

A PATH TO PATIENT- CENTERED DIGITAL HEALTH REGULATION

Solomon Center for Health Law and Policy
Yale Law School

Strathmore Health Strategy

July 2021

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EXECUTIVE SUMMARY

The use of digital health applications – sometimes called mobile health applications or mHealth – has increased dramatically in recent years. These applications provide patients with a range of health care services – from diagnosing atrial fibrillation to tracking changes in moles to providing guidance on nutrition and wellness. Digital health applications thus far have been subject to limited regulatory oversight, with many digital health applications receiving little to no review by the Food and Drug Administration prior to going on the market.

The existing regulatory pathways do not take into account the iterative nature of digital health applications, limiting their appropriateness in the digital health context. This project has identified four key limitations in many currently available digital health applications that must be included and addressed in future digital health regulatory reform.

DIGITAL HEALTH ACCURACY:

The accuracy of digital health applications is generally not rigorously evaluated or regulated. Many digital health applications contain inaccurate information or produce inaccurate outputs, potentially leading to unsafe outcomes for patients. Patients value accuracy in digital health applications but are not necessarily able to assess this themselves, making it even more important that regulators step in to monitor and validate the safety, effectiveness, and accuracy of digital health applications. ***Digital health applications must be accurate, reviewed for accuracy, and disclose areas of inaccuracy.***

DIGITAL HEALTH USABILITY:

Patient usability of digital health applications is a key factor in patient uptake and patient outcomes. However, many digital health applications are not designed in a way to promote patient usability – making it difficult for patients to take necessary health measurements, lacking important notification features, lacking interoperability with electronic health records and other digital health applications, or presenting information in a confusing way. Accuracy of digital health applications can be undermined by challenges to patient usability and interpretation. ***Digital health applications must be usable and understandable for patients.***

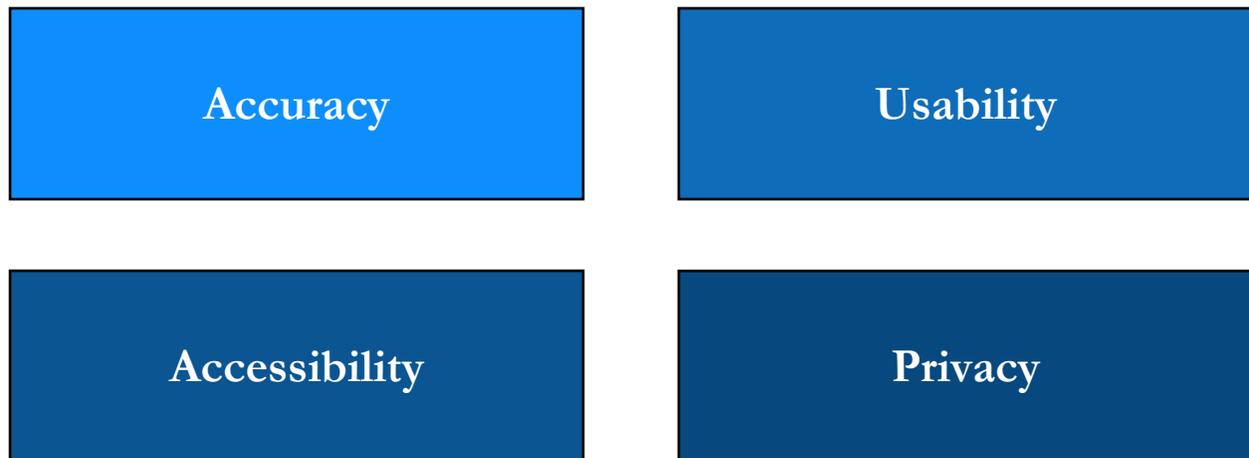
DIGITAL HEALTH ACCESSIBILITY:

Digital health applications have the potential to increase access to health care services to many populations, but also risk exacerbating existing health disparities and leaving out certain populations. To ensure accessibility, a diverse group of patients from the target populations should be involved in the development and review of digital health applications. The specific needs of people of color, people with disabilities, children, and the elderly, among other populations, must be taken into account to ensure a safe and effective digital health application for these subgroups and for all patients. ***Diverse patient needs must be included in the development and review of digital health applications to promote accessibility for all patients.***

DIGITAL HEALTH PRIVACY:

Digital health applications entail major privacy and security concerns. While these applications collect patients' health information, the majority of digital health applications are not subject to most federal and state privacy regulations. These privacy and security risks are illustrated by the numerous health data breaches in recent years. Further, many patients are unaware that this personal information is collected, mined, and used by non-health-related stakeholders with divergent interests. *Patients' private information must be protected and patients must be able to opt in and out of key privacy options.*

Moving forward, lawmakers, patient advocates, and application developers should develop reforms to make these principles a reality and to achieve patient-centered digital health regulation.



About The Project

The **Solomon Center for Health Law and Policy at Yale Law School** in partnership with **Strathmore Health Strategy** led this interdisciplinary study of the regulation of digital health applications in the United States.

Research was conducted by Ryan Knox, Senior Research Fellow at the Solomon Center for Health Law and Policy at Yale Law School; Cara Tenenbaum, Principal at Strathmore Health Strategy; and nineteen Solomon Center Student Fellows from Yale's medical, business, public health, and law schools in Fall 2020 and Spring 2021. This research identified studies in key areas of digital health research to develop the policy priorities and recommendations set forth in this Policy Paper.

On March 18, 2021, the Solomon Center for Health Law and Policy hosted a patient-group stakeholder meeting, which was attended by representatives of eight organizations advocating for a range of different disease areas. Initial findings were presented for feedback and input, and the preliminary recommendations were modified based on patient group feedback.

INTRODUCTION

The use of digital health applications – sometimes called mobile health applications or mHealth – has increased dramatically in recent years. These applications provide patients with a range of health care services and serve multiple functions within the healthcare system, including diagnosis, acute event detection, health recommendations and advice, self-monitoring and symptom tracking, and treatment. Some applications provide diagnoses for atrial fibrillation, track changes in moles and menstrual cycles, help identify changes in users’ mental health, or provide guidance on nutrition and wellness.

Overall, digital health applications provide three main services to patients: health information, diagnosis, and interventions. Each of these services empower patients to take control of their health and enhance patient autonomy. However, digital health applications, without regulation or the involvement of healthcare professionals, may pose risks to patients. Misdiagnosis or incorrect health recommendations may result in unnecessary healthcare or unsafe healthcare decision-making.

Digital health applications thus far have been subject to limited federal regulatory oversight. Currently, the Food and Drug Administration (FDA) regulates digital health applications differently based on the level of risk they pose to patients. Applications that integrate closely with medical devices and those that treat or diagnose disease are more closely regulated while those that pose less risk are largely subject to FDA’s enforcement discretion. As such, many digital health applications that patients use have little FDA review prior to going on the market.

Further, none of the existing regulatory pathways take into account the iterative nature of digital health applications, limiting their appropriateness in the digital health context. This regulatory scheme has had limited success in providing patients with and incentivizing the development of safe and effective digital health applications. Reform is needed to address these limitations and promote the development of and patient access to high quality digital health applications.

Other groups have previously recognized these limitations and have proposed guidelines for the development of digital health applications. For example, in 2016, the American Medical Association, the American Heart Association, DHX Group, and the Healthcare Information and Management Systems Society collaborated to found a group, known as Xcertia, “dedicated to improving the quality, safety, and effectiveness of mobile health applications.” Xcertia released proposed guidelines for the safe use of digital health applications covering five target areas: operability, privacy, security, content, and usability.¹ These guidelines focused on best practices for digital health application developers in order to protect patients and inform users of important information and risks associated with the particular digital health application.

This project expands upon this and other work in the digital health space by centering the patient perspective in advocating for reforms in the development and regulation of digital health applications. In particular, this project has identified four key limitations in digital health applications – hereinafter

¹ See XCERTIA, XCERTIA MHEALTH APP GUIDELINES (August 2019), <https://www.himss.org/sites/hde/files/media/file/2020/04/17/xcertia-guidelines-2019-final.pdf>.

called the “principles” – that must be included and addressed in any future digital health regulatory reform. These four principles indicate challenges in the current incentives for digital health application developers and a lack of patient-focus in digital health application. Further, these principles outline a framework of priorities for patient-digital health regulation reform.

First, many digital health applications are not accurate, containing incorrect, incomplete, or unsafe information. Further pre-market research, testing, and review are needed to confirm the accuracy of digital health applications and ensure their safety and effectiveness for patients. **Second, many digital health applications are not designed in a way to promote patient usability.** This undermines both accuracy of the digital health application when used by patients and the patient uptake of digital health applications in the first place. **Third, digital health applications are not accessible for diverse populations.** Diverse patient needs must be included in the development and review of digital health applications to promote accessibility for all patients. **Fourth, many digital health applications do not adequately protect the privacy of patients’ personal information.** Additional steps must be taken to ensure the privacy and security of patients’ information so that digital health applications do not put patients at risk. Reform is needed to recalibrate these regulations and incentives and provide patients with safe, effective, and high-quality digital health applications.

This project outlines steps towards **patient-centered digital health regulation.** The current organizations involved in the digital health regulatory program (in particular the negotiation of the Medical Device User Fee Amendments) are mostly technology companies, including drug and device companies that have digital health products. Very few provider or patient groups are involved. We hope the principles, priorities, and recommendations set forth in this Policy Paper can support lawmakers in reforming the regulation of digital health application where the focus of consideration is on the patient – often the end-user of digital health applications.

There is currently significant political and public support for digital health – in particular, the founding of the FDA’s new Digital Health Center of Excellence in September 2020² and the surge of digital health and telehealth use during the COVID-19 pandemic.³ Further, some digital health companies have recently expressed a desire for more clarity in the FDA regulation of digital health applications. A recent article cited Pear Therapeutics’ desire for additional review and regulation to give patients

² *FDA Launches the Digital Health Center of Excellence*, U.S. FOOD & DRUG ADMIN. (Sept. 22, 2020), <https://www.fda.gov/news-events/press-announcements/fda-launches-digital-health-center-excellence>.

³ See Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, *Seminar Series: COVID-19 and the Law: The Health Care System in the Age of COVID-19*, YOUTUBE (Apr. 1, 2021), <https://www.youtube.com/watch?v=ODVqz6QGLiw> (Ryan Knox discussing telehealth in the COVID-19 pandemic); *Mobile Health (mHealth) Market To Reach USD 311.98 Billion By 2027 | Reports and Data*, GLOBAL NEWSWIRE (Apr. 28, 2020), <https://www.globenewswire.com/news-release/2020/04/28/2023512/0/en/Mobile-Health-mHealth-Market-To-Reach-USD-311-98-Billion-By-2027-Reports-and-Data.html> (describing increase in digital health application demand and use); ORHCA, COVID-19: DIGITAL HEALTH TRENDS & OPPORTUNITIES FOR 2021: ANALYSIS OF DIGITAL HEALTH USAGE FROM JANUARY 2020 TO JANUARY 2021 (2021), https://www.orchac.co.uk/media/1746/covid_report_jan_2021_final-version.pdf (finding an increase in digital health application downloads from January 2020 to January 2021).

and providers alike “the ability to differentiate validated, effective digital therapeutics from other apps, including general wellness or unvalidated products.”⁴

It is especially important now to revisit and reform the current digital health regulatory framework. There are several ways reform could be enacted. FDA can release guidance documents or new rules governing the regulation of digital health applications. Congress also has opportunities to make change. The current MDUFA expires September 30, 2022. The new MDUFA is a must-pass bill and will contain many policy riders which could also reform digital health regulation. Even so, future and ongoing reform of this rapidly developing area of health technology innovation will be needed to protect patients.

This Policy Paper discusses the challenges and limitations of the current regulation of digital health applications and proposes a path forward to achieving digital health regulation centered on patient needs and access.

The first part of this Policy Paper provides an introduction to the current landscape of the digital health market and digital health regulation. The first section, **The Digital Health Market**, identifies the key players in the digital health application market, the key health and disease areas for which digital health applications exist, and notable digital health applications. The second section, **Digital Health Regulation**, details the current regulatory landscape for digital health applications, focusing on regulation by the FDA and the Federal Trade Commission (FTC).

The second part of this Policy Paper, **Digital Health Challenges**, introduces the four principles of digital health regulation identified by this project and provides recommendation for reform to address each of these principles. The first section, **Digital Health Accuracy**, explains the current limitations in the accuracy of digital health applications advocates for regulations to promote and review the accuracy of digital health applications. The second section, **Digital Health Usability**, presents the limitations in the design of digital health applications which have affected patient uptake and patient outcomes and recommends reforms to improve the quality of digital health applications. The third section, **Digital Health Accessibility**, identifies the potential for digital health applications to exacerbate existing health disparities and highlights the need for diverse patients to be included in the development and review of digital health applications. The fourth section, **Digital Health Privacy**, describes the privacy and security concerns and risks associated with digital health applications and argues for regulations to protect patient privacy and enhance patient’s ability to protect their personal information.

