

Foundational Knowledge and Awareness

Guideline 1. Psychologists understand that gender is a nonbinary construct that allows for a range of gender identities and that a person's gender identity may not align with sex assigned at birth.

Guideline 2. Psychologists understand that gender identity and sexual orientation are distinct but interrelated constructs.

Guideline 3. Psychologists seek to understand how gender identity intersects with the other cultural identities of TGNC people.

Guideline 4. Psychologists are aware of how their attitudes about and knowledge of gender identity and gen-

der expression may affect the quality of care they provide to TGNC people and their families.

Stigma, Discrimination, and Barriers to Care

Guideline 5. Psychologists recognize how stigma, prejudice, discrimination, and violence affect the health and well-being of TGNC people.

Guideline 6. Psychologists strive to recognize the influence of institutional barriers on the lives of TGNC people and to assist in developing TGNC-affirmative environments.

Guideline 7. Psychologists understand the need to promote social change that reduces the negative effects of stigma on the health and well-being of TGNC people.

Life Span Development

Guideline 8. Psychologists working with gender-questioning and TGNC youth understand the different developmental needs of children and adolescents and that not all youth will persist in a TGNC identity into adulthood.

Guideline 9. Psychologists strive to understand both the particular challenges that TGNC elders experience and the resilience they can develop.

Assessment, Therapy, and Intervention

Guideline 10. Psychologists strive to understand how mental health concerns may or may not be related to a TGNC person's gender identity and the psychological effects of minority stress.

Guideline 11. Psychologists recognize that TGNC people are more likely to experience positive life outcomes when they receive social support or trans-affirmative care.

Guideline 12. Psychologists strive to understand the effects that changes in gender identity and gender expression have on the romantic and sexual relationships of TGNC people.

Guideline 13. Psychologists seek to understand how parenting and family formation among TGNC people take a variety of forms.

Guideline 14. Psychologists recognize the potential benefits of an interdisciplinary approach when providing care to TGNC people and strive to work collaboratively with other providers.

Research, Education, and Training

Guideline 15. Psychologists respect the welfare and rights of TGNC participants in research and strive to represent results accurately and avoid misuse or misrepresentation of findings.

Guideline 16. Psychologists Seek to Prepare Trainees in Psychology to Work Competently With TGNC People.

Suggested citation:

American Psychological Association. (2015). Guidelines for Psychological Practice with Transgender and Gender Nonconforming People. *American Psychologist*, 70 (9), 832-864. doi: 10.1037/a0039906

The Jerome N. Frank Legal Services Organization

YALE LAW SCHOOL

Via Email

November 20, 2023

Richard J. Hipolit Acting General Counsel U.S. Department of Veterans Affairs 810 Vermont Avenue NW Washington, DC 20420 richard.hipolit@va.gov

Re: Forthcoming lawsuit regarding VA delay in responding to rulemaking petition

Dear Acting General Counsel Hipolit,

We represent the Transgender American Veterans Association ("TAVA"), which is prepared to file suit on behalf of itself and its members challenging the unlawful failure of the Secretary of the Department of Veterans Affairs ("VA") to respond to its 2016 petition for rulemaking ("PFR"). TAVA intends to file a petition for mandamus under the All Writs Act, 28 U.S.C. § 1651(a), to compel a formal response from VA. We write you in your capacity as Acting VA General Counsel to raise the prospect of pre-litigation resolution of TAVA's claims.

VA currently excludes gender-confirmation surgery ("GCS") from the medical benefits package it provides to veterans. 38 C.F.R. § 17.38(c)(4); see also VHA Directive 2013-003; VHA Directive 2018-1341(3). On May 9, 2016, TAVA and two individual veterans submitted a formal rulemaking petition requesting that VA amend its medical benefits package to provide GCS (attached as Exhibit 1). The petition requested that VA amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4), that exclude medically necessary GCS for transgender veterans from the medical benefits package, and that VA instead promulgate regulations expressly including GCS for transgender veterans in that medical benefits package.

Since assuming office in 2021, Secretary McDonough has made multiple public promises that he intends to grant TAVA's petition and initiate the rulemaking it requested. After earlier litigation regarding this PFR in 2016, VA sought and received public comment on the petition in 2018. VA also submitted four notices of proposed rulemaking ("NPRM") to the Office of Information & Regulatory Affairs ("OIRA") for publication in the Unified Agenda, including as

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¹ See, e.g., Leo Shane III, VA to Offer Gender Surgery to Transgender Veterans for the First Time, MIL. TIMES (June 19, 2021), https://www.militarytimes.com/veterans/2021/06/19/va-to-offer-gender-surgery-to-transgender-vets-for-the-first-time; Rebecca Kheel, No Timeline for Trans Vet Surgeries, VA Says 2 Years After Announcing Coverage, MILITARY.COM (June 9, 2023), https://www.military.com/daily-news/2023/06/09/va-said-it-would-cover-transsurgery-two-years-later-it-still-doesnt.html; Town Hall with VA Secretary Denis McDonough, VA NEWS (Nov. 8, 2023), https://news.va.gov/125963/town-hall-with-va-secretary-denis-mcdonough-2.

² 83 Fed. Reg. 31711 (July 9, 2018).

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recently as spring 2023,³ one of which has gone through full OIRA cost-benefit analysis.⁴ In all of its submissions to OIRA's Unified Agenda, VA indicated an intended publication date for the NPRM in the Federal Register—yet failed to adhere to any of them.

Indeed, despite the public assurances and internal preparation that have recurred over the past several years, VA has not yet published a NPRM or a proposed rule in the Federal Register. It has been over seven years since TAVA first submitted the petition and over two years since Secretary McDonough first promised to take action on this matter. This inaction violates VA's statutory duties under the Administrative Procedure Act ("APA") to refrain from engaging in unreasonable delay, 5 U.S.C. § 706(1), and to conclude matters presented to it within a reasonable time, 5 U.S.C. § 555(b). TAVA is entitled to a writ of mandamus under the All Writs Act, 28 U.S.C. § 1651(a), compelling VA to formally respond to its rulemaking petition on this basis.

I. Members of TAVA are directly harmed by VA's exclusion of gender-confirmation surgery from the medical benefits package and its delay in addressing the exclusion.

VA's failure to respond to TAVA's petition harms both TAVA and its members. By failing to act on the petition for more than seven years, VA has undermined TAVA's mission of ensuring that all transgender veterans receive full services and dignified treatment at the hands of the VA, see Ex. 1 at 4, and has forced TAVA to divert its scarce resources to address the failure of VA to live up to the public pledge of its Secretary. Additionally, TAVA's members have been denied medically necessary care—which has been recommended by VA doctors, even though VA refuses to provide this treatment—as a result of VA's exclusion of "gender alterations" from the medical benefits package. See Ex. 1 at 6-7.

VA's failure to provide GCS subjects transgender veterans, including TAVA members, to increased risk of physical harm, psychological distress, and suicide. *See* Ex. 1 at 11-12, 21. GCS is effective and often essential treatment for gender dysphoria, which is the medical diagnosis for the distress caused by the incongruence between one's gender identity and one's sex assigned at birth.⁵ As major medical associations have long recognized, *see* Ex. 1 at 9,⁶ GCS is associated with significantly lower levels of psychological distress and suicidal ideation among transgender people. *See also* Ex. 1 at 11-12.⁷ This treatment is particularly important for the veteran

³ See RIN 2900-AR34, OFF. INFO. & REGUL. AFFS. (Fall 2021), https://rb.gy/ldslfb, RIN 2900-AR34, OFF. INFO. & REGUL. AFFS. (Spring 2022), https://rb.gy/kpldjc, RIN 2900-AR34, OFF. INFO. & REGUL. AFFS. (Fall 2022), https://rb.gy/6a0ozs, RIN 2900-AR34, OFF. INFO. & REGUL. AFFS. (Spring 2023), https://rb.gy/eai51e.

⁴ See OIRA Conclusion of EO 12866 Regulatory Review – RIN: 2900-AR34, OFF. INFO. & REGUL. AFFS. (Sept. 7, 2022), https://rb.gy/74ug6z [hereinafter "OIRA Review"].

⁵ See Am. Psychiatric Ass'n, *Gender Dysphoria*, in Diagnostic and Statistical Manual of Mental Disorders 451 (5th ed. 2013).

⁶ See also, e.g., Am. Med. Ass'n, Resolution 122 (A-08) (2008); William Byne et al., Report of the APA Task Force on Treatment of Gender Identity Disorder, 169 Am. J. PSYCHIATRY 1, 9 (2012); Wylie C. Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102 J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869, 3875 (2017); Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, 70 Am. PSYCHOL. ASS'N 832, 846 (2015).

⁷ See also, e.g., Anthony N. Almazan & Alex S. Keuroghlian, Association Between Gender-Affirming Surgeries and Mental Health Outcomes, 156 J. Am. Med. Ass' N 611, 617 (2021).

community, which is already at disproportionately high risk of depression and suicide. Moreover, forcing veterans to seek GCS outside of VA facilities disrupts their continuity of care, resulting in financial, physical, and emotional harm. Transgender veterans are more likely than cisgender veterans to rely on VA healthcare, since they are more likely to be uninsured and to face cost barriers to care even when they have insurance. Disruptions in the continuity of care, especially transition-related care otherwise received through VA, can have a multitude of negative effects on transgender patients. For instance, one transgender veteran who could not afford privately provided GCS in the United States had to travel out of the country to receive a cheaper operation—which was so mishandled that she has had to spend two years receiving additional procedures to correct for the harm done. 10

In addition to the harms perpetrated by VA's outright exclusion, VA's delay itself has also harmed TAVA and its members. VA has placed TAVA and its members in an unstable state of limbo, wherein they are repeatedly assured by the Secretary that VA-provided GCS will be available, but are given no indication of when nor which procedures will be covered. Transgender veterans have delayed medically necessary GCS, in reliance on the Secretary's public statements and in the expectation that they could use VA healthcare instead of expensive private treatments. But absent action from the Secretary, this waiting period may only exacerbate the mental health risks detailed above. TAVA and its members deserve an answer from VA as to when and how it plans to provide GCS to transgender veterans. At the very least, after 7.5 years, they deserve an answer from VA to their petition on the question of whether VA will provide GCS at all.

II. TAVA will challenge VA's unreasonable delay as unlawful in the Federal Circuit.

Unless prompt action is taken by VA to formally grant or deny TAVA's PFR, TAVA will file a petition for mandamus under the All Writs Act, 28 U.S.C. § 1651(a), in the United States Court of Appeals for the Federal Circuit to require VA to issue a response.

VA's nearly eight-year delay is a violation of both § 706(1) and § 555(b) of the APA, which respectively mandate that VA must not engage in unreasonable delay and that VA must resolve matters presented to it within a reasonable time. Based on application of multi-factor test set out in *Telecomms. Rsch. & Action Ctr. v. F.C.C.*, 750 F.2d 70, 80 (D.C. Cir. 1984), which governs analysis of mandamus claims based on unreasonable delay, TAVA is entitled to a writ of mandamus compelling a response from VA. First, no "rule of reason" governs VA's nearly eight-year delay on this matter. VA prepared all necessary materials, including multiple NPRMs for OIRA's Unified

⁸ See, e.g., VA OFF. MENTAL HEALTH & SUICIDE PREVENTION, NATI'L VETERAN SUICIDE PREVENTION ANNUAL REPORT 7 (2022), https://www.mentalhealth.va.gov/docs/data-sheets/2022/2022-National-Veteran-Suicide-Prevention-Annual-Report-FINAL-508.pdf (finding suicide rate for veterans is 57.3% higher than for non-veterans); Depression, U.S. DEP'T VETERANS AFFS., https://www.research.va.gov/topics/depression.cfm (reporting that 33.3% of veterans have some symptoms of depression, 20% have serious symptoms, and between 12.5% to 10% have major depression, while only 6.7% of all US adults have ever had at least one major depressive episode).