This Policy Paper ultimately concludes with **Conclusions and Policy Recommendations**, setting forth steps that lawmakers and policymakers should take to create patient-centered digital health regulations that will promote the principles of accuracy, usability, accessibility, and privacy.

⁴ Katie Palmer, *Digital therapeutics startups are ready for more regulation, not less*, STAT NEWS (Mar. 22, 2021), <https://www.statnews.com/2021/03/22/digital-therapeutics-fda-regulation/>.

DIGITAL HEALTH MARKET

The Digital Health Market Landscape

The digital health market has been growing in recent years. In 2017, the global digital health market was projected to reach \$46.2 billion by 2021.⁵ The COVID-19 pandemic, and the related increase in digital health and telehealth adoption, has increased this figure significantly and spurred significant investment in digital health.⁶ More recent studies have estimated that the global digital health market will grow to \$206.1 billion by 2026⁷ and \$311.98 billion by 2027.⁸ In the first quarter of 2021 alone, there was \$6.1 billion in digital health funding.⁹

The digital health market is very competitive. Many health-focused companies developed digital health applications, with major players including Medtronic, Fitbit, Omron Healthcare, and Insulet. In recent years, other large technology companies have entered the digital health space. In 2016, Alcatel, Apple, Samsung, and Verizon made large investments in digital health.¹⁰ Companies are also studying the potential for their products to be used in various health contexts. Apple, for example, has conducted several research projects on the Apple Watch to show its potential to identify risks to hearing health, heart health, and respiratory health as well as track declines related to Alzheimer's and Parkinson's.¹¹ Similarly, FitBit is partnering with Stanford Medicine to study the ability of digital health applications to identify and track infectious diseases like COVID-19 in college athletes.¹²

⁵ MOBILE HEALTH (MHEALTH) TECHNOLOGIES AND GLOBAL MARKETS, BCC RESEARCH (May 2017).

⁶ Stephen W. Bernstein, *Five Themes to Watch as Digital Health Takes Center Stage*, MEDICAL PRODUCT OUTSOURCING MAGAZINE (Mar. 3, 2021), https://www.mpo-mag.com/issues/2021-03-01/view_columns/five-themes-to-watch-as-digital-health-takes-center-stage/.

⁷ *The Global mHealth Market size is expected to reach \$206.1 billion by 2026, rising at a market growth of 31.6% CAGR during the forecast period*, GLOBENEWSWIRE (May 15 2020), <https://www.globenewswire.com/news-release/2020/05/15/2034353/0/en/The-Global-mHealth-Market-size-is-expected-to-reach-206-1-billion-by-2026-rising-at-a-market-growth-of-31-6-CAGR-during-the-forecast-period.html>.

⁸ *Mobile Health (mHealth) Market To Reach USD 311.98 Billion By 2027 | Reports and Data*, GLOBAL NEWSWIRE (Apr. 28, 2020), <https://www.globenewswire.com/news-release/2020/04/28/2023512/0/en/Mobile-Health-mHealth-Market-To-Rreach-USD-311-98-Billion-By-2027-Reports-and-Data.html>.

⁹ Megan Zweig & Jasmine DeSilva, *Q1 2021 Funding Report: Digital health is all grown up*, ROCK HEALTH (2021), <https://rockhealth.com/reports/q1-2021-funding-report-digital-health-is-all-grown-up/>.

¹⁰ MOBILE HEALTH (MHEALTH) TECHNOLOGIES AND GLOBAL MARKETS, *supra* note 5.

¹¹ Mario Aguilar, *Apple Watch research plows ahead, revealing the device's health potential*, STAT (Mar. 3, 2021), https://www.statnews.com/2021/03/03/apple-watch-health-research-hearing/?utm_source=STAT+Newsletters&utm_campaign=afc2a35883-Daily+Recap&utm_medium=email&utm_term=0_8cab1d7961-afc2a35883-153275922.

¹² Eric Wicklund, *Fitbit, Stanford Medicine Project Uses mHealth to Track College Athletes*, MHEALTH INTELLIGENCE (Apr. 1, 2021), <https://mhealthintelligence.com/news/fitbit-stanford-medicine-project-uses-mhealth-to-track-college>.

Private-sector investment in digital health grew almost seven-fold between 2013 and 2020, increasing from \$2.1 billion to \$14.1 billion.¹³ Digital health is and continues to be a major area of growth in the healthcare industry.

Digital health applications can be categorized by their associated disease or health condition. There are hundreds of thousands of digital health applications currently on the market, providing healthcare information or services for a range of disease areas. Between 2007 and 2017, there were more than 165,000 digital health smartphone applications developed, and more are released every year. **Table 1** includes several digital health applications and the type of health services they provide.

Table 1: Examples of Digital Health Applications

Health or Disease Area	Example Applications
Cardiovascular Disease	<p>Qardio is a heart health tracking app that provides detailed, accurate information about heart rate, blood pressure, and other cardiovascular health metrics.</p> <p>Blood Pressure Monitor tracks vital signs and records them alongside other details, such as medications, to create a limitless lifetime visualization of trends.</p> <p>KardiaMobile is an FDA-cleared personal EKG to detect atrial fibrillation</p>
COVID-19	<p>COVID Alert PA is designed to assist in alerting individuals that came in close proximity with someone who later tests positive for COVID-19, and to provide information about the virus and steps for controlling the spread of the virus.</p> <p>V-Safe is a CDC app that uses text messaging and web surveys to provide personalized health check-ins after a person receives a COVID-19 vaccine. Patients can input side effects after getting a COVID-19 vaccine and, if warranted, someone from CDC may follow-up with the user.</p>

[athletes?eid=CXTEL000000616298&elqCampaignId=18554&utm_source=nl&utm_medium=email&utm_campaign=newsletter&elqTrackId=53f1cf48a0fb47b49697092d4ca8d658&elq=ad468d05b7f54b3399b9c9c8363415eb&elqaid=19430&elqat=1&elqCampaignId=18554](https://www.athletes?eid=CXTEL000000616298&elqCampaignId=18554&utm_source=nl&utm_medium=email&utm_campaign=newsletter&elqTrackId=53f1cf48a0fb47b49697092d4ca8d658&elq=ad468d05b7f54b3399b9c9c8363415eb&elqaid=19430&elqat=1&elqCampaignId=18554).

¹³ Ravi N. Shah et al., *The Rise of Digital Health and Innovation Centers at Academic Medical Centers: Time for a New Industry Relationship Paradigm*, 2(3) J. AM. MED. ASS'N HEALTH FORUM e210339 (2021), https://jamanetwork.com/channels/health-forum/fullarticle/2778212?utm_source=twitter&utm_medium=social_jamajhf&utm_campaign=article_alert&utm_content=automated_rss.

Health or Disease Area	Example Applications
<p>Metabolic Disorders</p>	<p>Fooducate helps individuals figure out the best foods for keeping blood sugar in a healthy range. Individuals can look up the grade of a food’s calorie quality, so people can stay informed about the foods they consume.</p> <p>One Drop for Diabetes Health is a diabetes management app that uses blood glucose data to help identify activities to stay healthy.</p> <p>The Dexcom G6 is an FDA approved continuous glucose monitor that automatically sends real-time readings to the user’s mobile device. The G6 provides remote monitoring for up to 10 followers. It provides urgent alerts when hypoglycemia is imminent.</p>
<p>Neurological Diseases</p>	<p>MindMate features mental and physical workouts for those with dementia. It also has tools to help caregivers interact with their loved ones.</p> <p>Constant Therapy offers cognitive, language and speech therapy to support patients with Alzheimer’s and dementia, as well as those recovering from brain injuries including stroke.</p> <p>MyMSManager has a daily journal, allows users to measure fatigue, cognition, bladder control and depression. The daily journal has inputs for mood, pain level, disability and activity.</p>
<p>Oncology</p>	<p>Cancer Symptom Tracker allows users to track cancer symptoms and treatment side effects to better manage quality of life. Data can be shared with providers.</p> <p>Oleena is an app that connects patients and providers to help monitor the quality of life of patients undergoing cancer treatment. The app allows users to track symptoms/adverse events and provides recommendations on how to mitigate those symptoms. If necessary, the app connects the patient to their care team.</p> <p>MoleMapper uses the camera on a smartphone to track moles and how they change and grow over time. Rapid change or growth may indicate malignancy. The app reminds users to re-check moles regularly.</p>
<p>Respiratory Diseases</p>	<p>GOLD COPD helps doctors gauge the severity of an individual’s COPD and predict the risk of their condition getting worse – which then helps inform the treatment plan.</p> <p>AsthmaMD tracks medications, asthma triggers, and an individual’s action plan. It also charts asthma activity.</p> <p>QuitNow! encourages users to stop smoking. It tracks the time since your last cigarette, how long it has been and how much money users have saved. It provides small gamified achievements, like how many cigarettes the user has avoided.</p>

Health or Disease Area	Example Applications
<p>Wellness</p>	<p>Headspace offers guided meditation to help individuals practice mindfulness and reduce stress.</p> <p>The Apple Watch provides three concentric circles in a display: move, exercise and stand. The watch tracks the wearer’s time spent doing each of these activities; users are encouraged to “close the rings”.</p> <p>The Palm NRG system is comprised of socks and a palm device. The socks are equipped with TENS sensors and the device allows users to control the electrical stimulation.</p>
<p>Women’s Health</p>	<p>Clue, Flo, Natural Cycles, and Ovia are four major period and ovulation tracker and predictor applications.</p> <p>The Baby Scan app purports to display live 2D/3D scans. The scans can be stored immediately as a photo or video. The images are placed on a timeline so that the developments are in one simple overview.</p> <p>STDMaster claims to provide the risk of contracting an STI through a single sexual encounter using data from CDC and other sources.</p>
<p>Other</p>	<p>eKidneyCare is synced with pharmacies and includes a feature that prompts chronic kidney disease patients to review medications monthly. Then, the app sends any changes, additions, or medication problems to clinicians for resolution.</p> <p>Pear reSET is an FDA approved app to help treat substance use disorders. The digital therapy app consists of a specialized, 12-week program schedule that includes weekly check-ins.</p> <p>SoberTool helps track clean and sober days. The app includes daily motivational messages and reminders. The app has numerous milestones and allows users to work through triggers.</p> <p>Transplant Care contains health data, including lab results, scheduled check-ups, alerts and reminders for transplant patients.</p> <p>MyMeds reminds patients to take their medication as scheduled. It provides feedback to clinical team regarding the patient’s adherence.</p> <p>Flaredown is an app for this with chronic illnesses or those who want a universal tracker. It tracks patient inputs, like medications, food and activity as well as other metrics specified by the user, like abdominal pain or headaches.</p>

Digital Health Market Drivers and Barriers

Several factors have driven growth in digital health.¹⁴ These have included:

- Increasing patient engagement in healthcare
- Aiming to decrease healthcare costs
- A growing focus on preventive healthcare
- Prioritization of cost-effective solutions
- Growing elderly populations
- The growing incidence of chronic diseases
- Increased access to smartphones and broadband

The increased development and penetration of artificial intelligence and machine learning technologies and big data also present opportunities for further growth and investment and development in digital health.

Despite the growth and opportunities in the digital health market, there are significant barriers to widespread digital health adoption. Reimbursement of digital health applications is one major barrier. Payer reimbursement is relatively low in the digital health space, which can disincentive development and patient adoption. However, reimbursement has increased in recent years. For example, in June 2018, the Centers for Medicare and Medicaid Services (CMS) added smartphone-enabled continuous glucose monitors (CGMs) to the list of devices reimbursed by Medicare.¹⁵ Medicare and other payers, as well as employers, continue to expand the digital health services which they cover. Even so, further reimbursement will be needed to incentivize the development and adoption of high-quality digital health applications.

Conclusion

The digital health market is rapidly growing. Many new digital health applications are entering the market each year, presenting new opportunities to improve access to healthcare for patients across the country. However, there continue to be barriers to market penetration. Patients, providers, health systems and payers are reluctant to take risks that effect health outcomes. In the digital health space, this is in part due to the lack of reimbursement, among other factors. As the market grows and increases in both competitiveness and popularity, the regulatory environment should play a greater role reviewing products and notifying consumers of valuable applications and potential risks.

¹⁴ Greg Licholai, *Digital Healthcare Growth Drivers In 2020*, FORBES (Jan. 14, 2020), <https://www.forbes.com/sites/greglicholai/2020/01/14/digital-healthcare-growth-drivers-in-2020/?sh=503fd667511d>.

¹⁵ Kevin B. O'Reilly, *Proposed guidelines aim for safe, effective mobile health apps*, AM. MED. ASS'N (Jan. 22, 2018), <https://www.ama-assn.org/practice-management/digital/proposed-guidelines-aim-safe-effective-mobile-health-apps>; Stephen W. Bernstein, *Five Themes to Watch as Digital Health Takes Center Stage*, MEDICAL PRODUCT OUTSOURCING MAGAZINE (Mar. 3, 2021), https://www.mpo-mag.com/issues/2021-03-01/view_columns/five-themes-to-watch-as-digital-health-takes-center-stage/.

DIGITAL HEALTH REGULATION

Digital health applications are regulated by two major federal agencies – the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). Both agencies regulate distinct aspects of the digital health market. In particular, the FDA has pre-market authority over digital health applications that constitute devices under the Federal Food, Drug, and Cosmetic Act (FDCA). Both the FDA and the FTC have post-market authority over digital health applications, but review different areas of post-market conduct. This section reviews these agencies’ regulation of digital health applications.

FDA Regulation

The Federal Food, Drug, and Cosmetic Act defines a medical device as an instrument or apparatus with an intended purpose to diagnose, cure, mitigate, treat, or prevent a disease without depending upon the body’s own metabolism.¹⁶ The FDA has broad authority to regulate medical devices, including requiring pre-market notification,¹⁷ pre-market approval,¹⁸ quality system regulation,¹⁹ and post-market studies.²⁰

Many digital health applications meet the definition of medical devices. Three main categories recognized by the FDA are the provision of software as a medical device (SaMD), device software functions (DSF), and mobile medical applications (MMA).²¹ A SaMD is software intended to be used for medical purposes, independent of hardware. A DSF includes SaMD and Software in a Medical Device (SiMD), which encompasses software that functions as part of the device. MMAs are mobile applications with device software functionality intended to be used either as an “accessory to a regulated medical device or to transform a mobile platform into a regulated medical device.”²² Importantly, the non-device parallels to DSF and MMAs are called software functions and mobile applications.²³

¹⁶ 21 U.S.C. § 321(h).

¹⁷ 21 C.F.R. Part 807 Subpart E.

¹⁸ 21 C.F.R. Part 814.

¹⁹ 21 C.F.R. Part 820.

²⁰ *Postmarketing Requirements and Commitments: Legislative Background*, U.S. FOOD & DRUG ADMIN. <https://www.fda.gov/drugs/postmarket-requirements-and-commitments/postmarketing-requirements-and-commitments-legislative-background> (last updated June 14, 2018).

²¹ *Policy for Device Software Functions and Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications> (last updated Sept. 27, 2019).

²² *Id.*

²³ *Id.*

SaMD, DSFs, and MMAs can all be classified based on risk. The International Medical Device Regulators Forum (IMDRF), a voluntary group of global medical device regulators, has established a framework for risk categorization of SaMD based on the intended medical purpose and targeted healthcare situation or condition (**Table 2**).²⁴ The highest risk SaMD (category IV) has the highest impact on patients and public health and includes SaMD meant to treat or diagnose critical situations or conditions. The lowest risk SaMD (category I) is meant to inform clinical management for non-serious or serious situations or conditions and drive clinical management for non-serious conditions only.

Table 2: Risk Categorization of Software as a Medical Device (SaMD)

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

The FDA regulation of software functions and mobile applications depends both on device classification and risk level (**Table 3**). The FDA intends to apply “regulatory oversight” to DSFs and MMAs that would pose a risk to the patient’s safety if the device were to function not as intended. These include applications that transform a mobile platform into a device, control an existing device, or analyze patient data from a connected device. For low-risk software functions that may meet the definition of a medical device, the FDA intends to exercise “enforcement discretion.” Enforcement discretion means that “means that even if the medical app may meet the definition of a medical device, the FDA can choose to not enforce [its] requirements because [it has] determined that the risk to patients is low.”²⁵ These include applications that provide patients with educational information or notifications related to health conditions. Lastly, software functions that are not medical devices are not subject to FDA regulation – for example, medical flash cards and hospital bed scheduling

²⁴ IMDRF Software as a Medical Device Working Group, “Software as a Medical Device”: Possible Framework for Risk Categorization and Corresponding Considerations, INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (Sept. 18, 2014), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>.

²⁵ Bakul Patel, *The Regulatory Perspective: Q&A With FDA’s Bakul Patel*, 46(s2) BIOMED. INSTRUMENTATION & TECH. 84, 85 (2012).

programs. Additionally, wellness products are specifically carved out of the definition of medical device under the FDCA.²⁶

Table 3: FDA Regulation Of Software Functions

FDA regulation	Classified as a device?	Risk level?	Select examples of software functions
Regulatory oversight	Medical device (DSF / MMA)	Safety risk if device were to not function as intended	<ul style="list-style-type: none"> • Transform a mobile platform into a device, e.g., a sensor or electrode connected to a mobile platform that measures and displays the heart’s electrical activity • Control an existing device, e.g., those that control or change the settings of an implantable neuromuscular stimulator, cochlear implant, or blood pressure cuff • Analyze patient-specific device data during active patient monitoring e.g., those that process fetal heart rate and uterine contraction data to monitor labor progress
Enforcement discretion	May be a device	Low risk	<ul style="list-style-type: none"> • Provide a “Skill of the Day” to help those with psychiatric conditions maintain coping skills • Provide “educational information, reminders, or motivational guidance” for patients recovering from substance use disorder • Use GPS location to alert those with substance use disorder “when near a pre-identified, high-risk location” or those with asthma when near risky environmental factors
Not subject to FDA regulation	Not a device (neither DSF nor MMA)	Low / no risk	<ul style="list-style-type: none"> • Intended to be used as educational tools for healthcare providers or general patient education, e.g., software that provides and compares cost of drugs and medical products • Generic aids or general-purpose products, e.g., using the platform as a magnifying glass if not intended specifically for medical purposes • Related to developing or maintaining general fitness, health, or wellness, e.g., tools that provide dietary logs, calorie counters, activity trackers

There are no specialized FDA regulatory pathways for digital health applications. Currently the FDA regulates digital health products through the de novo, pre-market notification, or pre-market approval pathways for medical devices.²⁷ These processes either review whether the device is safe and effective or whether the device is substantially equivalent to a device that is already approved or cleared by the

²⁶ 21 U.S. Code § 360j(o)(1)(B).

²⁷ While the vast majority of digital health products are being reviewed as moderate to low risk, the Dexcom continuous glucose meters were approved as PMAs.

FDA. These approval pathways do not take into account the iterative nature of digital health applications, which often require frequent updates to improve the program’s accuracy and functioning.

However, the FDA has been working to improve its review and regulation of digital health applications. In 2019, the FDA launched a Precertification Pilot program for developers of SaMD, which is intended to allow streamlined product review for participating companies.²⁸ Nine companies are currently participating in the pilot program. The goal of the program is to help inform the development of a novel regulatory approach that provides more streamlined, efficient, and responsive regulatory oversight of software device manufacturers with a “robust culture of quality and organizational excellence.” Compared to the FDA’s more traditional approach, the program represents three fundamental shifts: 1) evaluation of the developer first, rather than the product itself, 2) continuous, rather than periodic, review of marketed SaMDs, and 3) enhanced regulatory decision support to improve efficiency. To implement those changes, the FDA is applying the Total Product Life Cycle (TPLC) Approach, taking into account excellence principles that companies must meet, streamlined review pathways dependent on SaMD risk classification, and monitoring of real-world performance. However, there are concerns that Precertification companies will not have enough incentive to generate sufficient post-market data on their products’ clinical utility and safety and that the excellence principles are not good proxies for safe and effective medical products.²⁹

The FDA’s most recent initiative, the Digital Health Center of Excellence (DHCoE), was launched on September 22, 2020, as part of a planned evolution of the Digital Health Program.³⁰ The goal of the DHCoE is to “empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation” by connecting and building partnerships, sharing knowledge, and advancing innovative regulatory approaches. The DHCoE provides services across a variety of stakeholders and functional areas, focusing not only the key categories of SaMDs, DSFs, and MMAs, but also on cybersecurity, artificial intelligence, and strategic partnerships.

Lastly, the FDA has post-market authority of medical products, including those that are under enforcement discretion.³¹ However, the FDA has rarely used this post-market authority with respect to digital health products.³² The FDA will take enforcement action if an application poses a risk to patients.

²⁸ *Developing a Software Precertification Program: A Working Model*, U.S. FOOD & DRUG ADMIN. (Jan. 2019), <https://www.fda.gov/media/119722/download>.

²⁹ Theodore T. Lee & Aaron S. Kesselheim, *U.S. Food and Drug Administration Precertification Pilot Program for Digital Health Software: Weighing the Benefits and Risks*, 168(10) ANNALS OF INTERNAL MED. 730 (2018).

³⁰ *Digital Health Center of Excellence*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/digital-health-center-excellence> (last updated Jan. 12, 2021).

³¹ See *Policy for Device Software Functions and Mobile Medical Applications*, *supra* note 21.

³² See *FDA Warning Letter to SyncThink Inc.*, U.S. FOOD & DRUG ADMIN. (July 31, 2017), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/syncthink-inc-498523-07312017>.

Federal Trade Commission (FTC) Regulation

The Federal Trade Commission (FTC) plays a different, although in some ways similar, role in digital health regulation as the FDA. Where the FDA has both pre-market and post-market authority to review digital health applications, the FTC has been empowered with wide-ranging statutory post-market authority. The FTC has particularly broad authority when it comes to antitrust actions and also has authority in regard to certain consumer protection and privacy violations.³³ The FTC, under the FTC Act and its Health Breach Notification Rule, prohibits any unfair methods of competition and unfair or deceptive practices and mandates any vendors of personal health records to notify consumers following a breach involving unsecured information.³⁴

Any digital health providers that fail to comply with FTC regulations may be subject to civil penalties and lawsuits. The FTC settled cases against several marketers of melanoma applications (including MelApp, Mole Detective) in which the FTC claimed “marketers deceptively claimed the apps accurately analyzed melanoma risk and could assess such risk in early stages” lacking evidence to support the claims.³⁵ Recently, the FTC settled a case against Flo, a menstrual tracking app, similarly for false or misleading advertising.³⁶

Conclusion

Both the FDA and the FTC have regulatory authority over digital health applications. However, there are significant limitations to the current regulatory framework. In particular, the FDA regulation of digital health applications does not take into account the iterative nature of digital health applications. Further, the Precertification Pilot program may not incentivize participating companies to conduct adequate post-market studies or to develop high quality applications and may not be a reliable model.

The FDA has expressed a desire to improve its regulation of digital health applications. Regarding the Precertification Pilot program, the FDA said that “[t]he pilot also will inform FDA as to whether it should seek other regulatory authorities to implement a modern, more effective, proactive, and efficient regulatory framework for software-based medical devices.”³⁷ In April 2021, the FDA

³³ *Mobile Health Apps Interactive Tool*, FED. TRADE COMM’N, <https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool#which> (last updated April 2016).

³⁴ *Federal Trade Commission Act*, FED. TRADE COMM’N, <https://www.ftc.gov/enforcement/statutes/federal-trade-commission-act> (last visited Oct. 19, 2020); *Health Breach Notification Rule*, FED. TRADE COMM’N, <https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/health-breach-notification-rule> (last visited Oct. 19, 2020).

³⁵ *FTC Cracks Down on Marketers of “Melanoma Detection” Apps*, FED. TRADE COMM’N (Feb. 23, 2015) <https://www.ftc.gov/news-events/press-releases/2015/02/ftc-cracks-down-marketers-melanoma-detection-apps>.

³⁶ *See Developer of Popular Women’s Fertility-Tracking App Settles FTC Allegations that It Misled Consumers About the Disclosure of their Health Data*, FED. TRADE COMM’N (Jan. 13, 2021), <https://www.ftc.gov/news-events/press-releases/2021/01/developer-popular-womens-fertility-tracking-app-settles-ftc>.

³⁷ *Software Precertification Program: Regulatory Framework for Conducting the Pilot Program within Current Authorities*, U.S. FOOD & DRUG ADMIN. (Jan. 2019), <https://www.fda.gov/media/119724/download>.

published a notice in the Federal Register that it was withdrawing a recommendation to temporarily exempt certain medical devices, including some digital health applications, from FDA review.³⁸

We expect further development in the regulation of digital health applications in the coming years. In particular, it is likely that the next MDUFA will either codify the Precertification Pilot program or outline a different legislative authority for FDA to regulate digital health products. Any such developments or reforms should take into account the priorities and principles set forth in the next section of this Policy Paper.

³⁸ Making Permanent Regulatory Flexibilities Provided During the COVID–19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Withdrawal of Proposed Exemptions, 86 Fed. Reg. 20174-20177 (Apr. 16, 2021).

DIGITAL HEALTH REGULATORY CHALLENGES

Principles of Patient-Centered Digital Health Regulation

The current framework for digital health regulation has provided limited oversight of many applications and does not take into account the iterative nature of software. These challenges in the digital health regulatory system have provided suboptimal innovation incentives for developers and have resulted in a digital health landscape that is not patient-centered and may ultimately put patients at risk.

This project has identified four key limitations in many currently available digital health applications that must be included and addressed in any future digital health regulatory reform: accuracy, usability, accessibility, and privacy.