⁹ See Matthew Rae et al., Demographics, Insurance Coverage, and Access to Individuals Among Transgender Adults, KFF (Oct. 21, 2020), https://www.kff.org/health-reform/issue-brief/demographics-insurance-coverage-and-access-to-care-among-transgender-adults.

¹⁰ See, e.g., Nicole Comstock, California Veteran Shares Story of Gender Transition, FOX40 (May 11, 2015), http://fox40.com/2015/05/11/california-veteran-shares-story-of-gender-transition.

Agenda, as early as spring 2016¹¹ (shortly after TAVA filed its petition) and as recently as spring 2023.¹² VA's delay is plainly unreasonable. Second, VA's failure to respond has directly impacted human health and welfare by subjecting transgender veterans, including TAVA members, to increased risks of depression, suicide, and financial harm while denying them essential medical care. *See supra* Part I. VA's delay prejudices important interests of transgender veterans in access to the medically necessary care to which they are entitled by virtue of their service. VA provides these surgeries to cisgender veterans seeking treatment for conditions other than gender dysphoria, *see* Ex. 1 at 14, but not to transgender veterans with gender dysphoria for whom the procedures in question may be the difference between life and death. Third, responding to TAVA's petition would not delay VA actions of a higher or competing priority. The cost of publishing an already-drafted NPRM is negligible, in terms of both financial and administrative resources. And—by VA's own admission in its submissions to OIRA's Unified Agenda—the costs of the actual rule requested by TAVA are not economically significant, ¹³ meaning it does not represent a tangible tradeoff with other agency priorities. That VA has publicly indicated its support for providing GCS is immaterial to this analysis, as no bad-faith finding is required for mandamus to issue.

Absent a judicially reviewable decision by VA on TAVA's petition, mandamus is the only form of relief available to TAVA. The unreasonableness of VA's delay has only sharpened the clarity and indisputability of TAVA's right to an issuance of mandamus, which is appropriate given the high stakes of these circumstances. TAVA is entitled to a writ of mandamus from the Federal Circuit compelling VA to respond to its PFR.

III. VA must respond to TAVA's petition.

VA's failure to respond for more than seven years constitutes an unreasonable delay prohibited by the APA. This silence consigns transgender veterans who rely on VA healthcare for transition care to a liminal state wherein VA's official actions are entirely discordant with its public statements and internal preparations. VA's refusal to make these statements and preparations official is an insult to the transgender veterans who have made enormous sacrifices to serve their country and who are entitled to medically necessary healthcare, including GCS, as a result. We urge VA to issue a publication in the Federal Register constituting a formal grant or denial of TAVA's PFR. Specifically, we urge VA to grant TAVA's PFR by issuing a NPRM or proposed rule that will repeal 38 C.F.R. § 17.38(c)(4) and any implementing directives and include GCS for transgender veterans in the medical benefits package.

Please confirm your receipt of this correspondence and provide a response within 30 days, or our client will have no choice but to proceed with an enforcement action. If this matter proceeds

¹¹ See RIN 2900-A69, OFF. REGUL. & INFO. AFFS. (Fall 2016), https://rb.gy/7n9vxr; RIN 2900-A69, OFF. REGUL. & INFO. AFFS. (Spring 2016), https://rb.gy/cgmlvz.

¹² See sources cited supra note 3.

¹³ The fall 2022, spring 2022, and spring 2023 OIRA Unified Agenda submissions are classified as "Other Significant" priority, which means the rulemaking is not 'economically significant' but is considered significant by the agency." Similarly, the fall 2021, spring 2022, and spring 2023 OIRA Unified Agenda submissions are all classified as non-major, which means they are unlikely to have an economic effect of \$100 million or more. *See* sources cited *supra* note 3; *Unified Agenda: How Are The Terms on the Unified Agenda Tab Defined?*, REGULATIONS.GOV, https://www.regulations.gov/faq; *see also* OIRA Review, *supra* note 4 (clarifying that the rule is not economically significant under the definitions provided).

this litigation, TAVA reserves the right to seek additional relief and to recover attorneys' fees and costs.

We look forward to hearing from you and working towards a resolution.

Sincerely,

By: /s/ Michael Wishnie
John Baisley, Law Student Intern
Alexandra Johnson, Law Student Intern
K.N. McCleary, Law Student Intern
Sonora Taffa, Law Student Intern,
Michael J. Wishnie, Supervising Attorney
Veterans Legal Services Clinic
Yale Law School
P.O. Box 209090
New Haven, CT 06520-9090
(203) 432-4800
michael.wishnie@ylsclinics.org

cc: Richard Revesz, richard.l.revesz@omb.eop.gov; Dr. Shereef M. Elnahal, shereef.elnahal@va.gov; Brian Boynton, brian.m.boynton@usdoj.gov. Case: 24-108

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Filed: 01/25/2024



810 Vermont Avenue NW Washington DC 20420 www.va.gov/ogc

In Reply Refer To: 022

December 22, 2023

Ilona Turner Sasha Buchert Transgender Law Center 1629 Telegraph Avenue, Suite 400 Oakland, CA 94612

Dear Counsellors,

I am writing on behalf of the U.S. Department of Veteran Affairs (VA) and Secretary Denis McDonough.

On, May 9, 2016, Dee Fulcher, Giuliano Silva and Transgender American Veterans Association submitted a petition for rulemaking to repeal or amend 38 C.F.R. § 17.38(c)(4).

VA believes that Gender Affirming Care should be available to any Veteran who needs it, and VA plans to take necessary steps to expand the availability of that care to Veterans. VA announced its intentions on this matter in Summer 2021 based on the uniform recommendation of its Veterans Health Administration Governing Board and the recognized need for this care. As VA has already decided it should offer these services, VA has reviewed the 2016 petition and believes action is appropriate. Any change in VA policies or services like those that are the subject of the 2016 petition must be implemented in a manner that has been thoroughly considered to ensure that the services made available to Veterans meet VA's rigorous standards for quality health care. VA plans to act as soon as practicable to address these issues and will do so by initiating rulemaking proceedings to address issues raised in the petition.

Thank you for your attention to this matter and your advocacy on behalf of our Nation's Servicemembers and Veterans. We have sent a similar letter to each of the attorneys for the petitioners.

Sincerely yours,

Richard J. Hipolit

Deputy General Counsel for Veterans

Richard J. Hipolice

Programs Performing the Delegable Duties of

the General Counsel

Case: 24-108 Document: 2-3 Page: 156 An official website of the United States Government. Filed: 01/25/2024

The new required 'Summary'

Rulemaking Dockets.

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Agenda Stage of Rulemaking	 Each entry in the Agenda is associated with one of the following five rulemaking stages: Prerule Stage: actions agencies will undertake to determine whether or how to initiate rulemaking. Such actions occur prior to a Notice of Proposed Rulemaking (NPRM) and may include Advance Notices of Proposed Rulemaking (ANPRMs) and reviews of existing regulations. Proposed Rule Stage:* actions for which agencies plan to publish a Notice of Proposed Rulemaking as the next step in their rulemaking process or for which the closing date of the NPRM Comment Period is the next step. Final Rule Stage: actions for which agencies plan to publish a final rule or an interim final rule or to take other final action as the next step. Long-Term Actions: items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda. Some of the entries in this section may contain abbreviated information. Completed Actions: actions or reviews the agency has completed or withdrawn since publishing its last agenda. This section also includes items the agency began and completed between issues of the Agenda.
CFR Citation	The section(s) of the Code of Federal Regulations (CFR) (https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR) that will be affected by the action.
Energy Effects	An indication of whether or not the agency has prepared or plans to prepare a Statement of Energy Effects for the action, as required by Executive Order 13211 "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," signed May 18, 2001 (66 FR 28355).
Federalism Implications	An indication of whether or not the action has "federalism implications" as defined in Executive Order 13132. This term refers to actions "that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Independent regulatory agencies are not required to supply this information.
Government Levels Affected	An indication of whether or not the action is expected to affect levels of government and, if so, whether the governments are State, local, tribal, or Federal.
Included in the Regulatory Plan	An indication of whether or not the rulemaking was included in the agency's current regulatory plan published in the fall of any given year.
International Impacts	An indication of whether or not the regulation is expected to have international trade and investment effects, or otherwise may be of interest to the Nation's international trading partners.
Legal Authorities	The section(s) of the United States Code (U.S.C.) or Public Law (Pub. L.) or the Executive Order (E.O.) that authorize(s) the regulatory action. Agencies may provide popular name references to laws in addition to these citations.
Legal Deadline	An indication of whether or not the action is subject to a statutory or judicial deadline, the date of that deadline, and whether the deadline pertains to an NPRM, a Final Action, or some other action.

Major Rule	An indication of whether or not the rule is "major" under 5 U.S.C. 801 /Pub L. 104-121) Case: 24-108 Document: 2-3 Page: 158 Filed: 01/25/2024 because it has resulted or is likely to result in an annual effect on the economy of \$100 million or more or meets other criteria specified in that Act. The Act provides that the Administrator of the Office of Information and Regulatory Affairs will make the final determination as to whether a rule is major.
Priority	 An indication of the significance of the regulation. Agencies assign each entry to one of the following five categories of significance: Section 3(f)(1) Significant: As defined in Executive Order 12866 and amended by E.O 14094, a rulemaking action that will have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities The definition of an "economically significant" rule is similar but not identical to the definition of a "major" rule under 5 U.S.C. 801 (Pub. L. 104-121). (See below.) Other Significant: A rulemaking that is not "economically significant" but is considered significant by the agency. This category includes rules that the agency anticipates will be reviewed under Executive Order 12866 or rules that are a priority of the agency head. These rules may or may not be included in the agency's regulatory plan. Substantive/Nonsignificant: A rulemaking that has substantive impacts, but is neither Significant, nor Routine and Frequent, nor Informational/Administrative/Other. Routine and Frequent: A rulemaking that is a specific case of a multiple recurring application of a regulatory program in the Code of Federal Regulations and that does not alter the body of the regulation. Informational/Administrative/Other: A rulemaking that is primarily informational or pertains to agency matters not central to accomplishing the agency's regulatory mandate but that the agency places in the Unified Agenda to inform the public of the activity.
Publication Period	Specific month and year that the rulemaking action is published in the Unified Agenda.
Regulatory Flexibility Analysis Required	An indication of whether or not an analysis is required by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because the rulemaking action is likely to have a significant economic impact on a substantial number of small entities as defined by the Act.
RIN	Number assigned to each regulation that allows it to be cross-referenced with the Regulatory Agenda, a document that summarizes upcoming regulations for each Federal agency.
Small Entities Affected	The types of small entities (businesses, governmental jurisdictions, or organizations) on which the rulemaking action is likely to have an impact as defined by the Regulatory Flexibility Act. Some agencies have chosen to indicate likely effects on small entities even though they believe that a Regulatory Flexibility Analysis will not be required.
Timetable Actions	Listed by dates and citations (if available), all past steps and a projected date for at least the next step for the regulatory action. A date displayed in the form 12/00/11 means the agency is predicting the month and year the action will take place but not the day it will occur. In some instances, agencies may indicate what the next action will be, but the date of that action is "To Be Determined." "Next Action Undetermined" indicates the agency does not know what action it will take next.