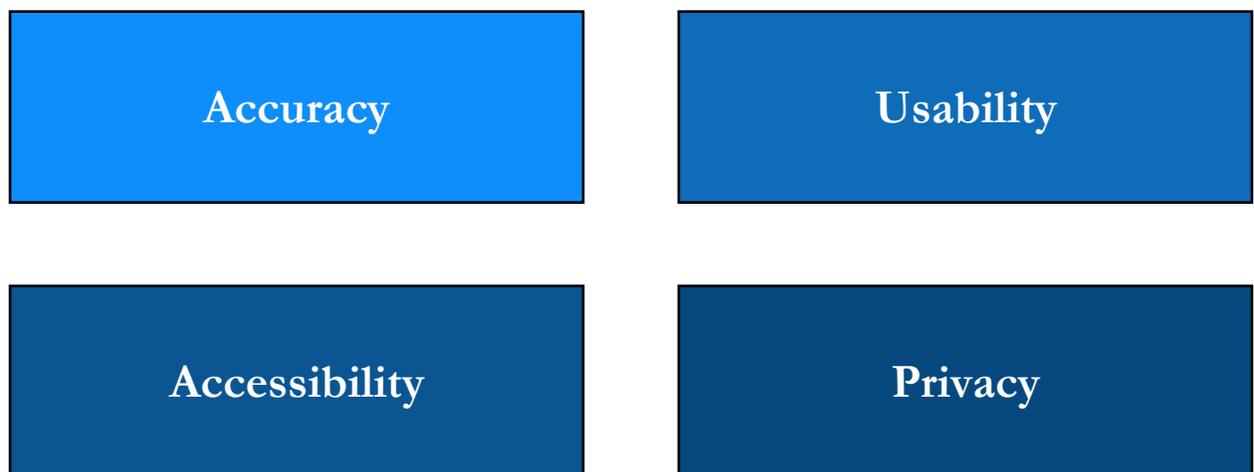
DIGITAL HEALTH ACCURACY: Digital health applications must be accurate, reviewed for accuracy, and disclose areas of inaccuracy.

DIGITAL HEALTH USABILITY: Digital health applications must be usable and understandable for patients.

DIGITAL HEALTH ACCESSIBILITY: Diverse patient needs must be included in the development and review of digital health applications to promote accessibility for all patients.

DIGITAL HEALTH PRIVACY: Patients' private information must be protected and patients must be able to opt in and out of key privacy options.

This section will detail these four principles of digital health regulation and provide policy recommendations to address these limitations and provide for patient-centered digital health regulation in the future.



Accuracy

Usability

Accessibility

Privacy

DIGITAL HEALTH ACCURACY

The accuracy of digital health applications is generally not rigorously evaluated or regulated. Many digital health applications contain inaccurate information or produce inaccurate outputs, potentially leading to unsafe outcomes for patients. Patients value accuracy in digital health applications but are not necessarily able to assess this themselves, making it even more important that regulators step in to monitor and validate the safety, effectiveness, and accuracy of digital health applications. ***Digital health applications must be accurate, reviewed for accuracy, and disclose areas of inaccuracy.***

With the growth in digital health popularity, rigorous evaluation of the accuracy of digital health applications is becoming increasingly important, especially for applications that aim to diagnose and treat medical conditions. However, the accuracy of digital health applications is often not studied at all. A 2019 study found that digital health companies “tended not to study the clinical effectiveness of their products in terms of key healthcare metrics like patient outcomes, cost, and access to care.”³⁹ Of the 20 top-funded digital health companies, no peer-reviewed publications were found associated with nine companies, and the majority of the studies were from only three companies. Further, for many digital health applications that are studied, many studies do not look at clinical effectiveness or high-cost, high-burden populations.⁴⁰ Poor trial design means their accuracy often cannot be properly evaluated or they produce low quality clinical evidence.⁴¹ Some trials do not evaluate all necessary outcomes, including sensitivity and specificity, to fully understand an application’s accuracy as a diagnostic tool.⁴²

This lack of research has led to many digital health applications that are inaccurate and potentially harmful to patients. For example, one study of more than 100 sexual health applications showed that one-third of the applications were not even “mostly” accurate and almost one-third had at least one piece of potentially harmful information.⁴³ Another study found that only eight of 368 urogynecology

³⁹ Adam B. Cohen & Kyan Safavi, *The Oversell And Undersell Of Digital Health*, HEALTH AFF. BLOG (Feb. 27, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190226.63748/full/>.

⁴⁰ *Id.*

⁴¹ Michael L. Millenson et al., *Beyond Dr. Google: the evidence on consumer-facing digital tools for diagnosis*, 5(3) DIAGNOSIS 95 (2018); Tara Donker et al., *Smartphones for Smarter Delivery of Mental Health Programs: A Systematic Review*, 15(11) J. MED. INTERNET RES. e247 (2013).

⁴² Tess Bright & Danuk Pallawela, *Validated Smartphone-Based Apps for Ear and Hearing Assessments: A Review*, 3(2) J. MED. INTERNET RES. REHABILITATION & ASSISTIVE TECHNOLOGIES e13 (2016).

⁴³ Jo Gibbs et al., *‘Can you recommend any good STI apps?’: A review of content, accuracy and comprehensiveness of current mobile medical applications for STIs and related genital infections*, 93(4) SEXUALLY TRANSMITTED INFECTIONS 234 (2017).

apps were “determined to be accurate and useful.”⁴⁴ Perhaps most shockingly, a study found that 100 percent of fetal heart rate monitors were inaccurate.⁴⁵

More studies are being directed at evaluating the quality, reliability, and accuracy of digital health applications. With this increasing review, there is growing evidence that many digital health applications contain inaccuracies in content, function, outputs, and recommendations. This section details the limited accuracy of many digital health applications, demonstrating the need for increased regulatory scrutiny of digital health applications.

Out-of-Date Information

First, it has been found that apps can contain content that is out-of-date relative to the most recent, evidence-based recommendations. For instance, a review of cardiovascular applications available in China found that only 43 percent had content that was up to date.⁴⁶ This type of inaccuracy is problematic in that patients may be adhering to clinical information that is no longer standard of care or may be relying on criteria that are no longer relevant. Medical knowledge is constantly evolving, and app-makers are in a race against this type of inaccuracy and need to be vigilant about updating their content to the most current standards.

Incomplete Information

Second, although the content of digital health applications may be accurate, many exclude key pieces of information. For instance, many digital health applications aimed at educating patients about common conditions such as sleep apnea and cancer have been found to contain incomplete information.⁴⁷ For example, a review of sleep self-management applications did not allow users to include intake of chemicals like caffeine and alcohol, which are proven to effect sleep.⁴⁸ Similarly, a study of 14 applications for prostate cancer education found that only one included the full breadth of information in the American Cancer Society Prostate Cancer Prevention and Early Detection Guidelines.⁴⁹ Another study found that applications for heart failure self-care did not have all the features necessary to adequately help patients, such as information on weight monitoring, behavior

⁴⁴ Shannon L. Wallace et al., *In Search of Mobile Applications for Urogynecology Providers*, 25(6) FEMALE PELVIC MED. & REPRODUCTIVE SURGERY 439 (2019).

⁴⁵ Marti D. Soffer & Katherine T. Chen, *In Search of Accurate Fetal Heart Rate Monitoring Mobile Applications*, 25(9) TELEMED. & EHEALTH 870 (2019).

⁴⁶ Bo Xie et al., *Chinese Cardiovascular Disease Mobile Apps' Information Types, Information Quality, and Interactive Functions for Self-Management: Systematic Review*, 5(12) J. MED. INTERNET RES. MHEALTH & UHEALTH e195 (2017).

⁴⁷ Yong K. Choi et al., *Smartphone Applications to Support Sleep Self-Management: Review and Evaluation*, 14(10) J. CLINICAL SLEEP MED. 1783 (2018); Roberto Collado-Borrell et al., *Smartphone applications for cancer patients; what we know about them?*, 40(1) FARMACIA HOSPITALARIA 25 (2016).

⁴⁸ Choi et al., *supra* note 47.

⁴⁹ Otis L. Owens et al., *Systematic Review of Commercially Available Mobile Phone Applications for Prostate Cancer Education*, 13(1) AM. J. MEN'S HEALTH 1557988318816912 (2019).

tracking, and comorbidities, and the best application only had 18 of the 25 necessary features.⁵⁰ This form of inaccuracy may lead patients to make misinformed decisions affecting their health.

Incorrect Information

Third, many digital health applications have been found to contain incorrect information. For example, a 2020 study of digital health applications tracking menstrual cycle, ovulation prediction, and other fertility topics found that 31 applications (22.1 percent) had serious inaccuracies in their tools, content, or both.⁵¹ Similarly, a 2016 study of menstruation tracking applications found only 20 (19 percent) of applications reviewed contained fully accurate clinical information.⁵² In a review of applications for kidney stones, investigators independently rated each application on a scale of 1 to 4 for clinical accuracy, with 4 representing the most accurate content and found that 14 percent scored a 1 for accuracy and that 48 percent scored a 2.⁵³ This type of content inaccuracy is particularly troubling, since applications with inaccurate information could encourage and spread medical misinformation and result in hazardous outcomes for patients.

Inaccurate Sensors and Connected Devices

Digital health applications may also use or be connected to inaccurate devices and sensors. For example, applications are often connected to sensors either on the mobile device (e.g., smartphone, smartwatch) or an external hardware (e.g., heart rate monitor, blood pressure machine, or another dedicated wearable). The accuracy of these sensors is critical in determining the accuracy of applications' outputs and recommendations. However, many of these are not intended or designed to be used in the medical context and collect invalid data, rendering the application useless or potentially even harmful.

Broad categories of applications use potentially inaccurate sensors. A 2017 analysis testing various applications that claim to measure blood pressure, blood oxygen percentage, and heart rate against clinical equipment found that the applications' accuracy was insufficient to recommend for clinical use and that the applications often fail to produce clinically usable data.⁵⁴ Many consumer wrist-worn devices are also not as accurate as their clinical counterparts, especially during periods of activity or exertion.⁵⁵ A review of studies of sleep applications found that sleep monitoring via wearables,

⁵⁰ Sahr Wali et al., *Evaluation of Heart Failure Apps to Promote Self-Care: Systematic App Search*, 7(11) J. MED. INTERNET RES. MHEALTH & UHEALTH e13173 (2019).

⁵¹ Rhonda Zwingerman et al., *A Critical Appraisal of Fertility and Menstrual Tracking Apps for the iPhone*, 42(5) J. OBSTETRICS & GYNAECOLOGY CANADA 583 (2019).

⁵² Michelle L. Moglia et al., *Evaluation of Smartphone Menstrual Cycle Tracking Applications Using an Adapted APPLICATIONS Scoring System*, 127(6) OBSTETRICS & GYNECOLOGY 1153 (2016).

⁵³ D.J. Stevens et al., *Smartphone apps for urolithiasis*, 43(1) UROLITHIASIS 13 (2015).

⁵⁴ John C. Alexander et al., *Comparison of smartphone application-based vital sign monitors without external hardware versus those used in clinical practice: a prospective trial*, 31(4) J. CLINICAL MONITORING & COMPUTING 825 (2017).

⁵⁵ Robert Wang et al., *Accuracy of Wrist-Worn Heart Rate Monitors*, 2(1) J. AM. MED. ASS'N CARDIOLOGY 104 (2017); Elizabeth A. Thomson et al., *Heart rate measures from the Apple Watch, Fitbit Charge HR 2, and electrocardiogram across*

especially via a single modality, is unreliable and inaccurate, and often have no correlation to clinical monitoring tools like polysomnography.⁵⁶ Finally, smartphone cameras are not calibrated to be medical devices. Using them in algorithm-based skin cancer detection applications has proven unreliable even when images are taken by experts.⁵⁷

Inaccurate Outputs and Treatment Recommendations

Many digital health applications produce inaccurate outputs and recommendations. For example, a study of melanoma detection apps found they underdiagnosed melanoma and had low sensitivity and specificity.⁵⁸ A review of smartphone camera apps to detect atrial fibrillation found a very good rate of true negatives, but also a high rate of false positives leading to unnecessary follow-up care.⁵⁹ A 2014 study testing the accuracy of 14 medical calculation applications found that six of the 14 applications had 100 percent accuracy and when there were errors, 47 percent were clinically significant and resulted in a significant change in prognosis.⁶⁰ Failure to validate information entered by patients and check for incomplete information can also result in highly inappropriate recommendations. For example, only one of 46 reviewed applications to calculate insulin dose had no issues in the information collected and provided by the application.⁶¹

Accuracy Risks Related to Artificial Intelligence and Machine Learning

Digital health applications are increasingly using artificial intelligence/machine-learning (AI/ML) algorithms to generate outputs. The accuracy of these AI/ML algorithms are often determined based on benchmark tests or datasets that may not translate to real world clinical situations. While AI/ML

different exercise intensities, 37(12) J. SPORTS SCI. 1411 (2019); Lisa Cadmus-Bertram, *The Accuracy of Heart Rate Monitoring by Some Wrist-Worn Activity Trackers*, 166(8) ANNALS OF INTERNAL MED. 610 (2017).

⁵⁶ Elise Guillodo et al., *Clinical Applications of Mobile Health Wearable-Based Sleep Monitoring: Systematic Review*, 8(4) J. MED. INTERNET RES. MHEALTH & UHEALTH e10733 (2020); Sushanth Bhat et al., *Is there a clinical role for smartphone sleep apps? Comparison of sleep cycle detection by a smartphone application to polysomnography*, 11(7) J. Clinical Sleep Med. 709 (2015); Ignacio Perez-Pozuelo et al., *The future of sleep health: a data-driven revolution in sleep science and medicine*, NPJ DIGITAL MED. 3, 42 (2020).

⁵⁷ Karoline Freeman et al., *Algorithm based smartphone apps to assess risk of skin cancer in adults: systematic review of diagnostic accuracy studies*, 368 BMJ m127 (2020).

⁵⁸ Xavier Chadwick et al., *Mobile Medical Applications for Melanoma Risk Assessment: False Assurance or Valuable Tool?*, UNIV. OF ARIZONA, <https://arizona.pure.elsevier.com/en/publications/mobile-medical-applications-for-melanoma-risk-assessment-false-as> (last accessed May 12, 2021) (Paper presented at 2014 47th Hawaii International Conference on System Sciences); Rahel Buechi et al., *Evidence assessing the diagnostic performance of medical smartphone apps: a systematic review and exploratory meta-analysis*, 7 BMJ OPEN e018280 (2017).

⁵⁹ Jack W. O'Sullivan et al., *Accuracy of Smartphone Camera Applications for Detecting Atrial Fibrillation: A Systematic Review and Meta-analysis*, 3(4) J. AM. MED. ASS'N NETWORK OPEN e202064 (2020), doi:10.1001/jamanetworkopen.2020.2064.

⁶⁰ Rachel Bierbrier et al., *Evaluation of the Accuracy of Smartphone Medical Calculation Apps*, 16(2) J. MED. INTERNET RES. e32 (2014).

⁶¹ Kit Huckvale et al., *Smartphone apps for calculating insulin dose: a systematic assessment*, 13 BMC MED. 106 (2015).

have been shown to outperform clinicians in narrowly controlled test sets, performance on benchmark data alone offers insufficient evidence of clinical utility.

Importantly, there is a substantial risk of bias being introduced into AI/ML algorithms and resulting mHealth apps, the result being an app that is systematically and disproportionately less accurate for certain groups of users. This bias can be introduced at several levels, starting from the inception of the app and design of its objectives, because these decisions can perpetuate bias of the developers. However, there is an even more specific risk of bias being introduced in the data used to train AI/ML. Validation and training requires testing against data sets, and these data sets can introduce bias by over-representing and under-representing certain groups of people. In particular, historically marginalized populations have been found to be underrepresented in these datasets, and it has been found that bias against persons of color and women does develop in AI/ML as a result.

There is a growing body of literature showing that bias from training data sets is present in various AI/ML applications. For instance, most clinical data sets used to develop algorithms consist mostly of fair-skinned individuals and contain far fewer images of darker skinned individuals. This limits the accuracy of these algorithms, as studies have shown that these algorithms may not be transferable when the data sets do not match the patient.⁶² The lesson to be learned is that while AI/ML is powerful and useful, it is only as equitable and accurate as the data and inputs that designers and programmers choose to use.

Evaluation of Accuracy

Consumers value accuracy, but do not know how to evaluate it themselves and often rely on physicians or word of mouth to decide whether or not to trust a digital health application.⁶³ Further, it is hard for patients themselves to evaluate which digital health applications are high quality, having little if any way of understanding the quality of the information provided. For example, a study of digital health applications used in occupational therapy found that the applications used “most frequently were not always high-quality apps” and that applications used “least frequently were not always low-quality apps.”⁶⁴ Similarly, a study of web results for “best diabetes app 2017” found little to no justification for the selection of applications in the “best” lists; one-third of them did not have blood glucose management features and one-half did not have medication management features.⁶⁵

⁶² See Manu Goyal et al., *Artificial intelligence-based image classification methods for diagnosis of skin cancer: Challenges and opportunities*, 127 *COMPUTERS IN BIOLOGY & MED.* 104065 (2020).

⁶³ VanAnh Vo et al., *Patients' Perceptions of mHealth Apps: Meta-Ethnographic Review of Qualitative Studies*, 7(7) *J. MED. INTERNET RES.* e13817 (2019).

⁶⁴ Kelsea LeBeau et al., *Assessing the Quality of Mobile Apps Used by Occupational Therapists: Evaluation Using the User Version of the Mobile Application Rating Scale*, 7(5) *J. MED. INTERNET RES. MHEALTH & UHEALTH* e13019 (2019).

⁶⁵ Geronimo Jiminez et al., *Examining Diabetes Management Apps Recommended From a Google Search: Content Analysis*, 7(1) *J. MED. INTERNET RES. MHEALTH & UHEALTH* e11848 (2019).

Conclusions and Policy Recommendations

While there are certainly accurate and valid digital health applications available, they are unfortunately mixed in with inaccurate and therefore, potentially dangerous counterparts. Studies reveal that there are inaccuracies in the content, data handling, outputs, and user recommendations of applications meant to influence user health decisions and actions.

With so many patients having ready access and desire to use digital health applications, there is clearly a potential threat to consumer safety that can, without appropriate regulation, go unnoticed and proceed without consequences. Patients may rely on a calculator for their insulin dose that is incorrect, an error which could quickly become life-threatening, and patients may put in symptoms to a symptom checker only to be assured that they should not seek care when care is indicated. Oversight is needed to ensure the zeal for digital health is not overshadowing dedication to consumer and patient safety.

In order to address these limitations in the accuracy of digital health applications, we recommend the following regulatory reforms be adopted:

- Develop an FDA regulatory pathway that takes into account the iterative nature of digital health applications, including periodic requiring post-market studies and reporting
- Develop specific FDA risk-stratified regulatory pathways for digital health applications with risk-proportional, graded degrees of regulatory burden and clear guidelines about clinical evidence required for approval
- Require post-market monitoring of approved digital health applications using real-world data, including monitoring for inaccurate our out-of-date information, incomplete information, incorrect information, inaccurate analyses, or adverse events
- Require summaries be submitted on a regular basis that outline evidence-based content updates, updated accuracy test results, and major application function adjustments
- Create a simple rating system, with the input of patient organizations, of what clinical evidence exists for a digital health applications that will help patients understand how accurate the application may be
- Require high risk digital health applications include clear messaging that recommendations are not replacements for consultation with a licensed provider
- Create a reporting framework so can users report accuracy concerns in digital health applications to developers and regulators
- Create data standards for the development and training of AI/ML to ensure good governance and reduce risk of bias being introduced and perpetuated by digital health applications

DIGITAL HEALTH USABILITY

Patient usability of digital health applications is a key factor in patient uptake and patient outcomes. However, many digital health applications are not designed in a way to promote patient usability – making it difficult for patients to take necessary measurements, lacking important notification features or interoperability with electronic health records and other digital health applications, or presenting information in a confusing way. Accuracy of digital health applications can be undermined by challenges to patient usability. ***Digital health applications must be usable and understandable for patients.***

The usability of digital health applications hinges on design. Many digital health applications are not designed with the patient’s experience in mind, making it difficult for patients to take necessary measurements. Poor design means an application may lack important notification features or interoperability with electronic health records and other digital health applications or present information in a confusing way. Poor usability can prevent patient uptake, undermine the accuracy of the digital health applications, and result in poor patient outcomes.

This section identifies three key factors that promote the design of digital health applications that are usable for patients: (1) interface design and technology compatibility, (2) notifications and goal management, and (3) interoperability with electronic health records. The section concludes with recommendations for digital health application developers to improve the usability of their applications, which in turn may improve accuracy, quality, and outcomes.

Interface Design and Technology Compatibility

The design of digital health applications – both in terms of interface design and the technologies that applications use and require – are key to patient adoption and continued use.

The interface design is particularly important for patient experience. Studies have shown that users’ most satisfying experiences with a digital health application occurred mainly within the first few weeks of use, and were typically with the application’s features, charts, and visual resources.⁶⁶ On the other hand, the study identified that technical problems on the application and difficulty using it were the main barriers and challenges in patient experience.⁶⁷

The technology and software required to use a digital health application also play key roles in patient usability and adoption. In particular, the ability to use digital health applications across platforms is

⁶⁶ See Isaac Vaghefi & Bengisu Tulu, *The Continued Use of Mobile Health Apps: Insights From a Longitudinal Study*, 7(8) J. MED. INTERNET RES. MHEALTH & UHEALTH e12983 (2019); Anna-Katharina Böhm et al., *Real-World Evidence of User Engagement With Mobile Health For Diabetes Management: Longitudinal Observational Study*, 8(11) J. MED. INTERNET RES. MHEALTH & UHEALTH e22212 (2020).

⁶⁷ Daiana Biduski et al., *Assessing long-term user experience on a mobile health application through an in-app embedded conversation-based questionnaire*, 104 COMPUTERS IN HUMAN BEHAVIOR 106169 (2020).

important for full market penetration and patients' ability to use the application on multiple devices over time. One study selected 18 digital health applications and found that 50 percent (nine applications) ran on iOS only, 11 percent ran on Android only, and 39 percent were available for cross-platform use.⁶⁸ The MyHealthApps repository had the most cross-platform apps (63 percent from here were compatible on Apple and Android).⁶⁹ In general, digital health application developers should aim to reach as many people as possible through their product. If applications are only accessible on certain platforms, it could affect the ability of patients to use, and continue to use, the product.

In addition to the software platform, developers should also keep in mind compatibility across different types of devices.⁷⁰ Digital health applications might be accessed on smartphones, or even desktops, tablets, and wearable medical devices. The display of the features can vary depending on the device, and should keep this in mind in designing a positive user experience (e.g., desktop version, web version).

The required hardware technology associated with devices also introduces potential for incompatibility and barriers to patient adoption.⁷¹ One study found that out of apps sampled, 39 percent required the use of the phone camera, and 33 percent utilized aspects of the touch screen.⁷² These were the two most frequently used devices, while microphone and accelerometer usage was less frequent. However, the sensors differ by the type of device. The iOS platform is solely controlled by Apple, so there are more homogeneous hardware components for sensors. Thus, apps using sensors on the iOS platform might have more stable development. On the other hand, Androids may be manufactured by many vendors with different sensor components. Therefore, there is less standardization in sensor hardware. In any event, the availability of these devices and the standardization across platforms may affect both patient usability and ultimately the accuracy and outcomes associated with the digital health application.

Notifications, Goal Management, and Other Features

Certain features in digital health applications promote patient usability and uptake. For example, patients largely favor tracking tools, two- or three-dimensional visualization, and context-awareness in digital health applications.⁷³

⁶⁸ Clarence Baxter et al., *Assessment of Mobile Health Apps Using Built-In Smartphone Sensors for Diagnosis and Treatment: Systematic Survey of Apps Listed in International Curated Health App Libraries*, 8(2) J. MED. INTERNET RES. MHEALTH & UHEALTH e16741 (2020).

⁶⁹ *Id.*

⁷⁰ Anastasiia Lastovetska, *Healthcare Mobile App Development: Types, Trends, & Features*, MLSDEV (Apr. 2, 2021), <https://mlsdev.com/blog/healthcare-mobile-app-development>.

⁷¹ *Systematic Survey of Apps Listed in International Curated Health App Libraries*, 8(2) J. MED. INTERNET RES. MHEALTH & UHEALTH e16741 (2020).

⁷² Baxter et al., *supra* note 68.

⁷³ Chang Liu et al., *Status and trends of mobile-health applications for iOS devices: A developer's perspective*, 84 J. SYSTEMS & SOFTWARE 2022 (2011).

Patients are incredibly concerned with digital health application notifications. Application alerts and reminders help boost engagement, although users prefer control over them. Some patients prefer text reminders so that they do not have to go into the application to access information, enabling the consumers to manage and control notifications. However, the notifications must be accurate in order to be effective for patients. A study of diabetes applications showed that more than one-third of applications did not alert users to hypoglycemia or hyperglycemia. Of the ones that did provide explicit alert messages, less than one-third of those provided a prompt notification for action and in most applications “consecutive low or high blood glucose values did not trigger an escalation of alerts that could prevent severe hypoglycemia or hyperglycemia.”⁷⁴ Here, it is clear the usability will impact the accuracy and outcomes of the application and must be considered together in the development of the digital health application.

Additionally, patients are interested in the ability to establish goals and manage them within the application. Users like daily or weekly trends showcased by the application, with email or text reminders about goals for the week. Actionable recommendations (e.g., “Only 2000 steps away from your goal today!”) provide users with a sense of control and optimism for achieving goals.⁷⁵ These features can create a positive patient experience, increase patient usability, and potentially improve patient outcomes.