Unfunded Mandates	An indication of whether or not the rule is covered by section 202 of the Unfunded Mandates Case: 24-108 Document: 2-3 Page: 159 Filed: 01/25/2024 Reform Act of 1995 (Pub. L. 104-4). The Act requires that, before issuing an NPRM likely to result in a mandate that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of more than \$100 million in 1 year, agencies, other than independent regulatory agencies, shall prepare a written statement containing an assessment of the anticipated costs and benefits of the Federal mandate.
Unified Agenda	The Unified Agenda of Federal Regulatory and Deregulatory Actions is published semiannually by the Office of Management and Budget through RegInfo.gov (https://reginfo.gov/). Some regulatory actions have corresponding data in both RegInfo.gov (https://reginfo.gov/) and Regulations.gov (https://regulations.gov) and can be cross-referenced. In these cases, the Unified Agenda information is displayed on Regulations.gov (https://regulations.gov) to improve context and searchability.

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In Reply Refer To: **00REG**



Office of the Secretary Washington DC 20420

Date: July 29, 2016

Subj: Economic Impact Analysis for RIN 2900- AP69, Removing Gender Alterations

Restriction from the Medical Benefits Package

I have reviewed this rulemaking package and determined the following.

1. This rulemaking will not have an annual effect on the economy of \$100 million or more, as set forth in Executive Order 12866.

- 2. This rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601-612.
- 3. This rulemaking will not result in the expenditure of \$100 million or more by State, local, and tribal governments, in the aggregate, or by the private sector, under the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.
- 4. Attached please find the relevant cost impact documents.

(Attachment 1): Agency's Impact Analysis, dated June 22, 2016 (Attachment 2): CFO Concurrence memo, dated July 24, 2016

Approved by:

Michael P. Shores, MSRC Acting, Director Regulation Policy & Management (00REG) Office of the Secretary

(Attachment 1)

Impact Analysis for RIN 2900 AP69/WP2015-003

Title of Regulation: Removing Gender Alterations Restriction from the Medical Benefits Package

Purpose: To determine the economic impact of this rulemaking. This impact analysis describes a cost allocation pilot for the additional services that will be provided by the rule change. This costing pilot will allow for data acquisition to improve projections of ongoing costs by utilizing actual costs for services associated with this rule change.

The Need for the Regulatory Action: Section 1710 of title 38 United States Code (U.S.C.) requires VA to "furnish hospital care and medical services which the Secretary determines to be needed" for eligible veterans. VA has established a "medical benefits package" in 38 CFR 17.38, which describes the types of medically needed care and services available for such eligible veterans, as well as certain exclusions. Services that are considered "gender alterations" are specifically excluded from being provided as part of the medical benefits package under 38 CFR 17.38(c)(4).

This rulemaking proposes to remove a restriction in Department of Veterans Affairs (VA) regulation that prohibits VA from providing medical services that are considered "gender alterations." In the past, gender dysphoria, previously referred to as transsexualism or gender identity disorder, was a disorder for which transition-related surgeries and procedures were considered treatment, but such surgeries and procedures required further research to assure their safety and reliability. Due to the prior limited knowledge about both gender dysphoria and effective transition-related procedures, surgical procedures in particular were not deemed to be medically necessary. However, increased understanding of both gender dysphoria and surgical techniques in this area have improved significantly, and surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria (e.g., American Medical Association, the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians). Additionally, recent medical research shows that gender dysphoria is a serious condition that has had severe medical consequences for certain patients if transition-related surgeries and procedures are not provided¹. In 2014, the U.S. Department of Health and Human Services (HHS) lifted its ban on transition-related care for Medicare patients.² In 2015, the Office of Personnel Management (OPM) required that insurance plans for the Federal Employees Health Benefits Program include coverage for all transition-related care.³ A new HHS rule (effective July 18, 2016) requires health care plans under the Affordable Care Act (ACA) to be inclusive of comprehensive transgender care. ⁴ This

⁴ See Section 1557 of the Patient Protections and Affordable Care Act (May 13. 2016) available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-11458.pdf



¹ See Padula, W.V. Heru, S., & Campbell, J.D. Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A cost-effectiveness Analyses (2015) J. of Gen. Intern. Medicine DOI 10.1007/s11606-015-3529-6

² See Decision No. 2576, Department of Health and Human Services, Departmental Appeals Board (May 30, 2014), available at http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.

³ U.S. Office of Personnel Management, FEHB Program Carrier Letter, Letter No. 2015-12 (June 23, 2015), *available at* https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-12.pdf.

rule change prohibits denial of health services based on gender identity, such as denying gender alteration procedures. In light of medical advances, recent research, and the standard in insurance coverage at the federal level, VA would revise its regulation to remove the prohibition on medical services that are considered "gender alterations." In this way, medical decisions would be made on a case-by-case basis; determining which procedures are medically necessary to treat gender dysphoria for the individual being treated.

VHA already provides transgender care under Directive 2013-003: Currently, VHA provides most services for transgender veterans including cross-sex hormones, psychotherapy, pre and post-operative care, including evaluations of readiness for surgical procedures and care associated with post-surgery complications.

Added benefits if "gender alteration" exclusion is removed from the Medical Benefits Package: Treatment decisions would be made by the medical team working with each unique Veteran. If this change is made, when transition-related procedures are indicated and deemed medically necessary by the treatment team, services would be provided and/or paid for by the VHA. This could include a variety of procedures that are currently disallowed (e.g., hysterectomy, penectomy, phalloplasty or metoidioplasty with urethral extension, vaginectomy, vaginoplasty, scrotoplasty, breast augmentation or reduction and reconstruction, electrolysis, facial feminization/masculinization, tracheal shave/ chondrolaryngoplasty). For ease of communication, these are described below as feminizing procedures and masculinizing procedures.

Utilization of transition-related procedures outside VHA: Very little published data exists on transgender healthcare utilization and/or costs. However, some recent research suggests that for large, civilian employers whose insurance plans offer transition-related care (including surgeries listed above), an average of .044 per thousand employees file claims for transition care annually.⁵ This means that on average, one out of every 22,727 employees file claims for transition-related care each year.⁶ This care can include any type of transition-related care, including hormones, gender counseling, surgeries, etc.

However, transgender people are over-represented in the veteran population by a factor of at least two.⁷ The over-representation of transgender people in the veteran

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⁵ See Jody L. Herman (2013), Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers (Los Angeles: Williams Institute). The .044 figure cited above was derived from data from a subset of the largest employers. ⁶ For additional research on utilization rates of transition-related care, see City and County of San Francisco and San Francisco Human Rights Commission (2007), San Francisco City and County Transgender Health Benefit; Department of Insurance, State of California (2012), Economic Impact Assessment: Gender Nondiscrimination in Health Insurance; Human Rights Campaign, (no date), Transgender-Inclusive Benefits: Medical Treatment Cost and Utilization; Jamison Green & Associates (2012), Transgender-Inclusive Health Benefits: Data for Cost Calculation. Presented by Andre Wilson of Jamison Green & Associates to the Department of Insurance, State of California, February 2012. ⁷ According to a recent report, there are an estimated 134,300 veterans who self-identify as transgender out of a total veteran population of 21,999,108. Thus, individuals who self-identify as transgender make up 0.61% of the overall veteran population, as compared to 0.3% of the nation's civilian adult population. The percent of veterans who self-identify as transgender may be .0061/.003 = 2x greater than the percent of non-veterans who self-identify as transgender. See Gary J. Gates and Jody L. Herman (2014), Transgender Military Service in the United States (Los Angeles: Williams Institute). The total population of veterans is from Table 1L: VETPOP2014 Living Veterans by Age Group, Gender, 2013-2014, available at http://www.va.gov/vetdata/Veteran Population.asp (last accessed November 28, 2014). For the percent

population can be explained by developmental theories that argue the appeal of structured environments (such as the military) during periods of identity confusion or denial. By extension, transgender individuals are twice as likely to be enrolled in the VHA as to work for civilian organizations such as the large employers from which the .044 figure was derived. Thus, the average VHA utilization rate is expected to be at least twice as high as in the civilian study.

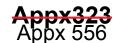
It is not known exactly how many transgender veterans use VHA services. However, using data from 2013 and the .044 figure from above, VHA can estimate that 687 unique VHA-utilizing veterans will require transition-related care. Given that transition-related care is highly individualized, it is not possible to know what aspects of care will be required for each unique veteran. Again, it is important to note that the majority of this care is already covered by VHA including hormones and gender identity counseling. Fortunately, the addition of medically necessary transition-related procedures is viewed as an event-based expense per unique veteran, rather than ongoing medical expense to the system, especially since post-operative complications and care are already covered benefits. The proposed change would add transition-related procedures deemed medically necessary by the unique veteran's VHA treatment team to the existing benefits.

We have predicted that 687 unique VHA utilizing veterans will require transition-related care each year. As a check on the validity of the estimate, consider that researchers determined recently that the number of new transgender diagnoses in the VHA system increased from 226 in 2006 to 522 in 2013. Once VHA removes its surgery exclusion, and after a period of adjustment during which VHA will meet the surgical needs of veterans who already have transgender diagnoses and who are already enrolled in the system, the annual number of VHA enrollees seeking transition-related surgery should not, in general, exceed the number of new transgender diagnoses each year.

Unadjusted annual costs of providing transition-related procedures to each unique transgender Veteran: When estimating the costs of added benefits, the figure of 687 unique veterans per year was used. In addition, while many of these veterans will not have any surgical interventions, these unadjusted projections assume that everyone will access all the services newly available to them. In this way, we offer the most conservative (highest) cost projection possible.

As with many healthcare services, determining actual costs of procedures is difficult. To generate these figures we relied on two sources: 1) For procedures not currently conducted within VHA (facial feminization procedures and electrolysis), we used recently (2013) published data on average costs of each intervention¹⁰. For these

¹⁰ From Meier SC & Lubuski CM. (2013). The demographics of the transgender population (pp. 289-327). In AK Baumle (ed), The International Handbook on the Demography of Sexuality. Springer. Because there were no VHA data on electrolysis or facial feminization, the average figures reported for these two procedures were included despite these costs being from procedures conducted in civilian clinics.



of adult Americans who self-identify as transgender, See Gary J. Gates (2011), How Many People Are Lesbian, Gay, Bisexual and Transgender (Los Angeles: Williams Institute).

 $^{^8}$ The 2013 VHA population was 7,809,269. The 687 figure was derived as follows: 2013 VHA Population/1000 * (average utilization rate per thousand civilians * transgender veteran prevalence factor), or 7,809,269/1000 * (.044*2) = 687.

⁹ Michael R. Kauth, Jillian C. Shipherd, Jan Lindsay, John R. Blosnich, George R. Brown, and Kenneth T. Jones (2014), Access to Care for Transgender Veterans in the Veterans Health Administration: 2006-2013, American Journal of Public Health 104, S4, 533.

procedures we utilized the average of costs reported for each procedure in civilian clinics. 2) Actual VHA cost data was used for procedures that are currently being performed by VHA staff for reasons other than gender transition (e.g., genital reconstruction due to blast injuries, mastectomies and breast reconstruction following a cancer diagnosis)¹¹. Data were gathered from FY2008 through Q2 of FY2015 and averaged across years. For any breast-related procedures, costs were doubled with the assumption that both breasts would be modified for transition purposes.

For these cost estimates, it was assumed that two-thirds of the 687 transgender veterans would seek feminizing procedures and one-third would seek masculinizing procedures. This assumption is based on the statistically higher number of veterans with a male birth sex (relative to female sex at birth). Thus, in these estimates we anticipate that 458 unique VHA using Veterans would receive all feminizing procedures and 229 veterans would receive all masculinizing procedures. The figures described below do not include travel that may be associated with the listed procedures.

Feminizing Procedures

Procedure	Cost per person	Unique Veterans	Unadjusted ^{Cost to VHA}
Breast augmentation ¹¹	\$10,199	458	\$4,671,142
Genital reconstruction ¹¹	\$56,019	458	\$25,656,702
Facial feminization ¹⁰	\$52,500	458	\$24,045,000
Electrolysis ¹⁰	\$2,900	458	\$1,328,200
	Per person		Unadjusted Cost Overall
Totals	\$121,618		\$55,701,044

Masculinizing Procedures

Procedure	Cost per person	Unique Veterans	Unadjusted Cost to VHA
Breast reduction/chest reconstruction ¹¹	\$15,286	229	\$3,500,494
Hysterectomy/ Genital reconstruction ¹¹	\$80,731	229	\$18,487,399

¹¹ Data was derived from the following CPT Coded procedures performed within VHA FY2008 through April FY2015. All breast procedure costs were doubled, with the assumption that the procedure would be done on both sides to facilitate transition. Costs were averaged across all procedures/years. The number of procedures included in the calculation of costs are listed below for each included code:

Per person		Unadjusted Cost Overall	
Totals	\$96,017	^{\$} 21,987,893	

Feminization procedures: Code 19325 Enlarge breast with implant (data from 147 procedures); Code 54125 Removal of penis (data from 88 procedures); Code 54520 Removal of testis (data from 1979 procedures); Code 54660 Revision of testis (data from 85 procedures); Code 54690 Laparoscopy orchiectomy (data from 15 procedures); Code 55180 Revision of scrotum (data from 24 procedures); Code 57291 Construction of vagina (data from 1 procedure); Code 57292 Construction of vagina with graft (data from 1 procedure); Code 57295 Revision of vaginal graft via vagina (data from 57 procedures); Code 57296 Revision of vaginal graft open abdomen (data from 2 procedures); Code 57426 Revision of vaginal graft laparoscopic (data from 2 procedures).

Masculinization procedures: Code 58150 Total hysterectomy (data from 2918 procedures); Code 58552 Laparoscopic vaginal hysterectomy incl T/O (data from 362 procedures); Code 58554 Laparoscopic vaginal hysterectomy incl W/T/O complete (data from 26 procedures); Code 58571 TLH W/T/O uterus 250 G or less (data from 238 procedures); Code 58573 TLH W/T/O uterus over 250 G (data from 33 procedures); Code 56625 Complete removal of vulva (data from 9 procedures); Code 56800 Repair of vagina (data from 5 procedures); Code 56805 Repair of clitoris (data from 1 procedure); Code 57110 Remove vagina wall complete (data from 2 procedures); Code 19350 Breast reconstruction (data from 5 procedures); Code 19371 Removal of breast capsule (data from 22 procedures).

There is no way to know how many unique VHA-utilizing veterans will seek and be medically cleared for these transition-related procedures. There are many personal and medical reasons why veterans may not seek or receive any or all of these procedures. However, to be conservative these unadjusted estimates assume that all of the unique 687 VHA utilizing veterans will receive all of these interventions. Using this approach, the maximum estimated per person costs range between \$96,017 and \$121,618 per veteran. If each unique veteran sought and attained every service available to them in VHA, the range of total unadjusted costs to VHA would be potentially as high as \$77,690,998 each year to include both feminizing (\$55,700,128) and masculinizing (21,990,870) procedures to 687 veterans. However, this figure assumes that every veteran would receive every possible procedure, an assumption that is highly unlikely due to the various personal and medical reasons why a veteran might not seek or receive any given procedure.

Adjusted costs of providing transition-related surgery: Using similar methodology as described above, the City and County of San Francisco estimated that offering transition-related care to its employees would cost \$1.75 million per year, but the actual cost over five years averaged \$77,283 per year. In other words, San Francisco's estimate was more than 22x too high. Therefore, in our adjusted projected costs, we have divided these figures by a factor of 22 in order to have real-world, data-driven estimates of adjusted projected costs.

Feminizing Procedures

Procedure	Potential Cost to VHA	Adjusted Costs*	
Breast	\$4,675,264	\$212,512	
augmentation			
Genital	\$25,653,496	\$1,166,068	
reconstruction			
Facial feminization	\$24,041,336	\$1,092,788	
Electrolysis	\$1,330,032	\$60,456	

¹² Jody L. Herman (2013), Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers (Los Angeles: Williams Institute), 11.

	Overall	Adjusted Cost Overall	
Totals	\$55,700,128	\$2,531,824	

^{*}Adjusted costs are divided by 22

Masculinizing Procedures

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Procedure	Potential Cost to VHA	Adjusted Costs*			
Breast	\$3,501,410	\$159,155			
reduction/chest					
reconstruction					
Hysterectomy/Genital	\$18,489,460	\$840,430			
reconstruction					
	Overall	Adjusted Cost Overall			
Totals	\$21,990,870	\$999,585			

^{*}Adjusted costs are divided by 22

Summary of Projected Costs using Unadjusted and Adjusted Projections:

F	- Y	Cost per person	Unadjusted Annual Costs	Adjusted Annual Costs
20)18	\$96,017- \$121,618	\$77,690,998	\$3,531,409

Thus, based on available data, the projected cost impact of adding these services to the Medical Benefits Package varies widely from a low of just over \$3.5 million dollars annually (\$2,531,824 Feminizing; \$999,585 Masculinizing) a high of nearly \$78 million per year. The wide variability in adjusted and unadjusted costs makes it difficult to project annual costs appropriately. As such, this proposal includes a three year cost allocation pilot to gather data on actual costs associated with this care. In this way, it will be possible to determine accurate cost allocations for care beyond the costing pilot.

Limitations of this cost projection: As with many healthcare related costs, determining the costs of associated procedures can be difficult. There were several data-driven assumptions that underlie the cost projections regarding the number of unique VHA utilizing veterans who may attain transition-related procedures. There are very few published reports or publically available data on transition-related costs. Moreover, the costs per procedure in this report were based on published data from the private sector, but are not necessarily the most current or applicable. In addition, where VHA data was used it is important to realize that the procedures were not for the purposes of gender transition but for other medical causes. Thus, even though these are the most relevant figures to generate cost estimates, it is not known how or if costs will differ for similar procedures conducted for gender transition purposes. In addition, in some cases there were only a few procedures conducted, and sometimes only one, which contributes to higher costs due to the infrequency of the procedure. These estimates were generated from the best available published data and from VHA data sources to assure the most accurate projections.

Importantly, VHA currently must pay for post-operative care and complications from transition surgeries performed outside the system. By ensuring that the entire transition process is handled within the VHA system, we have better continuity of care and better control of pricing. Many Veterans are enduring post-operative complications related to international travel from surgical centers and poor surgical care; by increasing access through VHA processes for this care these types of complications can be reduced and continuity of care will be enhanced. On more than one occasion we have learned of veterans who sought transition-related surgeries outside of the U.S. and then returned home, sitting on the surgical site for an extended airline trip. These veterans then presented to VHA emergency rooms seeking assistance. Outcomes are poorer than when there has been planned post-surgical care.

Finally, transition-related surgery has been proven effective at mitigating serious health conditions including suicidality, substance abuse and dysphoria that, left untreated, impose treatment costs on the VHA.¹³,¹⁴

Cost allocation pilot: Given the limitations of the data as described above, and the resulting wide variability in cost estimates, a three year costing pilot is being proposed with this rule change. Annual review of actual incurred costs of these added benefits will improve each successive year's budget projections. By the end of the pilot it will be possible to provide data-driven cost projections to inform future budget planning.

In the initial months of access to these procedures, techniques that are more commonly performed at many VA facilities (e.g., removal of testes or uterus) for other medical purposes (e.g., cancer treatment) will be newly available for the purposes of transition-related care, but likely accessed by only a small number of veterans for minimal costs. In FY 2018, it is anticipated that systems of referral for more complex transition-related procedures will become widely available and costs will begin to increase as veterans are referred for this care. In FY2018 we anticipate meeting the lower projected cost estimates of 3.5 million, in FY 2019 and 2020, we predict a greater demand for services from previously identified veterans and also new veterans seeking services, potentially resulting in a doubling of demand and costs.

Feminizing Procedures

Procedure	Cost per person	Adjusted cost	Unique Veterans	Adjusted Cost to VHA
Breast augmentation	\$10,199	\$464	458	\$212,512
Genital reconstruction	\$56,019	\$2,546	458	\$1,166,068
Facial feminization	\$52,500	\$2,386	458	\$1,092,788

¹³ For a review of the evidence of the efficacy of transition-related surgery, see Department of Health and Human Services Departmental Appeals Board Decision No. 2576 (May 30, 2014). For an analysis of cost savings that would be accrued by offering transition-related surgery, see Department of Insurance, State of California (2012), Economic Impact Assessment: Gender Nondiscrimination in Health Insurance, 9-12.

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¹⁴ For a review of the cost-effectiveness analysis where provider both cost per quality-adjusted life year (QUALY) for successful transition reducing negative outcomes (e.g., HIV, depression, suicidality, drug abuse, mortality) with an incremental cost-effectiveness ratio of \$9314/QUALY. Estimations are that costs of adding comprehensive transgender care (over no benefits) is \$0.016 per member per month.

Electrolysis	\$2,900	\$132	458	\$60,456
Totals				\$2,532,824

Masculinizing Procedures

Procedure	Cost per person	Adjusted cost	Unique Veterans	Adjusted Cost to VHA
Breast reduction/chest reconstruction	\$15,286	\$695	229	\$159,155
Hysterectomy/Genital reconstruction	\$80,371	\$3,670	229	\$840,430
Totals				\$999,585

Total of All Procedures FY 2018

\$3,531,409

Feminizing Procedures

Procedure	Cost per person	Adjusted cost	Unique Veterans	Adjusted Cost to VHA
Breast augmentation	\$10,199	\$928	458	\$425,024
Genital reconstruction	\$56,019	\$5,092	458	\$2,332,136
Facial feminization	\$52,500	\$4,772	458	\$2,185,576
Electrolysis	\$2,900	\$264	458	\$120,912
Totals	·			\$5,063,648

Masculinizing Procedures

Procedure	Cost per person	Adjusted cost	Unique Veterans	Adjusted Cost to VHA
Breast reduction/chest reconstruction	\$15,286	\$1,390	229	\$318,310
Hysterectomy/Genital reconstruction	\$80,371	\$7,340	229	\$1,680,860
Totals				\$1,999,170



^{*} adjusted costs divided by 22 per published results from San Francisco example

Total of All Procedures FY 2019

Total for All Procedures FY 2020 (FY 2019*3.9%)

\$7,062,818 \$7,338,268

^{*} adjusted costs for FY 2018-FY 2019 multiplied by 2 to account for potential doubling of demand

FY	Projected Costs
2018	\$3,531,409
2019	\$7,062,818
2020	\$7,338,268
Projected Costs	\$17,932,495

Estimated Impact: VA has determined that there are costs associated with this rulemaking. The costs estimated during the budget pilot from the publication of the rule through the first 3 years to be just over \$17.9 million. Annual review of actual incurred costs of these added benefits will improve each successive year's budget projections. Should demand for the services outstrip the cost allocations per year, the Under Secretary for Health has the authority to adjust budget allocations to assure access to care. This analysis sets forth the basic assumptions, methods, and data underlying the analysis and discusses the uncertainties associated with the estimates.