Interoperability with Electronic Health Records

As digital health applications are increasingly used by patients and integrated with the healthcare system, interoperability of digital health platforms with electronic health records will be essential. One way interoperability is useful is that it allows users to integrate data collected by the application into the patient’s health record, streamlining communication with health providers and facilitating tracking health outcomes. Currently, less than half of digital health applications are able to integrate with electronic health records.⁷⁶ A barrier to integration includes the wearable device’s platform being incompatible with the electronic health record, so patient data does not consistently and effectively transmit. To address this challenge, applications could be designed with ‘plug and play’ interoperability to allow different systems to interact seamlessly and consolidate patient data.

Developers should also consider making applications interoperable with other healthcare system sources, such as with overall management systems in hospitals or clinics.⁷⁷ Some technologies in particular increase interoperability between digital health applications and other sources of medical data, including cloud solutions, home based medical devices, consumer electronics, external healthcare

⁷⁴ Elaine Lum et al., *Decision Support and Alerts of Apps for Self-management of Blood Glucose for Type 2 Diabetes*, 321(15) J. AM. MED. ASS’N 1530 (2019).

⁷⁵ Isaac Vaghefi & Bengisu Tulu, *The Continued Use of Mobile Health Apps: Insights From a Longitudinal Study*, 7(8) J. MED. INTERNET RES. MHEALTH & UHEALTH e12983 (2019).

⁷⁶ Alicia Phaneuf, *How mHealth apps are providing solutions to the healthcare market’s problems*, BUSINESS INSIDER (Dec. 4, 2019), <https://www.businessinsider.com/mhealth-apps-definition-examples>.

⁷⁷ Lastovetska, *supra* note 70.

data sources, and connected home-based medical devices.⁷⁸ Developers should explore these technologies in an effort to maximize patient access to and use of the digital health application and their data held on it.

The federal government is taking steps to promote interoperability in the healthcare system. For example, the 21st Century Cures Act prohibits providers and healthcare technology developers from engaging in information blocking, which is when a healthcare system entity interferes with another's legitimate access to patient health information.⁷⁹ These rules come with significant penalties, and are a first step in promoting the interoperability of digital health applications. The U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology also has issued rules adopting "new health information technology... certification requirements to enhance patients' smartphone access to their health information at no cost through the use of application programming interfaces."⁸⁰ Implementing these rules may also support digital health application interoperability as well as technology compatibility. Even so, developers must continue to take steps to promote interoperability.

Conclusions and Policy Recommendations

The usability of digital health applications can determine the success and utility of digital health applications. While the federal government has taken some early steps to promote patient usability of digital health applications – specifically with regard to technology compatibility and interoperability – digital health application developers will need to take additional steps to make their applications work for patients.

While there are some best practices in digital health application design, we recommend that these factors not be included in a set of regulatory requirements, but that developers and regulators conduct additional research on factors affecting patient usability and submit this information to a regulator or publish these findings. In general, we recommend the following steps:

- Patient needs and perspectives must be made central to the design and development process, with a focus on the features that patients value and that improve the performance and health outcomes of an application.
- Developers should design applications that maximize compatibility with different software and hardware platforms as well as different sensor technologies. These should be tested to ensure the accuracy of the data and outcomes across different platforms. Policy may be an important instrument to ensure a path to minimum sensor standards such so as to ensure the quality of the data on which digital care monitoring efforts and care plans are built.

⁷⁸ *Id.*

⁷⁹ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25642 (2020). *See also* Ben Moscovitch, *How President Biden Can Improve Health Data Sharing For COVID-19 And Beyond*, HEALTH AFF. BLOG (Mar. 1, 2021), <https://www.healthaffairs.org/doi/10.1377/hblog20210223.611803/full/>.

⁸⁰ *HHS Extends Compliance Dates for Information Blocking and Health IT Certification Requirements in 21st Century Cures Act Final Rule*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Oct. 29, 2020), <https://www.hhs.gov/about/news/2020/10/29/hhs-extends-compliance-dates-information-blocking-health-it-certification-requirements-21st-century-cures-act-final-rule.html>.

- Developers should use fields and application programming interfaces to maximize interoperability of digital health applications with other applications, electronic health records, and other sources of health information. Regulators should continue to implement policies maximizing interoperability and information sharing in the healthcare sector.

DIGITAL HEALTH ACCESSIBILITY

Digital health applications have the potential to increase access to health care services to many populations, but also risk exacerbating existing health disparities and leaving out certain populations. To ensure accessibility, a diverse group of patients should be involved in the development and review of digital health applications. The specific needs of people of color, people with disabilities, children, and the elderly, among other populations, must be taken into account to ensure a safe and effective digital health application for all patients. ***Diverse patient needs must be included in the development and review of digital health applications to promote accessibility for all patients.***

The adoption and utility of digital health applications depend on many factors, including access to technology, reliable internet access and appropriateness of the application for the user. While digital health tools have the capability to dramatically improve patient care, these new technologies may perpetuate existing disparities in healthcare. In particular, digital health has the potential to widen disparities due to a variety of accessibility concerns. Some of these concerns are related to the “digital divide” – the gap in access to technology, access to internet coverage, and digital literacy that prevents some populations from utilizing telehealth and digital health tools.⁸¹ Other concerns relate to the appropriateness of digital health populations for some historically disadvantaged populations, including people of color, people with disabilities, and people with limited English or who are non-English speaking.

The COVID-19 pandemic rapidly increased the adoption of telehealth and digital health technologies. As a result, it is particularly important now to address the accessibility limitations of the current digital health application market and regulatory landscape. This section describes key challenges in digital health accessibility among certain subgroups of the population.

Elderly Populations

One major group impacted by the digital divide is the elderly, who face significant barriers to utilization of digital health applications. Studies have shown that the elderly are less likely to have the technology at home necessary for telehealth or digital health engagement.⁸² One study in the diverse, low-income New York neighborhood of East Harlem found that only 33 percent of participants over the age of

⁸¹ David Velasquez & Ateev Mehrotra, *Ensuring The Growth Of Telehealth During COVID-19 Does Not Exacerbate Disparities In Care*, HEALTH AFF. BLOG. (May 8, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200505.591306/full/>

⁸² Lauren A. Eberly et al., *Patient Characteristics Associated With Telemedicine Access for Primary and Specialty Ambulatory Care During the COVID-19 Pandemic*, 3(12) J. AM. MED. ASS'N NETWORK OPEN e2031640 (2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774488>; Eric T. Roberts & Ateev Mehrotra, *Assessment of Disparities in Digital Access Among Medicare Beneficiaries and Implications for Telemedicine*, 180(10) J. AM. MED. ASS'N INTERNAL MED. 1386, 1386 (2020).

65 used smartphones.⁸³ After adjusting for race, socioeconomic status, and other demographic factors, older participants were found to be less likely to own a cell phone, and those that owned cell phones were less likely to report that their cell phone was a smart phone.⁸⁴ The elderly also have decreased digital literacy, an additional barrier to using digital health applications.⁸⁵ These factors largely prevent many elderly people from benefitting from digital health applications.

People of Color

People of color have historically accessed digital health technologies less and have been less involved in the development and implementation stages of mHealth interventions. Multiple studies have found that Black patients are less likely to access their electronic health records through online patient portals than their white counterparts.⁸⁶ People of color are also less likely to have the technology at home necessary to use digital health applications, further preventing them from engaging with digital health tools.⁸⁷

Lack of racial diversity in digital health application development also poses challenges to the effectiveness of some digital health applications for people of color. In the case of artificial intelligence and machine learning algorithms, lack of data of non-European populations in the development have been shown to result in inaccurate analyses.⁸⁸ One machine learning algorithm was associated with misclassifying a benign genetic variant as pathogenic,⁸⁹ an error that would have been prevented with a more diverse sample. Some studies have found that digital health applications that use pictures of

⁸³ Nita Vangeepuram et al., *Smartphone ownership and perspectives on health apps among a vulnerable population in East Harlem, New York*, 4(31) MHEALTH (2018), doi: 10.21037/mhealth.2018.07.02.

⁸⁴ *Id.*

⁸⁵ Kenneth Lam et al., *Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic*, 180(10) J. AM. MED. ASS'N INTERNAL MED. 1389, 1389-90 (2020).

⁸⁶ Douglas W. Roblin et al., *Disparities in use of a personal health record in a managed care organization*, 16(5) J. AM. MED. INFORMATICS ASS'N 683 (2009), doi:10.1197/jamia.M3169; James S. Kahn et al., *Personal health records in a public hospital: experience at the HIV/AIDS clinic at San Francisco General Hospital*, 17(2) J. AM. MED. INFORMATICS ASS'N 224 (2010), doi:10.1136/jamia.2009.000315; Manisha Jhamb et al., *Disparities in Electronic Health Record Patient Portal Use in Nephrology Clinics*, 10(11) CLINICAL J. AM. SOCIETY OF NEPHROLOGY 2013 (2015), doi: 10.2215/CJN.01640215; Jessica S. Ancker et al., *Use of an electronic patient portal among disadvantaged populations*, 26(10) J. General Internal Med. 1117 (2011), doi: 10.1007/s11606-011-1749-y.

⁸⁷ Eberly et al., *supra* note 82; Roberts & Mehrotra, *supra* note 82.

⁸⁸ Milena A. Gianfrancesco et al., *Potential Biases in Machine Learning Algorithms Using Electronic Health Record Data*, 178(11) J. AM. MED. ASS'N 1544 (2018); Cade Metz, *Who Is Making Sure the A.I. Machines Aren't Racist?*, N.Y. TIMES (Mar. 15, 2021), <https://www.nytimes.com/2021/03/15/technology/artificial-intelligence-google-bias.html?referringSource=articleShare>; Adriana Krasniansky, *Understanding Racial Bias in Medical AI Training Data*, HARV. BILL OF HEALTH (Oct. 29, 2019), <https://blog.petrieflom.law.harvard.edu/2019/10/29/understanding-racial-bias-in-medical-ai-training-data/>.

⁸⁹ Gianfrancesco et al., *supra* note 88 (citing Arjun K. Manrai et al., *Genetic Misdiagnoses and the Potential for Health Disparities*, 375(7) NEW ENG. J. MED. 655 (2016)).

the skin for analysis (often with artificial intelligence or machine learning algorithms) are less accurate when used on non-white skin.⁹⁰

Other digital health inaccuracies may be related to the sensors, as opposed to the algorithms. Digital health applications that rely on smart watch or exercise band optical sensors (the green light facing a user's skin) are particularly likely to generate less accurate readings on users with more pigmented skin.⁹¹ This is due to the fact that the optical sensor utilizes green light, which is readily absorbed by melanin in the skin, reducing sensor penetrance and efficacy for users with higher levels of skin pigmentation. Consequently, measures of heart rate, blood oxygenation, and activity levels may be consistently inaccurate for swaths of users based on race. This inaccurate sensor input can potentially be translated to inaccurate outputs, resulting in potential racial disparities in digital health application accuracy and resulting safety and efficacy.

Low-Income Populations

Low-income populations also experience barriers to digital health adoption. Similar to the elderly and people of color, low-income populations are less likely to have the technologies at home necessary to use telehealth or digital health technologies.⁹² Half of low-income Americans also lack access to broadband at home, which is necessary for many digital health applications.⁹³ Relatedly, low-income patients may lack consistent connection to Wi-Fi hotspots or have restrictive cellular data plans that do not allow them to access digital health platforms.⁹⁴ Both prevent low-income populations from engaging with digital health tools.

⁹⁰ See, e.g., Ewa M. Nowara et al., *A Meta-Analysis of the Impact of Skin Tone and Gender on Non-Contact Photoplethysmography Measurements*, PROCEEDINGS OF THE IEEE/CVF CONFERENCE ON COMPUTER VISION AND PATTERN RECOGNITION (CVPR) WORKSHOPS 284 (2020), https://openaccess.thecvf.com/content_CVPRW_2020/html/w19/Nowara_A_Meta-Analysis_of_the_Impact_of_Skin_Tone_and_Gender_CVPRW_2020_paper.html (finding that apps that use AI and photoplethysmography to measure things like heart rate and cardiac electrical activity are less accurate when used on dark skin); Goyal et al., *supra* note 62 (explaining that AI algorithms used to identify skin cancer are less accurate on non-Caucasian people); Seung Seog Han et al., *Classification of the Clinical Images for Benign and Malignant Cutaneous Tumors Using a Deep Learning Algorithm*, 138(7) J. INVESTIGATIVE DERMATOLOGY 1529 (2018), <https://www.sciencedirect.com/science/article/pii/S0022202X18301118> (finding that skin cancer identification AI trained on images of Asian skin were less accurate when used on Caucasian skin).

⁹¹ See Peter J. Colvonen et al., *Limiting racial disparities and bias for wearable devices in health science research*, 43(10) SLEEP zsa159 (2020), <https://academic.oup.com/sleep/article/43/10/zsa159/5902283>.