Submitted by:

Jillian C. Shipherd, Ph.D. and Michael R. Kauth, Ph.D. Directors, LGBT Program (10P4Y) Patient Care Service Department of Veterans Affairs June 22, 2016

(Attachment 2)

Memorandum

Department of Veterans Affairs

Date: July 24, 2016

From: VHA Chief Financial Officer (10A3)

Subj: Impact Analysis for RIN 2900-AP69, Removing Gender Alterations Restriction from the

Medical Benefits Package; Lesbian, Gay, Bisexual, and Transgender (LGBT) Program

Chief Impact Analyst, Office of Regulation Policy and Management, Office of the General

Counsel (02REG)

- 1. The VHA Chief Financial Officer concurs with the costs associated with the attached impact analysis for RIN 2900-AP69, Removing Gender Alterations Restriction from the Medical Benefits Package, LGBT Program (10P4Y). However, VHA would require additional appropriated funds to support the proposed change in regulation(s).
- 2. The VHA Chief Financial Officer concurs with the attached impact analysis to remove a restriction in Department of Veterans Affairs (VA) regulation that prohibits VA from providing medical services that are considered "gender alterations." In the past, gender dysphoria, previously referred to as transsexualism or gender identity disorder, was a disorder for which transition-related surgeries and procedures were considered treatment, but such surgeries and procedures required further research to assure their safety and reliability. Due to the prior limited knowledge about both gender dysphoria and effective transition-related procedures, surgical procedures in particular were not deemed to be medically necessary. However, increased understanding of both gender dysphoria and surgical techniques in this area have improved significantly, and surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria. Implementation of the proposal would be subject to appropriation of additional funds.
- 3. This impact analysis describes a cost allocation three year pilot for the additional services that will be provided by the rule change. This costing pilot will allow for data acquisition to improve projections of ongoing costs by utilizing actual costs for services associated with this rule change.
- 4. Questions regarding this cost analysis may be directed to Ed Bernard, Acting AsCFO, Office of Resource Management, at (202) 443-5078.

Mark Yow



DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS

FIFTH EDITION
TEXT REVISION

DSM-5-TRTM





Case: 24-108 Document: 2-3 Repage: 172 Filed: 01/25/2024

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Gender Dysphoria

In this chapter, there is one overarching diagnosis of gender dysphoria, with separate developmentally appropriate criteria sets for children and for adolescents and adults. The area of sex and gender is highly controversial and has led to a proliferation of terms whose meanings vary over time and within and between disciplines. An additional source of confusion is that in English "sex" connotes both male/female and sexuality. This chapter employs constructs and terms as they are widely used by clinicians from various disciplines with specialization in treating gender dysphoria. In this chapter, sex and sexual refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia. Disorders of sex development or differences of sex development (DSDs) included the historical terms hermaphroditism and pseudohermaphroditism. DSDs include somatic intersex conditions such as congenital development of ambiguous genitalia (e.g., clitoromegaly, micropenis), congenital disjunction of internal and external sex anatomy (e.g., complete androgen insensitivity syndrome), incomplete development of sex anatomy (e.g., gonadal agenesis), sex chromosome anomalies (e.g., Turner syndrome; Klinefelter syndrome), or disorders of gonadal development (e.g., ovotestes).

Gender is used to denote the public, sociocultural (and usually legally recognized) lived role as boy or girl, man or woman, or other gender. Biological factors are seen as contributing, in interaction with social and psychological factors, to gender development. Gender assignment refers to the assignment as male or female. This occurs usually at birth based on phenotypic sex and, thereby, yields the birth-assigned gender, historically referred to as "biological sex" or, more recently, "natal gender." Birth-assigned sex is often used interchangeably with birth-assigned gender. The terms assigned sex and assigned gender encompass birth-assigned sex/gender but also include gender/sex assignments and reassignments made after birth but during infancy or early childhood, usually in the case of intersex conditions. Gender-atypical refers to somatic features or behaviors that are not typical (in a statistical sense) of individuals with the same assigned gender in a given society and historical era; gender-nonconforming, gender variant, and gender diverse are alternative nondiagnostic terms. Gender reassignment denotes an official (and sometimes legal) change of gender. Gender-affirming treatments are medical procedures (hormones or surgeries or both) that aim to align an individual's physical characteristics with their experienced gender. Gender identity is a category of social identity and refers to an individual's identification as male, female, some category in between (i.e., gender fluid), or a category other than male or female (i.e., gender neutral). There has been a proliferation of gender identities in recent years. Gender dysphoria as a general descriptive term refers to the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender. However, it is more specifically defined when used as a diagnostic category. It does not refer to distress related to stigma, a distinct although possibly co-occurring source of distress. Transgender refers to the broad spectrum of individuals whose gender identity is different from their birth-assigned gender. Cisgender describes individuals whose gender expression is congruent with their birth-assigned gender (also nontransgender). Transsexual, a historic term, denotes an individual who seeks, is undergoing,

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or has undergone a social transition from male to female or female to male, which in many, but not all, cases also involves a somatic transition by gender-affirming hormone treatment and genital, breast, or other gender-affirming surgery (historically referred to as *sex reassignment surgery*).

Although not all individuals will experience distress from incongruence, many are distressed if the desired physical interventions using hormones and/or surgery are not available. The current term is more descriptive than the previous DSM-IV term *gender identity disorder* and focuses on dysphoria as the clinical problem, not identity per se.

Gender Dysphoria

Diagnostic Criteria

Gender Dysphoria in Children

F64.2

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):
 - 1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
 - In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
 - 3. A strong preference for cross-gender roles in make-believe play or fantasy play.
 - 4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
 - 5. A strong preference for playmates of the other gender.
 - 6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
 - 7. A strong dislike of one's sexual anatomy.
 - 8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
- B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Specify if:

With a disorder/difference of sex development (e.g., a congenital adrenogenital disorder such as E25.0 congenital adrenal hyperplasia or E34.50 androgen insensitivity syndrome).

Coding note: Code the disorder/difference of sex development as well as gender dysphoria.

Gender Dysphoria in Adolescents and Adults

F64.0

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
 - 1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).

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 A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).

- 3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
- 4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
- 5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
- 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:

With a disorder/difference of sex development (e.g., a congenital adrenogenital disorder such as E25.0 congenital adrenal hyperplasia or E34.50 androgen insensitivity syndrome).

Coding note: Code the disorder/difference of sex development as well as gender dysphoria.

Specify if:

Posttransition: The individual has transitioned to full-time living in the experienced gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one gender-affirming medical procedure or treatment regimen—namely, regular gender-affirming hormone treatment or gender reassignment surgery confirming the experienced gender (e.g., breast augmentation surgery and/or vulvovaginoplasty in an individual assigned male at birth; transmasculine chest surgery and/or phalloplasty or metoidioplasty in an individual assigned female at birth).

Specifiers

The specifier "with a disorder/difference of sex development" should be used in the context of individuals who have a specific and codable disorder/difference of sex development documented in their medical record.

The "posttransition" specifier may be used in the context of continuing treatment procedures that serve to support the new gender assignment.

Diagnostic Features

Individuals with gender dysphoria have a marked incongruence between the gender to which they have been assigned (usually based on phenotypic sex at birth, referred to as birth-assigned gender) and their experienced/expressed gender. This discrepancy is the core component of the diagnosis. There must also be evidence of distress about this incongruence. Experienced gender may include alternative gender identities beyond binary stereotypes. Consequently, distress may involve not only the experience that the individual is a male or female gender other than the one assigned at birth but also an experience that the individual is an intermediate or alternative gender that differs from the individual's birth-assigned gender.

Gender dysphoria manifests itself differently in different age groups. The following examples may be less prominent in children raised in surroundings with fewer gender stereotypes.

Prepubertal individuals assigned female at birth with gender dysphoria may express a marked, persistent feeling or conviction that they are a boy, express aversion to the idea of

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being a girl, or assert they will grow up to be a man. They often prefer boys' clothing and hairstyles, may be perceived by strangers as boys, and may ask to be called by a boy's name. Sometimes they display intense negative reactions to parental attempts to have them wear dresses or other feminine attire. Some may refuse to attend school or social events where such clothes are required. These children may demonstrate marked gender nonconformity in role-playing, dreams, gender-typed play and toy preferences, styles, mannerisms, fantasies, and peer preferences. Contact sports, rough-and-tumble play, traditional boyhood games, and boys as playmates are most often preferred. They show little interest in stereotypically feminine toys (e.g., dolls) or activities (e.g., feminine dress-up or role-play). Occasionally, they refuse to urinate in a sitting position. Some may express a desire to have a penis or claim to have a penis or that they will grow one when older. They may also state that they do not want to develop breasts or menstruate.

Prepubertal individuals assigned male at birth with gender dysphoria may express a marked, persistent feeling or conviction that they are a girl or assert that they will grow up to be a woman. They may express aversion to the idea of being a boy. They often prefer dressing in girls' or women's clothes or may improvise clothing from available materials (e.g., using towels, aprons, and scarves for long hair or skirts). These children may demonstrate marked gender nonconformity in gender-typed play and toy preferences, styles, mannerisms, and peer preferences. They may role-play female figures (e.g., playing "mother") and may be intensely interested in female fantasy figures. Traditional feminine activities, stereotypical games, and pastimes (e.g., "playing house"; drawing feminine pictures; watching television or videos of favorite female characters) may be preferred. Stereotypical female-type dolls (e.g., Barbie) may be favorite toys, and girls are their preferred playmates. They avoid rough-and-tumble play and have little interest in stereotypically masculine toys (e.g., cars, trucks). They may state that they find their penis or testes disgusting, that they wish them removed, or that they have, or wish to have, a vagina.

Increasingly, parents are presenting to specialized clinics after their child with gender

dysphoria has already socially transitioned.

As the onset of puberty for individuals assigned female at birth is somewhere between ages 9 and 13, and between 11 and 14 for individuals assigned male at birth, their symptoms and concerns may arise in a developmental phase somewhere between childhood and adolescence. As secondary sex characteristics of younger adolescents are not yet fully developed, these individuals may not state dislike of them, but they may be markedly dis-

tressed by imminent physical changes.

In adolescents and adults with gender dysphoria, the discrepancy between experienced gender and physical sex characteristics is often, but not always, accompanied by a desire to be rid of primary and/or secondary sex characteristics and/or a strong desire to acquire some primary and/or secondary sex characteristics of another gender. To varying degrees, older adolescents and adults with gender dysphoria may adopt the behavior, clothing, and mannerisms of their experienced gender. They feel uncomfortable being regarded by others, or functioning in society, as members of their assigned gender. Some adults and adolescents may have a strong desire to be of a different gender and treated as such, and they may have an inner certainty to feel and respond as their experienced gender without seeking medical treatment to alter body characteristics. They may find other ways to resolve the incongruence between experienced/expressed and assigned gender by partially living in the desired role or by adopting a gender role neither conventionally male nor conventionally female.

Associated Features

When visible signs of puberty develop, individuals assigned male at birth may shave their facial, body, and leg hair at the first signs of growth. They sometimes bind their genitals to make erections less visible. Individuals assigned female at birth may bind their breasts,

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walk with a stoop, or use loose sweaters to make breasts less visible. Increasingly, adolescents request, or may obtain without medical prescription and supervision, drugs that suppress production of gonadal steroids (e.g., gonadotropin-releasing hormone [GnRH] agonists) or that block gonadal hormone actions (e.g., spironolactone). Clinically referred adolescents often want hormone treatment and many also wish for gender-affirming surgery. Adolescents living in an accepting environment may openly express the desire to be and be treated as their experienced gender and dress partly or completely as their experienced gender, have a hairstyle typical of their experienced gender, preferentially seek friendships with peers of another gender, and/or adopt a new first name consistent with their experienced gender. Older adolescents, when sexually active, often do not show or allow partners to touch their sexual organs. For adults with an aversion toward their genitals, sexual activity is constrained by the preference that their genitals not be seen or touched by their partners. Not infrequently, adults may seek hormone treatment (sometimes without medical prescription and supervision) and gender-affirming surgery. Others are satisfied with either hormone treatment or surgery alone, or without any gender-affirming medical treatment.

In children, adolescents, and adults with gender dysphoria, an overrepresentation of autism spectrum traits has been observed. Also, individuals with autism spectrum disorder are more likely to exhibit gender diversity.

Adolescents and adults with gender dysphoria before gender-affirming treatment and legal gender change are at increased risk for mental health problems including suicidal ideation, suicide attempts, and suicides. After gender reassignment, adjustment may vary, and suicide risk and mental health problems may persist.

In prepubertal children, increasing age is associated with having more behavioral or emotional problems; this is related to the increasing nonacceptance of gender-nonconforming behavior by others. Children and adolescents who feel supported and accepted in their gender nonconformity may show less or even no psychological problems.

Prevalence

There are no large-scale population studies of gender dysphoria. Based on gender-affirming treatment–seeking populations, the prevalence for gender dysphoria diagnosis across populations has been assessed to be less than 1/1,000 (i.e., <0.1%) for both individuals assigned male at birth and individuals assigned female at birth. Because many adults with gender dysphoria do not seek care at specialty treatment programs, prevalence rates are likely underestimates. Prevalence estimates based on surveys of self-reporting general population samples in the United States and Europe suggest higher numbers, although varied methods of assessment make comparisons difficult across studies. Self-identification as transgender ranges from 0.5% to 0.6%; experiencing oneself as having an incongruent gender identity ranges from 0.6% to 1.1%; feeling that one is a person of a different sex ranges from 2.1% to 2.6%; and the desire to undergo medical treatment ranges from 0.2% to 0.6%.

Development and Course

Because expression of gender dysphoria varies with age, there are separate criteria sets for children versus those for adolescents and adults. Criteria for children are defined in a more concrete, behavioral manner than those for adolescents and adults. Young children are less likely than older children, adolescents, and adults to express extreme and persistent anatomic dysphoria. In adolescents and adults, incongruence between experienced gender and assigned gender is a central feature of the diagnosis. Factors related to distress and impairment also vary with age. A very young child may show signs of distress (e.g., intense crying) only when parents tell the child that he or she is "really" not a member of another gender but only "desires" to be. Distress may not be manifest in social environments supportive of the child's gender nonconformity and may emerge only if there is parental/

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social interference with the child's gender variance. In adolescents and adults, distress may manifest because of strong incongruence between experienced gender and birth-assigned gender. Such distress may, however, be mitigated by supportive environments and knowledge that biomedical treatments exist to reduce incongruence. Impairment (e.g., school refusal, development of depression, anxiety, peer and behavioral problems, and substance abuse) may be a correlate of gender dysphoria.

Gender dysphoria without a disorder of sex development. For clinic-referred children studied in Canada and the Netherlands, onset of gender-nonconforming behaviors is usually between ages 2 and 4 years. This corresponds to the developmental time period in which most children begin expressing gendered behaviors and interests. For some preschool-age children, both marked, persistent gender-atypical behaviors and the expressed desire to be another gender may be present, or labeling themselves as a member of another gender may occur. In other cases, the gender expression appears later, usually at entry into elementary school. Children may sometimes express discomfort with their sexual anatomy or will state the desire to have a sexual anatomy corresponding to their experienced gender ("anatomic dysphoria"). Expressions of anatomic dysphoria become more common as children with gender dysphoria approach and anticipate puberty.

No general population studies exist of adolescent or adult outcomes of childhood gender variance. Some prepubescent children expressing a desire to be another gender will not seek gender-affirming somatic treatments when they reach puberty. They frequently report nonheterosexual orientations and frequently marked gender-nonconforming behavior, although not necessarily a transgender identity in adolescence/young adulthood. Some children with gender dysphoria in childhood that remits in adolescence may experience a recurrence in adulthood.

In individuals assigned male at birth, studies from North America and the Netherlands found persistence ranged from 2% to 39%. In individuals assigned female at birth, persistence ranged from 12% to 50%. Persistence of gender dysphoria is modestly correlated with dimensional measures of severity ascertained at the time of a childhood baseline assessment. Early social transition may also be a factor in persistence of gender dysphoria in adolescence.

Studies have shown a high incidence of sexual attraction to those of the individual's birth-assigned gender, regardless of the trajectory of the prepubescent child's gender dysphoria. For individuals whose gender dysphoria continues into adolescence and beyond, most self-identify as heterosexual. In those who no longer have gender dysphoria by the time of adolescence, a majority self-identify as gay, lesbian, or bisexual.

Two broad trajectories have been described for development of gender dysphoria in individuals who identify as either male or female.

As opposed to gender-nonconforming children, individuals with *prepubertal-onset gender dysphoria* have symptoms that meet diagnostic criteria for gender dysphoria in child-hood. The dysphoria can continue into adolescence and adulthood; alternatively, some individuals go through a period in which the gender dysphoria either desists or is denied. At such times, these individuals may self-identify as being gay or lesbian. Some may identify as heterosexual and cisgender. However, it is possible that some of these individuals may experience a recurrence of gender dysphoria later in life.

Regardless of whether the individual's gender dysphoria persists or desists at a later date, either the onset of puberty or the realization that puberty will begin with development of secondary sex characteristics can prompt distressing feelings of gender incongruence that can exacerbate the individual's gender dysphoria.

The early/prepubertal-onset group often present for clinical, gender-affirming care during childhood, during adolescence, or in young adulthood. This may reflect a more intense gender dysphoria compared with individuals with late/postpubertal-onset gender dysphoria, whose distress may be more variable and less intense.

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Late-onset or pubertal/postpubertal-onset gender dysphoria occurs around puberty or even much later in life. Some of these individuals report having had a desire to be of another gender in childhood that was not expressed verbally to others or had gender-nonconforming behavior that did not meet full criteria for gender dysphoria in childhood. Others have no recollection of any signs of childhood gender dysphoria. Parents of individuals with gender dysphoria of pubertal/postpubertal-onset often report surprise, as they saw no signs of gender dysphoria during childhood.

Gender dysphoria in association with a disorder of sex development. Individuals with DSDs who require early medical intervention or decisions about gender assignment come to clinical attention at an early age. Depending on the condition, they may have been gonadectomized (often because of risk of future malignancy) before puberty so that administration of exogenous hormones is part of routine care to induce puberty. Infertility is common whether due to the condition itself or to gonadectomy, and genital surgery may have been done in infancy or childhood with the intent of affirming the assigned gender to both the affected individual and caregivers.

Affected individuals may exhibit gender-nonconforming behavior starting in early childhood in a manner that is predictable depending on the specific DSD syndrome and the gender assignment, and thresholds for supporting social and medical gender transition in minors have traditionally been much lower for those with compared to those without DSDs. As individuals with some DSD syndromes become aware of their condition and medical history, many experience uncertainty about their gender, as opposed to developing a firm conviction that they are of another gender. The proportion who develop gender dysphoria and progress to gender transition varies markedly depending on the particular syndrome and gender assignment.

Risk and Prognostic Factors

Temperamental. Gender-variant behavior among individuals with prepubertal-onset gender dysphoria can develop in early preschool age. Studies suggest that a greater intensity of gender nonconformity and an older age at presentation make persistence of gender dysphoria into adolescence and adulthood more likely. A predisposing factor under consideration, especially in individuals with postpubertal-onset gender dysphoria (adolescence, adulthood), includes history of transvestism that may develop into autogynephilia (i.e., sexual arousal associated with the thought or image of oneself as a woman).

Environmental. Individuals assigned male at birth with gender dysphoria without a DSD (in both childhood and adolescence) more commonly have older brothers when compared with cisgender males.

Genetic and physiological. For individuals with gender dysphoria without a DSD, some genetic contribution is suggested by evidence for (weak) familiality of gender dysphoria among nontwin siblings, increased concordance for gender dysphoria in monozygotic compared with dizygotic same-sex twins, and some degree of heritability of gender dysphoria. Research suggests that gender dysphoria has a polygenetic basis involving interactions of several genes and polymorphisms that may affect in utero sexual differentiation of the brain, contributing to gender dysphoria in individuals assigned male at birth.

As to endocrine findings in individuals with gender dysphoria, no endogenous systemic abnormalities in sex-hormone levels have been found in 46,XY individuals, whereas there appear to be increased androgen levels (in the range found in hirsute women but far below normal male levels) in 46,XX individuals. Overall, current evidence is insufficient to label gender dysphoria without a DSD as a form of intersexuality limited to the central nervous system.

In gender dysphoria associated with a DSD, the likelihood of later gender dysphoria is increased if prenatal production and utilization (via receptor sensitivity) of androgens are grossly variant relative to what is usually seen in individuals with the same assigned gen-

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der. Examples include 46,XY individuals with a history of normal male prenatal hormone milieu but inborn nonhormonal genital defects (as in cloacal bladder exstrophy or penile agenesis) and who have been assigned to the female gender. The likelihood of gender dysphoria is further enhanced by additional, prolonged, highly gender-variant postnatal androgen exposure with somatic virilization as may occur in female-raised and noncastrated 46,XY individuals with 5-alpha reductase-2 deficiency or 17-beta-hydroxysteroid dehydrogenase-3 deficiency or in female-raised 46,XX individuals with classical congenital adrenal hyperplasia with prolonged periods of nonadherence to glucocorticoid replacement therapy. However, the prenatal androgen milieu is more closely related to gendered behavior than to gender identity. Many individuals with DSDs and markedly gender-variant behavior do not develop gender dysphoria. Thus, gender-nonconforming behavior by itself should not be interpreted as an indicator of current or future gender dysphoria. There appears to be a higher rate of gender dysphoria and patient-initiated gender change from assigned female to male than from assigned male to female in individuals prenatally exposed to a full complement of masculinizing hormonal influences.

Culture-Related Diagnostic Issues

Individuals with gender dysphoria have been reported across many countries and cultural contexts around the world. The equivalent of gender dysphoria has also been reported in individuals living in cultural contexts with institutionalized gender identity categories other than men/boys or women/girls that sanction gender nonconforming development. These include India, Sri Lanka, Myanmar, Oman, Samoa, Thailand, and Indigenous Peoples of North America. It is unclear however, in such cultural contexts, whether the diagnostic criteria for gender dysphoria would be met with these individuals.

The prevalence of coexisting mental health problems differs among cultures; these differences may also be related to differences in attitudes toward gender nonconformity in children, adolescents, and adults. However, also in some non-Western cultures, anxiety has been found to be relatively common in individuals with gender dysphoria, even in cultures with accepting attitudes toward gender-variant behavior.

Sex- and Gender-Related Diagnostic Issues

Sex differences in rate of referrals to specialty clinics vary by age group. In children, sex ratios of individuals assigned male at birth to individuals assigned female at birth range from 1.25:1 to 4.3:1. Studies show increasing numbers of children and adolescents presenting to specialty clinics, presentation at younger ages, more frequent early social transition, and a shift to a greater number of individuals assigned female at birth in adolescents and young adults than individuals assigned male at birth. In adults, estimates generally suggest more individuals assigned male at birth seek gender-affirming treatment, with ratios ranging from 1:1 to 6.1:1 in most studies in the United States and Europe.