⁹² Eberly et al., *supra* note 82; Roberts & Mehrotra, *supra* note 82.

⁹³ Utsha Khatri et al., *These Key Telehealth Policy Changes Would Improve Buprenorphine Access While Advancing Health Equity*, HEALTH AFF. BLOG (Sept. 11, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200910.498716/full/>; Mark E. Dornauer & Robert Bryce, *Too Many Rural Americans Are Living In the Digital Dark. The Problem Demands A New Deal Solution*, HEALTH AFF. BLOG (Oct. 28, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20201026.515764/full/>.

⁹⁴ Patrick Liu et al., *Use of Mobile Health Applications in Low-Income Populations: A Prospective Study of Facilitators and Barriers*, 13(9) CIRCULATION: CARDIOVASCULAR QUALITY & OUTCOMES e007031 (2020).

Rural Populations

Rural populations also face significant barriers to digital health utilization. Nearly twenty-five percent of adults living in rural areas in the United States say that access to high-speed internet is a major problem.⁹⁵ An estimated one third of Americans in rural areas lack broadband access at home, as compared to only two percent of Americans in urban areas.⁹⁶ One study found that rural participants in a digital health cardiac rehabilitation study reported connectivity interruptions.⁹⁷ These barriers undermine the effective use of digital health applications by people in rural areas.

Language Barriers

People with no or limited English proficiency have additional challenges in using digital health tools. Many digital health applications are only in English and few have other languages or translation services available for non-English speaking patients.⁹⁸ This prevents access to digital health applications for thousands of people in the United States and across the globe.

In addition to the language used in the applications themselves, a key consideration in engaging non-English speakers is the cultural applicability of specific digital health applications. Previous studies have shown that taking cultural considerations into the design of digital health applications improve patient experience and utilization.⁹⁹ Greater involvement and engagement of non-English speaking populations in the design and planning of digital health applications has proved a promising solution to these concerns.¹⁰⁰

People with Disabilities

People with disabilities also face challenges to digital health adoption. Many digital health technologies are not accessible for people with disabilities, including those with visual or hearing impairments.¹⁰¹ One study found that people with vision impairments often struggle to use digital health applications

⁹⁵ Andrew Perrin, *Digital gap between rural and nonrural America persists*, PEW RESEARCH CTR. (May 31, 2019), <https://www.pewresearch.org/fact-tank/2019/05/31/digital-gap-between-rural-and-nonrural-america-persists/>.

⁹⁶ Khatri et al., *supra* note 93; Dornauer & Bryce, *supra* note 93.

⁹⁷ Sandra J. Hamilton et al., *Smartphones in the secondary prevention of cardiovascular disease: a systematic review*, 18(1) BMC CARDIOVASC DISORDERS 25 (2018), doi: 10.1186/s12872-018-0764-x.

⁹⁸ See Nicole Wetsman, *Telehealth Wasn't Designed For Non-English Speakers*, THE VERGE (June 4, 2020), <https://www.theverge.com/21277936/telehealth-english-systems-disparities-interpreters-online-doctor-appointments>.

⁹⁹ See Wen-Ting Hsieh et al., *A Novel mHealth Approach for a Patient-Centered Medication and Health Management System in Taiwan: Pilot Study*, 6(7) J. MED. INTERNET RES. MHEALTH & UHEALTH e154 (2018); Ahmed Housni Alsswey et al., *Culture in the design of mHealth UI: An effort to increase acceptance among culturally specific groups*, 38(2) THE ELECTRONIC LIBRARY 257 (2019), <https://www.emerald.com/insight/content/doi/10.1108/EL-04-2019-0097/full/html>.

¹⁰⁰ See LaPrincess C. Brewer et al., *Back to the Future: Achieving Health Equity Through Health Informatics and Digital Health*, 8(1) J. MED. INTERNET RES. MHEALTH & UHEALTH e14512 (2020).

¹⁰¹ Rupa S. Valdez et al., *Ensuring Full Participation of People with Disabilities in an Era of Telehealth*, J. AM. MED. INFORMATICS ASS'N 1, 1-4 (2020).

that do not have auditory input/output capability or aren't compatible with screen readers.¹⁰² The study also noted that digital health applications that do have accessibility features often lose these features with updates to the phone or operating system. People with hearing difficulties may also have difficulties with audio components of digital health applications and many applications lack ASL interpreters or captioning for other virtual services.¹⁰³ Recent studies have demonstrated that including individuals with disabilities in the development and design of digital health applications proves promising for developing tailored and effective applications.¹⁰⁴

Health Literacy

Another consideration regarding both the accessibility and usability of digital health applications is health literacy. Populations with low health literacy include “patients who are older, have limited education, lower income, chronic conditions, and those who are non-native English speakers.”¹⁰⁵ Previous studies have demonstrated that individuals with limited health literacy are less likely than to access care.¹⁰⁶ With regards to digital health applications in particular, lower health literacy has been demonstrated to decrease an individual's likelihood of engaging in particular digital health applications.¹⁰⁷

Although digital health applications are intended to promote patient involvement in their own healthcare, they are often not written in a manner that is accessible to all patients. For example, one review found that eleven out of forty-two studies show that most of the online health-related content are difficult for patients to understand.¹⁰⁸ Some gene-related test results even require college-level reading skills to interpret. Web-based application developers also have tried to minimize the problems by introducing some functions to help users comprehend textual medical contents. At least one study

¹⁰² Nicole A. Thompson et al., *Use of mHealth Technologies by People with Vision Impairment*, CALIFORNIA STATE UNIV. NORTHRIDGE (2019), <http://scholarworks.csun.edu/handle/10211.3/210395> (presented at the 34th Annual Assistive Technology Conference Scientific/Research Proceedings, San Diego).

¹⁰³ Ben Lippincot et al., *Survey of User Needs: Mobile Apps for mHealth and People with Disabilities*, in INTERNATIONAL CONFERENCE ON COMPUTERS HELPING PEOPLE WITH SPECIAL NEEDS 266-273 (2020), https://link.springer.com/chapter/10.1007/978-3-030-58805-2_32.

¹⁰⁴ Leming Zhou et al., *Making Self-Management Mobile Health Apps Accessible to People With Disabilities: Qualitative Single-Subject Study*, 8(1) J. MED. INTERNET RES. MHEALTH & UHEALTH e15060 (2020), doi: 10.2196/15060.

¹⁰⁵ Kathleen T. Hickey et al., *Low health literacy: Implications for managing cardiac patients in practice*, 43(8) THE NURSE PRACTITIONER 49-55 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6391993/#:~:text=Low%20health%20literacy%20is%20associated,are%20non%2Dnative%20English%20speakers.&text=Approximately%2080%20million%20adults%20in,limited%20or%20low%20health%20literacy>; Kenneth Lam et al., *Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic*, 180(10), J. AM. MED. ASS'N INTERNAL MED. 1389, 1389-90 (2020).

¹⁰⁶ Helen Levy & Alex Janke, *Health Literacy and Access to Care*, 21 (Supp. 1) J. HEALTH COMMUNICATION 43-50 (2016), doi: 10.1080/10810730.2015.1131776.

¹⁰⁷ Lyndsay A. Nelson et al., *Disparities in the use of a mHealth medication adherence promotion intervention for low-income adults with type 2 diabetes*, 23(1) J. AM. MED. INFORMATICS ASS'N 12-18 (2016), doi: 10.1093/jamia/ocv082.

¹⁰⁸ Henna Kim & Bo Xie, *Health literacy in the eHealth era: A systematic review of the literature*, 100(6) PATIENT EDUCATION & COUNSELING 1073-1082 (2017), doi: 10.1016/j.pec.2017.01.015.

of mobile digital health applications found the information to be easier to understand.¹⁰⁹ In any case, health literacy should be considered in digital health application development to promote accessibility for all patients.

Conclusions and Policy Recommendations

Digital health applications both demonstrate an opportunity to promote access to healthcare in the United States and pose the risk of exacerbating existing inequities in the healthcare system. While there are limitations in the current digital health landscape, studies have shown that digital health applications can be successful and effective when tailored to be accessible to certain populations.¹¹⁰

Regulatory and policy reforms by both the government and digital health application developers must be taken in order to promote the design and development of digital health applications that will not continue existing inequities and will be accessible to all patients. To accomplish these goals, we recommend the following steps:

- Large and diverse populations – including people of different races, ages, and disabilities – should be included and involved in the entire lifecycle of development of digital health applications, as appropriate, including planning, prototyping, testing, and quality improvement.
- Greater focus on and transparency with regards to the diversity of study populations should be reported to provide evidence surrounding efficacy of digital health applications.
- Digital health application developers should perform pre-market and post-market studies regarding the effectiveness and accessibility of their products to marginalized populations.

¹⁰⁹ *Id.*

¹¹⁰ Jeffrey P. Migneault et al., *A culturally adapted telecommunication system to improve physical activity, diet quality, and medication adherence among hypertensive African-Americans: a randomized controlled trial*, 43(1) ANNALS OF BEHAVIORAL MED. 62-73 (2012), doi: 10.1007/s12160-011-9319-4; Chandra Y. Osborn & Shelagh A. Mulvaney, *Development and feasibility of a text messaging and interactive voice response intervention for low-income, diverse adults with type 2 diabetes mellitus*, 7(3) J. DIABETES SCI. & TECH. 612-22 (2013), doi: 10.1177/193229681300700305; Tatiana M. Davidson et al., *Evaluation of an mHealth Medication Regimen Self-Management Program for African American and Hispanic Uncontrolled Hypertensives*, 5(4) J. Personalized Med. 389-405 (2015), doi: 10.3390/jpm5040389; Jessica Chandler et al., *Impact of a Culturally Tailored mHealth Medication Regimen Self-Management Program upon Blood Pressure among Hypertensive Hispanic Adults*, 6(7) INT’L J. ENVIRONMENTAL RESEARCH & PUBLIC HEALTH 1226 (2019), doi: 10.3390/ijerph16071226; Vangeepuram et al., *supra* note 83; Kim & Xie, *supra* note 108.

DIGITAL HEALTH PRIVACY

Digital health applications pose privacy and security concerns. While these applications collect patients' health information, the majority of digital health applications are not subject to most federal and state privacy regulations. These privacy and security risks are illustrated by the numerous health data breaches in recent years. Further, many patients are unaware that this personal information may be collected, mined, sold, and used by non-health-related stakeholders with divergent interests. ***Patients' private information must be protected and patients must be able to opt in and out of key privacy options.***

Digital health applications raise significant data privacy and security concerns. Most federal and state privacy regulations do not apply to digital health application developers, permitting them to collect – and sometimes sell – health and personal data with few privacy limitations. In recent years, there have been several health data breaches and lawsuits related to health technology companies' privacy practices.¹¹¹ In some cases, personal health information collected by digital health applications can still be linked back to patients, even when it is deidentified.¹¹² These practices put patients at risk.

This section details the privacy and security risks and challenges related to digital health applications, provides an overview of federal and state privacy laws and concerns related to applications' privacy policies, and makes recommendations for reforms to better protect patients' privacy.

Federal Privacy Laws

The main federal health privacy law is the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA is structured around who holds individually identifiable health information instead of what health data is protected. Only “covered entities” (health plans, medical providers and organizations, and clearinghouses) and “business associates” (covered entities' subcontractors who process data on the custodian's behalf) are subject to HIPAA. Further, HIPAA protects only identifiable health information, so its framework does not apply to commercial and research digital health applications.¹¹³ This greatly limits HIPAA's applicability to digital health application companies. Only when developers create, receive, maintain, or transmit protected health information (PHI) on behalf of a covered entity or business associate are required to comply with or certain provisions of HIPAA.

¹¹¹ Mark Robinson, *Nobody Reads the Terms and Conditions: A Digital Advanced Directive Might Be Our Solution*, HARV. BILL OF HEALTH (Apr. 22, 2019), <https://blog.petrieflom.law.harvard.edu/2019/04/22/nobody-reads-the-terms-and-conditions-a-digital-advanced-directive-might-be-our-solution/>.

¹¹² *Id.*

¹¹³ Ann Marie Helm & Daniel Georgatos, *Privacy and mHealth: How Mobile Health “Apps” Fit Into a Privacy Framework Not Limited to HIPAA*, 64(1) SYRACUSE L. REV. 131–179 (2014); Mark A. Rothstein, *Currents in Contemporary Ethics: Research Privacy Under HIPAA and the Common Rule*, 33(1) J. L. MED. & ETHICS 154 (2005).

In parallel, the Federal Trade Commission (FTC) has a broad authority over consumer data and requires companies to notify users when there has been a data breach under its Health Breach Notification Rule.¹¹⁴ Yet, the FTC Act does not contain substantive privacy standards or have privacy or security requirements.

State Privacy Laws

Many states have their own privacy laws that may or may not apply to digital health applications. In particular, the California Consumer Privacy Act of 2018 (CCPA) has many privacy protections (including the right to opt out of the sale of their information) that may apply to digital health companies doing business in California.¹¹⁵ The California Privacy Right Act (CPRPA), which will go into force in 2023, may also provide heightened protections to certain health information.¹¹⁶

Even though state privacy laws may provide some protections absent at the federal level, the patchwork of privacy protections may leave patients at risk.

Digital Health Privacy Policies

Despite the lack of overarching federal or state laws, many developers have their own privacy policies. However, the privacy policies of individual digital health applications may also put patients' information at risk. Many applications do not have any privacy policies. One study of the 600 most common digital health applications found that less than one third (only 183, or 30.5%) had privacy policies and most of those were general and not specific to the nature of the digital health application.¹¹⁷

When applications do have privacy policies, they may be difficult for patients to understand and not actually protect patient data. One study found that more than 70 percent of the studied applications “shared users’ sensitive information with third party data aggregators, without the users’ knowledge or consent. As a result, users’ health data from medical apps was frequently marketed and sold to third parties including advertisers, insurers, and employers.”¹¹⁸ Studies of privacy policies for digital health

¹¹⁴ 16 C.F.R. Part 318.

¹¹⁵ California Consumer Privacy Act of 2018, Cal. Civ. Code § 1798.100 *et seq.* (2018). *See also California Consumer Privacy Act*, STATE OF CALIF. DEP’T OF JUSTICE OFFICE OF THE ATTORNEY GENERAL, <https://oag.ca.gov/privacy/ccpa> (last accessed June 29, 2021).

¹¹⁶ *See* California Consumer Privacy Act of 2018, Cal. Civ. Code § 1798.100 *et seq.* (2018).

¹¹⁷ Ali Sunyaev et al., *Availability and quality of mobile health app privacy policies*, 22(e1) J. AM. MED. INFORMATICS ASS’N e28 (2015). *See also* Lisa Parker et al., *How private is your mental health app data? An empirical study of mental health app privacy policies and practices*, 64 INT’L J. L. & PSYCHIATRY 198 (2019).

¹¹⁸ Lori Andrews, *A New Privacy Paradigm in the Age of Apps*, 53(3) WAKE FOREST L. REV. 421 (2018).

applications around mental health, such as depression¹¹⁹ and smoking cessation¹²⁰ found serious inadequacies in the privacy policies – both studies showed less than half of the applications even disclosed their policies accurately. And in 2019, the Washington Post published a story about employers having access to employees’ fertility data through a pregnancy-tracking application.¹²¹

If there are policies, not everyone reads them or understands the implications of what is covered, what may happen with their data once they are released or how they may be combined with other data.¹²² Most of these privacy policy agreements neither address data ownership nor specify what type of data is collected.¹²³ People are often unaware of these practical privacy issues, as digital health application developers may not disclose their data collection, mining, and third-party disclosure practices.¹²⁴

Data Security Practices

Digital health applications often lack adequate data security protections. Electronic platforms are vulnerable to third-party attacks.¹²⁵ Data coming from digital health applications are vulnerable to many security threats, including malware, software damage, and information alteration. Digital health applications might be hacked or send unencrypted information, making it possible to intercept. This is particularly unsafe if the mobile device is stolen or lost.¹²⁶ Some studies have demonstrated significant vulnerabilities in the transmission of data. For example, a 2016 study of 137 digital health applications found that 60 percent of applications studied transmitted health data through unsecured methods.¹²⁷

¹¹⁹ Kristen O’Loughlin, *Reviewing the data security and privacy policies of mobile apps for depression*, 15 INTERNET INTERVENTIONS 110 (2019), <https://www.sciencedirect.com/science/article/pii/S2214782918300460>.

¹²⁰ Kit Huckvale et al., *Assessment of the Data Sharing and Privacy Practices of Smartphone Apps for Depression and Smoking Cessation*, 2(4) J. AM. MED. ASS’N NETWORK OPEN e192542 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730782>.

¹²¹ Drew Harwell, *Is your pregnancy app sharing your intimate data with your boss?*, WASH. POST (Apr. 10, 2019), <https://www.washingtonpost.com/technology/2019/04/10/tracking-your-pregnancy-an-app-may-be-more-public-than-you-think/?arc404=true>.

¹²² Jessica Berg, *The E-health Revolution and the Necessary Evolution of Informed Consent*, 11(2) INDIANA HEALTH L. REV. 589 (2014).

¹²³ Scott R. Peppet, *Regulating the Internet of Things: First Steps Toward Managing Discrimination, Privacy, Security, and Consent*, 83 TEXAS L. REV. 85 (2014).

¹²⁴ Sunyaev et al., *supra* note 117.

¹²⁵ *Id.*

¹²⁶ Bonnie Kaplan & Sofia Ranchordas, *Alzheimer’s and mHealth: Regulatory, Privacy, and Ethical Considerations*, in EVERYDAY TECHNOLOGIES IN HEALTHCARE 31-52 (eds. C.M. Hayre et al. CRC Press 2019).

¹²⁷ Karandeep Singh et al., *Many Mobile Health Apps Target High-Need, High-Cost Populations, But Gaps Remain*, 35(12) HEALTH AFF. 2310 (2016).

There have been several cases of health information data breaches in recent years. In one case, the MyFitnessPal App case had some vulnerable code which allowed hackers to steal personal information.¹²⁸ One recent study found all 30 digital health applications studied were vulnerable to hacks of their application program interfaces, with some allowing hackers to access users' whole electronic health records.¹²⁹ These weak security protections further put patients' privacy at risk.

Conclusions and Policy Recommendations

The issue of privacy is one that is getting a tremendous amount of attention, and yet, no comprehensive solution has been implemented in the United States. A patchwork of state and federal privacy laws will not lead to a system wherein all developers and patients have clear expectations of privacy, or lack thereof, which are rigorously enforced.

Some organizations have proposed voluntary frameworks for digital health companies to conform their privacy, data security, and other policies.¹³⁰ For example, the Center for Democracy and Technology and the eHealth Initiative and Foundation proposed a self-regulatory privacy framework, titled a "Proposed Consumer Privacy Framework for Health Data," that intends to provide a set of flexible, tech-neutral guidelines that can find a balance between limiting the use of health information and mitigating regulatory risk of consumer privacy. These and other frameworks provide digital health application developers guidelines on how to improve their privacy practices until a mandatory framework is implemented.

A federal health data privacy framework needs to be developed to advance and enforce consumers' privacy protections and emphasize the accountabilities of those who control and process users' health and biometric information. **The framework should be based on the type of information being protected, not what entities are in possession of the information.** This framework should include a set of principles guiding health data access, aggregation, use, and disclosure policies. This framework must hold all current non-HIPAA-covered entities accountable to such standards and subject to enforcement mechanisms. The policies should require digital health application developers disclose all data collecting, using, and sharing practices, allow users to choose what data to share and with whom, and permit patients to opt-out of data sharing and data selling practices.

Health privacy laws must be reformed with a focus on the protection of patients. These recommendations for digital health privacy would be a first step to protecting patients' health information.

¹²⁸ Alyssa Newcomb, *Hacked MyFitnessPal Data Goes on Sale on the Dark Web—One Year After the Breach*, FORTUNE (Feb. 14, 2019), <https://fortune.com/2019/02/14/hacked-myfitnesspal-data-sale-dark-web-one-year-breach/>.

¹²⁹ Brian T. Horowitz, *Mobile health apps leak sensitive data through APIs, report finds*, FIERCE HEALTHCARE (Feb. 24, 2021), <https://www.fiercehealthcare.com/tech/mobile-health-apps-leak-sensitive-data-through-apis-report-finds>.

¹³⁰ Vrushab Gowda, *Beyond HIPAA: A Proposed Self-Policing Framework for Digital Health Products*, HARV. BILL OF HEALTH (Feb. 25, 2021), <https://blog.petrieflom.law.harvard.edu/2021/02/25/self-regulatory-guidelines-digital-health/>.

CONCLUSION AND POLICY RECOMMENDATIONS

Digital health applications present an opportunity to increase access to healthcare, improve quality of care, and promote patient involvement and autonomy in their own healthcare decision-making. There has been significant growth in the development and adoption of digital health applications in recent years, providing care to many patients across disease areas.

Despite this opportunity and growth, digital health applications have thus far been subject to limited regulatory oversight, and the regulations that do exist do not take into account the unique aspects of digital health applications, in particular the iterative nature of their development and updates. Further, patients have largely been left out of the focus of discussions for regulatory reform.

There has been greater attention paid to digital health in recent years, in particular in light of the COVID-19 pandemic's spurring increased adoption of digital health and telehealth tools. The FDA launched the Digital Health Center of Excellence to explore the current FDA regulation of digital health applications and experiment with alternative approval pathways. Lawmakers, patient advocates, and application developers should leverage this momentum to work towards achieving patient-centered digital health regulation and improving the quality of digital health applications.

This project identified four key limitations in the current digital health application landscape that should be prioritized in future digital health regulatory reform – accuracy, usability, accessibility, and privacy. We made the following specific recommendations to improve each identified principle.

* * * *

DIGITAL HEALTH ACCURACY

Digital health applications must be accurate, be continuously reviewed for accuracy, and disclose areas of inaccuracy. There are numerous digital health applications available that are less than accurate; they can range from incomplete to outdated to inaccurate and outright dangerous. The FDA needs authority to properly regulate these devices so that they remain up to date, accurate, and effective. We propose that this regulatory pathway rely not only on pre-market review, but on consistent post-market review, taking into account the iterative nature of digital health applications. While all digital health applications require additional review and regulation, this should be done through risk-stratified regulatory pathways. However, all digital health applications should be required to conduct post-market monitoring, collecting real-world data and reports of inaccuracies or adverse events and reporting such findings to regulators on a regular basis. Additionally, regulators and patient groups should create a rating system based on clinical evidence to help patients understand and evaluate how accurate an application may be.

DIGITAL HEALTH USABILITY

Digital health applications must be usable and understandable for patients. The usability of digital health applications can determine the difference between an application that is successful and

one that never gets downloaded. In addition to issues of interface, we are concerned that any lags in interoperability implementation will negatively affect the ability of the application to be used by the healthcare system, including sharing information between patients and providers. While there are some best practices in digital health application design, we recommend that these factors not be included in a set of regulatory requirements, but that developers and regulators conduct additional research on factors affecting patient usability and submit this information to a regulator or publish these findings. Further, developers should use fields and application programming interfaces to maximize interoperability of digital health applications with other applications, electronic health records, and other sources of health information. Regulators should continue to implement policies maximizing interoperability and information sharing in the healthcare sector.

DIGITAL HEALTH ACCESSIBILITY

Diverse patient needs must be included in the development and review of digital health applications to promote accessibility for all patients. Many populations are limited in their ability to benefit from digital health applications due to the digital divide – the gap in access to technology, access to internet coverage, and digital literacy that prevents some populations from utilizing telehealth and digital health tools. Further, some digital health applications may not be accurate or effective for some populations, in particular people of color, people with limited English proficiency, and people with disabilities. Steps must be taken to address these inequities. Large and diverse populations – including people of different races, ages, and disabilities – should be included and involved in the entire lifecycle of development of digital health applications, and information about the study populations should be reported to provide evidence surrounding efficacy of digital health applications. Digital health application developers should perform pre-market and post-market studies regarding the effectiveness and accessibility of their products to marginalized populations. Overall, we recommend that regulatory and policy reforms be taken by both the government and digital health application developers to promote the design and development of digital health applications that will not continue existing inequities and will be accessible to all patients.

DIGITAL HEALTH PRIVACY

Patients' private information must be protected and patients must be able to opt in and out of key privacy options. The current patchwork of state and federal privacy laws will not lead to a system wherein all developers and patients have clear expectations of privacy which are rigorously protected and enforced. We recommend that a federal health data privacy framework be developed that emphasizes the accountabilities of those who control and process users' health and biometric information. The framework should be based on the type of information being protected and not what entities are in possession of the information. We also recommend that the framework require digital health application developers disclose all data collecting, using, and sharing practices, allow users to choose what data to share and with whom, and permit patients to opt-out of data sharing and data selling practices. Overall, health privacy laws must be reformed with a focus on the protection of patients' private health information.

* * * *

These recommendations are first steps down a path to patient-centered digital health regulation. The need of patients and the diversity of their needs must be centered in any legislative scheme to regulate digital health applications. We hope these principles help guide the development of patient-centered

digital health regulations and emphasize patients' priority areas for reform – accuracy, usability, accessibility, and privacy.

Reform must be taken at several levels of government by many actors, including Congress, the Department of Health and Human Services, the Food and Drug Administration, the Federal Trade Commission, among others. Digital health companies should also take initiative to achieve these principles, conducting and publishing additional studies on the accuracy and usability of their applications and working to promote accessibility of applications to diverse populations. Ultimately, ongoing reform will be needed to account for the iterative nature of digital health applications and to focus the regulatory environment on the needs of patients.

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