Association With Suicidal Thoughts or Behavior

Rates of suicidality and suicide attempts for transgender individuals are reported to range from 30% to 80%, with risk factors including past maltreatment, gender victimization, depression, substance abuse, and younger age. Transgender adolescents referred to gender clinics have substantially higher rates of suicidal thoughts and behaviors when compared with nonreferred adolescents. Prior to receiving gender-affirming treatment and legal gender reassignment, adolescents and adults with gender dysphoria are at increased risk for suicidal thoughts and suicide attempts. After gender-affirming treatment, adjustment varies, and while improvement in coexisting symptoms is often seen, some individuals continue to experience prominent anxiety and affective symptoms and remain at increased risk for suicide.

Gender Dysphoria

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A study of 572 children referred for gender identity concerns in Canada and several comparison groups (siblings, other referred children, and nonreferred children) largely from other high-income countries found that gender-referred children were 8.6 times more likely to self-harm or attempt suicide than comparison children, even after adjustment for overall behavior and peer relationship problems, and particularly in the second half of childhood. Among adolescents, the highest rate of suicide attempt is among transgender young men, followed by those defining themselves as neither male nor female.

Functional Consequences of Gender Dysphoria

Gender nonconformity may appear at all ages after the first 2–3 years of childhood and may interfere with daily activities. In older children, gender nonconformity may affect peer relationships and may lead to isolation from peer groups and to distress. Many children experience teasing and harassment or pressure to dress in attire associated with their birth-assigned sex, especially when growing up in a nonsupportive and nonaccepting environment. Also in adolescents and adults, the distress resulting from gender incongruence often interferes with daily activities. Relationship difficulties, including sexual relationship problems, are common, and functioning at school or at work may be impaired. Gender dysphoria is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of depression, suicidality, and other mental disorder co-occurrence, school dropout, and economic marginalization, including unemployment, with attendant social and mental health risks, especially in individuals who lack family or social support. In addition, these individuals' access to health services and mental health services may be impeded by structural barriers, such as institutional discomfort about, inexperience with, or hostility toward working with this patient population.

Differential Diagnosis

Nonconformity to gender roles. Gender dysphoria should be distinguished from simple nonconformity to stereotypical gender role behavior by the strong desire to be of another gender than the assigned one and by the extent and pervasiveness of gender-variant activities and interests. The diagnosis is not meant to merely describe nonconformity to stereotypical gender role behavior (e.g., "tomboyism" in girls, "girly-boy" behavior in boys, occasional cross-dressing in adult men). Given the increased openness of gender-diverse expressions by individuals across the entire range of the transgender spectrum, it is important that the clinical diagnosis be limited to those individuals whose distress and impairment meet the specified criteria.

Transvestic disorder. Transvestic disorder is diagnosed in heterosexual (or bisexual) adolescent and adult males (rarely in females) for whom women's clothing generates sexual excitement and causes distress and/or impairment without drawing their assigned gender into question. It is occasionally accompanied by gender dysphoria. An individual with transvestic disorder who also has clinically significant gender dysphoria can be given both diagnoses. In some cases of postpubertal-onset gender dysphoria in individuals assigned male at birth who are attracted to women, cross-dressing with sexual excitement is a precursor to the diagnosis of gender dysphoria.

Body dysmorphic disorder. An individual with body dysmorphic disorder focuses on the alteration or removal of a specific body part because it is perceived as abnormally formed, not because it represents a repudiated assigned gender. When an individual's presentation meets criteria for both gender dysphoria and body dysmorphic disorder, both diagnoses can be given. Individuals wishing to have a healthy limb amputated (termed by some *body integrity identity disorder*) because it makes them feel more "complete" usually do not wish to change gender, but rather desire to live as an amputee or a disabled person.

Autism spectrum disorder. In individuals with autism spectrum disorder, diagnosing gender dysphoria can be challenging. It can be difficult to differentiate potential co-occurring

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gender dysphoria from an autistic preoccupation because of the concrete and rigid thinking around gender roles and/or poor understanding of social relationships characteristic of autism spectrum disorder.

Schizophrenia and other psychotic disorders. In schizophrenia, there may rarely be delusions of belonging to some other gender. In the absence of psychotic symptoms, insistence by an individual with gender dysphoria that he or she is another gender is not considered a delusion. Schizophrenia (or other psychotic disorders) and gender dysphoria may co-occur. Gender-themed delusions may occur in up to 20% of individuals with schizophrenia. They can usually be differentiated from gender dysphoria by their bizarre content and by waxing and waning with remissions and exacerbations of psychotic episodes.

Other clinical presentations. Some individuals with an emasculinization desire who develop an alternative, nonmale/nonfemale gender identity do have a presentation that meets criteria for gender dysphoria. However, some males seek genital surgery for either aesthetic reasons or to remove psychological effects of androgens without changing male identity; in these cases, the criteria for gender dysphoria are not met.

Comorbidity

Clinically referred children with gender dysphoria show elevated levels of anxiety, disruptive, impulse-control, and depressive disorders. Autism spectrum disorder is more prevalent in clinically referred adolescents and adults with gender dysphoria than in the general population. Clinically referred adolescents and adults with gender dysphoria often have high rates of associated mental disorders, with anxiety and depressive disorders being the most common. Individuals who have experienced harassment and violence may also develop posttraumatic stress disorder.

Other Specified Gender Dysphoria

F64.8

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The other specified gender dysphoria category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording "other specified gender dysphoria" followed by the specific reason (e.g., "brief gender dysphoria," in which symptoms meet full criteria for gender dysphoria but the duration is less than the required 6 months).

Unspecified Gender Dysphoria

F64.9

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The unspecified gender dysphoria category is used in situations in which the clinician chooses *not* to specify the reason that the criteria are not met for gender dysphoria, and includes presentations in which there is insufficient information to make a more specific diagnosis.

DECLARATION OF NATALIE ROSE KASTNER

I, Natalie Rose Kastner, declare as follows:

- 1. I make this declaration based on personal knowledge, and, if called as a witness, I could and would testify competently to the matters stated herein.
- 2. I am a veteran of the United States Army. I served as Combat Engineer (21B) from 2006 to 2008. I completed basic training at Fort Leonard Wood, Missouri, after which I was stationed at Fort Drum, New York. During my time in service, I was promoted from Private (E-1) to Private First Class (E-3). I was honorably discharged for medical reasons.
- 3. I am a transgender woman. I am a member of the Transgender American Veterans Association ("TAVA"). I joined the organization in 2022.
- 4. I live in Texarkana, Texas. I have three children who reside with their mother, also in Texas.
- 5. In March 2022, I was diagnosed with gender dysphoria by Dr. Mark J. Starr, a Veteran Health Administration ("VHA") provider at the Southern Arizona Veterans Affairs ("VA") Health Care System. Since July 2022, I have been undergoing hormone replacement therapy ("HRT") under the care of Dr. Shristi Lamichhane at the Overton Brooks VA Medical Center.
- 6. I have no medical training, besides the U.S. Army Combat Lifesaver Course that I completed during my time in service. Nevertheless, knowing that gender-confirmation surgery was not available from VA and was prohibitively expensive otherwise, I removed my right testicle at home on March 5, 2022, out of desperation. I did so without anesthesia. While

¹ My legal name is Joshua Nathanial Kastner, but until I succeed in changing my name legally, I use the preferred name Natalie Rose Kastner.

removing my testicle, I severed an artery, which could have killed me. I did not intend suicide; I intended to correct my body.

- 7. I drove myself to the nearest hospital emergency room. There, I received life-saving medical care.
- 8. I cannot imagine how many transgender women, without access to adequate medical care, have taken matters into their own hands and died. I am grateful that I am alive to share my story.
- 9. I informed the VA Texarkana Outpatient Clinic of my life-threatening incident in March 2022.
- 10. In Summer 2023, I asked my primary care physician at the VA Texarkana Outpatient Clinic, Dr. Mary O. Mbonu, about receiving gender-confirmation surgery. Dr. Mbonu referred me to VHA Directive 1341(3), which states "VA does not provide gender confirming/affirming surgeries in VA facilities or through non-VA care." Because I am facially ineligible and so it would be futile to request the treatment, I have not formally requested gender-confirmation surgery at VA.
- 11. If I had access through VA, I would pursue gender-confirmation surgery, including orchiectomy, vaginoplasty, and electrolysis.
- 12. I am currently not enrolled in civilian health insurance, so VA is my sole health care provider.
- 13. I have repeatedly attempted to access gender-confirmation surgery through civilian health insurance—including Blue Cross Blue Shield, Cigna, and the Health Insurance Marketplace—to no avail. I was formerly enrolled in the Blue Cross Blue Shield Medicare Advantage plan. Despite my best efforts, Blue Cross Blue Shield representatives informed me

that the insurance would not cover gender-confirmation surgery in the state of Texas. I understand that under Texas policies, gender-confirmation surgery is considered an elective surgery, and Blue Cross Blue Shield Medicare Advantage will cover only gender-confirmation surgery that is deemed "medically necessary."

- 14. I cannot afford to pay for gender-confirmation surgery out of pocket. Having consulted with various providers, I estimate that gender-confirmation surgery would cost, at a minimum, \$60,000. I am disabled and unable to work; I have a 70% VA disability rating. I rely on my VA disability compensation and Social Security benefits to live. I simply do not have the funds to access gender-confirmation surgery without insurance coverage.
- 15. As a result, I have been forced to consider relocating to a state, such as Illinois, where my gender-confirmation surgery might be covered by the Blue Cross Blue Shield Medicare Advantage plan. Such a move would be deeply painful and disruptive. I love my town and I have found a supportive community here. I love living in the same state as my children. But VA's delay in providing gender-confirmation surgery forces me to choose between necessary medical care and my children, friends, and family. It is an impossible choice.
- 16. VA's refusal to provide gender-confirmation surgery not only exacerbates my gender dysphoria, but also risks worsening my Type 2 diabetes. Without an orchiectomy, I continue to have a testis, which produces testosterone. To block that testosterone and manage my gender dysphoria, I must take spironolactone. Unfortunately, spironolactone can increase hemoglobin A1C and decrease kidney function. My lab results show that my kidney function went from normal (Stage G1) in March 2023 to Mild Decrease (Stage G2) in January 2024.
- 17. On March 10, 2023, I conveyed my concern about the impact of spironolactone on my diabetes in an appointment with Dr. Mbonu. Dr. Mbonu referred again to VA Directive

1341(3) and stated that the VA could not provide me with an orchiectomy. She also stated that,

because my kidneys did not show dangerously reduced function, there was no reason for her to

refer me for an orchiectomy.

18. It is difficult to put into words how profoundly and negatively I am affected by

the VHA's policy of denying gender-confirmation surgery to people like me. Every day that the

VA delays its response to TAVA's petition, I grapple with feelings of despair. I am trapped in a

state of limbo that daily damages every aspect of my life, from my physical and mental health to

my ability to sustain family relationships. I often regret not removing my second testicle that

night in March 2022, even though I know it may have killed me. I feel that I am left with no

viable options to live a full and dignified life.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true

and correct to the best of my information and belief.

Dated.

18/Jan /2024

Natalie Rose Kastner (Joshua

Nathanial Kastner)

DECLARATION OF RAY GIBSON

I, Ray Gibson, declare as follows:

1. I make this declaration based on personal knowledge, and, if called as a witness, I

could and would testify competently to the matters stated herein.

2. I am a veteran of the United States Air Force. I served as Data Processing Specialist

from 1978 to 1981. I was stationed at the Sunnyvale (Onizuka) Air Force Station. During my time

in service, I was promoted from Airman Basic (E-1) to Airman First Class (E-3). I also received

an Airman of the Quarter award. I was honorably discharged.

3. I am a Black transgender man, and I am a member of the Transgender American

Veterans Association ("TAVA").

4. I am 66 years old, and I live in the Atlanta, Georgia metro area.

5. I knew that I was transgender when I was six years old. I told my cousins that I

joined the service to become a better man.

6. While in the Air Force, I did not identify as transgender. I did not know the words

to describe myself at that time, and I did not know that there were people like me that existed. I

felt that I had to hide my identity to remain in military service.

7. I spoke with my primary care provider, Dr. Subha Parchuri, about being transgender

in 2014. I was diagnosed with gender dysphoria that same year at the Lawrenceville U.S.

Department of Veterans Affairs ("VA") Clinic. Since October 2015, I have been undergoing

hormone replacement therapy under the care of Dr. Vin Tangpricha at the Atlanta VA Medical

Center ("VAMC").

8. After service, I worked my way up to being a software consultant without a college degree. In 2006, I received a Bachelor of Arts in Information Technology from American Intercontinental University Online.

- 9. I retired in 2001 for health reasons. I am disabled and unable to work. I have depression, high blood pressure, chronic obstructive pulmonary disease, and kidney disease. Since 2003, I have also required a cane and sometimes a walker to walk due to neuropathy in my toes.
- 10. I receive disability compensation benefits from the VA, which has assigned me a 90% disability rating. I also have a 100% Social Security benefit rating.
- 11. In 2017, I asked my endocrinologist at the Atlanta VAMC about accessing mastectomy surgery. He informed me that I may be eligible for a mastectomy because there is a history of breast cancer in my family. But the VA would not cover the cost of tests that a living relative with breast cancer would need to undertake. I did not feel comfortable asking my only living relative with breast cancer to undertake these tests out of pocket, so that I might be eligible for a mastectomy.
- 12. I have always been and will always be my own advocate, but I am tired. I am exhausted by the challenges of being my own advocate. I am tired of fighting for the care that I so desperately need and deserve.
- 13. In 2021, I was forced to access mastectomy surgery outside of VA. VA is my sole health care provider. Without civilian health insurance, I had to cover the cost of my surgery and associated costs entirely out-of-pocket. My surgery cost over \$8,000. I also covered the cost of my travel from Georgia to Dallas, Texas, in addition to my one week stay at a hotel to recover from surgery.

14. I am not satisfied with the results of my mastectomy. Even though the VA covers post-operative care per Veterans Health Administration ("VHA") Directive 1341(3), I have yet to be able to access this care through Atlanta VAMC Community Care. VA staff, in my experience, are unsure what qualifies as eligible care under VHA Directive 1341(3). Being denied post-operative care at the Atlanta VAMC has been humiliating. Every day that I am denied post-operative care, I feel dehumanized by VA staff.

- 15. In addition to being denied post-operative care, I have been unable to access other VA-covered gender-affirming care at the Covington VA Clinic. The Covington VA Clinic is about five minutes away from my house, but I have been told by staff there that they do not treat transgender patients. I am forced to access some gender-affirming care at a civilian health clinic nearby, and drive over an hour away to the Lawrenceville VA Clinic to access all remaining care.
- 16. If I had access through VA, I would pursue additional gender-confirmation surgery, including phalloplasty. I also desire post-operative care for my mastectomy.
- 17. Because I am facially ineligible and so it would be futile to request the treatment, I have not formally requested phalloplasty at VA. As I live on a fixed income, it is currently impossible for me to save enough money to ever be able to afford phalloplasty out of pocket. I have been homeless several times in my life. To survive these periods of homelessness, I used up my entire life savings. Every year, I apply for public scholarships to help cover the cost of phalloplasty surgery. I believe that this surgery would cost me around \$250,000.
- 18. Not being able to access bottom surgery has negatively affected my entire life, from my standard of living to my dating life. If the VA does not provide access to gender-confirmation surgery, then people like me will be destined to a life of dysphoria. My gender dysphoria is suffocating.

19. I am old. I am racing against the ticking clock of my own health and age. Recovering from surgeries only gets harder and harder as I get older. The primary surgery I am interested in accessing, phalloplasty, requires multiple surgeries and long recovery periods. I fear that I will soon be too old to safely undergo this life-saving surgery.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

Dated: 01/20/2024

Ray Sibson

DECLARATION OF REBEKKA ESHLER

I, Rebekka Eshler, declare as follows:

1. I am the National President and a current board member of the Transgender American Veterans Association ("TAVA"). I have personal knowledge of the matters stated in this declaration and could and would so testify if called as a witness.

2. I am a veteran of the United States Army. I was stationed at Joint Base Elmendorf-Richardson in Anchorage, Alaska. I served as a Forward Observer from 2012 to December 2015. I was honorably discharged.

3. After my discharge, I received a Bachelor of Arts from University of Alaska Anchorage ("UAA"). At UAA, I served as the Student Veterans of America Chapter President and volunteered for an organization that provides medical response to natural disasters and humanitarian crises around the world.

- 4. Since 2019, I have worked as an Emergency Medical Technician ("EMT") at a homeless shelter in Alaska. In 2022, I was crowned Miss Trans Alaska. I went on to represent the State of Alaska at the Miss Trans USA 2022 pageant where I won Miss Congeniality.
- 5. During my service, I did not identify as transgender. I now believe that part of the reason I went into the military was to prove myself to friends and family who doubted my identity. In the Summer of 2018, I was diagnosed with gender dysphoria by Dr. Camilla Madden at the Anchorage U.S. Department of Veterans Affairs ("VA") Medical Center. Since September 2018, I have been undergoing hormone replacement therapy under the care of several different providers at the Anchorage VA Medical Center.
- 6. In 2019, knowing that VA did not cover gender-confirmation surgery, I asked for a referral letter for facial feminization surgery from the nurse at the Anchorage VA Medical Center

who oversaw my hormone therapy. She supported my decision to access facial feminization surgery outside of the VA, but she did not believe that she was authorized under Veterans Health Administration ("VHA") Directive 1341(3) to refer me for gender-confirmation surgery. I was forced to pay for a non-VA provider, whom I did not regularly see, to write a referral letter for facial feminization surgery.

- 7. I have been involved in TAVA since 2021, when I joined TAVA's board as the Director of Strategic Partnerships and Collaborations. In August 2022, I was elected President. My duties include building coalitions with other advocacy groups, developing relationships with organizations and individuals that align with our mission, influencing policy at VA, and setting public policy goals to assist transgender veterans. My duties also include recruiting, growing, and mentoring our membership, and providing support and outreach to transgender veterans on a range of issues, including accessing health care and changing identity documents.
- 8. TAVA is a 501(c)(3) organization that was founded in 2003 to advocate on behalf of transgender veterans within the VHA system. As one of the only national organizations focused exclusively on advocating on behalf of transgender veterans, TAVA is a leading voice and source of information for the transgender veteran community. Its mission is to work with VA, Congress, veterans, active-duty military personnel, and other veteran and LGBTQ advocacy groups to influence VA policy, regulations, and procedures regarding the provision of health care to veterans with gender dysphoria and to ensure that transgender veterans receive necessary and appropriate care. While TAVA primarily focuses on ensuring the fair and equal treatment of transgender individuals, it is committed to improving the health care of all American veterans.
- 9. TAVA's advocacy goals include: assisting veterans in navigating the VHA system, improving the quality and breadth of health care and other services provided to transgender service

members through VA, helping veterans correct name and gender information on military records, engaging in veteran suicide prevention efforts, and addressing transgender veteran homelessness, among other goals. TAVA also works with transgender individuals to assist them in securing VA benefits for themselves and their spouses and family. TAVA works towards these goals by educating VA as well as serving as a liaison between transgender veterans and VA to raise members' issues with staff and to connect members to appropriate resources.

- 10. TAVA has spent considerable time and resources on educating veterans, policymakers, and others about the exclusion of medically necessary gender-confirmation surgery from VA's medical benefits package, and on addressing the needs of transgender veterans affected by this exclusion. For example, we have produced educational materials for transgender veterans about the gender-affirming care that VA provides and its exclusion of coverage for gender-confirmation surgery. We have also prepared educational reports that include discussion of the harms caused by the surgery exclusion and sponsored community gatherings to discuss strategies to end this exclusion.
- 11. We have also spent considerable time and resources due to VA's delay in addressing TAVA's 2016 rulemaking petition regarding gender-confirmation surgery. For instance, TAVA prepared a comment to submit during the notice-and-comment period it anticipated would timely follow Secretary McDonough's 2021 promises that VA would provide gender-confirmation surgery. TAVA leadership also traveled to and engaged in meetings about how to implement this change to the medical benefits package. But these efforts have been futile thus far, as VA has failed to follow through on Secretary McDonough's assurances.
- 12. In my roles as TAVA's Director of Strategic Partnerships & Collaborations and now President, I have communicated with veterans across the country about the VA's exclusion

of gender-confirmation surgery and how it affects them. Our Board members have also spoken with national news outlets in an effort to educate the public about the VA's exclusion of gender-confirmation surgery and to call for reform.

- 13. TAVA has approximately 5,400 members throughout the country who have joined our mission through social media and, even though a significant percentage of those members are low-income, have volunteered time and resources to help the organization achieve its goals.
- 14. According to recent estimates, TAVA represents the interests of an estimated 163,000 transgender veterans of the U.S. Military.
- 15. Many of TAVA's members are transgender veterans currently enrolled at the VA. Some of those individuals have been diagnosed with gender dysphoria by VA and have been provided medical care related to their diagnosis. However, some members who have sought gender-confirmation surgery through VA, or coverage of such surgery by VA, have been denied such surgery or coverage because of the existing regulatory exclusion of "gender alterations" from covered benefits. Indeed, in every year from 2016 to 2023, multiple TAVA members have been denied gender-confirmation surgery by VA. Many of those veterans rely on the VA for the provision of their physical and mental health care, and many satisfy all the medical prerequisites for gender-confirmation surgery: they have been diagnosed with gender dysphoria (often by VA clinicians), they have spent multiple years living in a gender role consistent with their gender identity and are currently undergoing hormone therapy to assist in their transition, and they have been prescribed gender-confirmation surgery by qualified medical providers as medically necessary treatment for their condition. Nevertheless, these veterans have been unable to obtain medically necessary gender-confirmation surgery due to the VA's categorical exclusion of this surgery from its medical benefits package.

16. In submitting this petition, TAVA advocates on behalf of its members whose

mental and physical health daily deteriorates while waiting for medically necessary treatment as a

result of the VA's delay. Without a response, TAVA members are left in a state of limbo, unable

to make important life plans. Relying on the VA's repeated assurances that it plans to provide

gender-confirmation surgery, veterans are hesitant to upend their lives, families, and finances in

an attempt to access such surgery through alternative means. Some TAVA members are

considering leaving their families and moving to a different state, where their civilian health

insurance might cover gender-confirmation surgery. Other TAVA members are facing the

impossible prospect of draining their life savings or going into debt to pay for gender-confirmation

surgery out of pocket. If the VA were to formally respond, one way or another, TAVA members

would be able to plan to access this medically necessary care.

17. Many TAVA members have been prescribed, and desire to receive, medically

necessary transition-related surgeries, but the VA's delay in providing a formal response to the

rulemaking petition has prevented them from making plans to receive this care. Many TAVA

members have experienced and continue to experience extreme and sometimes life-threatening

hardships because they still have not obtained coverage for these health care services that their

doctors deem to be medically necessary.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true

and correct to the best of my information and belief.

Dated:

01/20/2024

Rebekka Eshler

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