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Digital Mental Health Technologies:

Gaps and Opportunities in Current U.S. Regulatory Authorities

Prepared for The Commonwealth Fund
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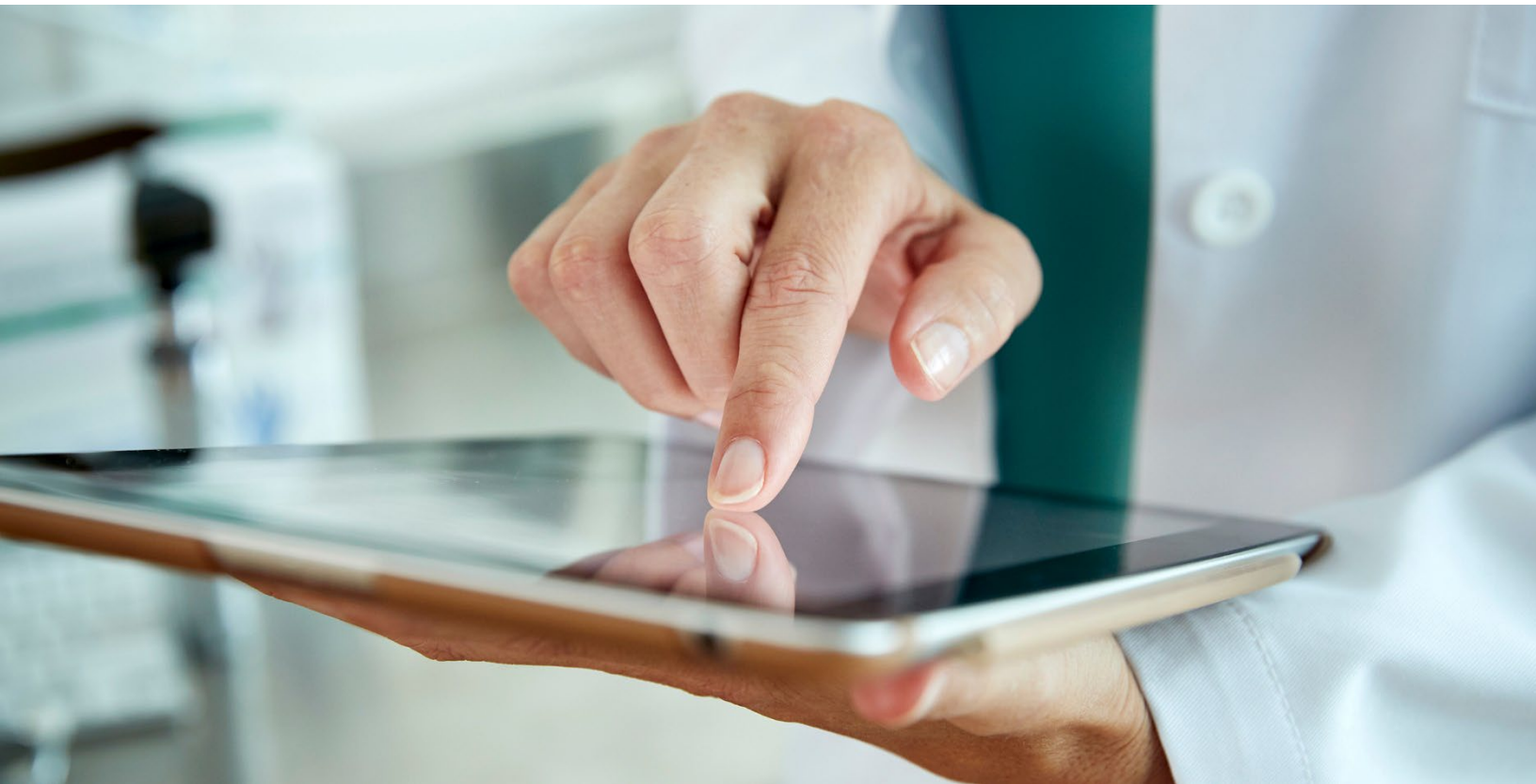

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EXECUTIVE SUMMARY

The use of digital mental health technology (DMHT) has rapidly increased in recent years, its adoption hastened by access challenges and increased need during the COVID-19 pandemic as well as broader access to and familiarity with digital technology. The scope of DMHT is wide, referring broadly to the technology that supports the prevention, screening, diagnosis, and treatment of mental health and substance use disorders (MH/SUD) and can range from tools to support clinicians in providing care (e.g., telehealth) to applications and tools that support self-care, provide evidence-based therapy, or support diagnosis and outcomes analysis, with varying regulatory implications.[1,2] DMHT has the potential to address challenges in access and availability of workforce to meet increased MH/SUD needs; however, the proliferation of DMHTs has created a confusing set of choices for payers, providers, and consumers seeking to determine the effectiveness, quality, and privacy protections associated with a particular DMHT.

With support from the Commonwealth Fund, Leavitt Partners, an HMA Company, conducted a landscape assessment of key statutory and regulatory authorities across the U.S. government (USG). We analyzed federal authorities across the DMHT life cycle, including research and development, consumer access and Food and Drug Administration (FDA) regulatory approaches, reimbursement, utilization from the perspective of federal programs, as well as broader activities and authorities addressing data and compliance, which may affect the uptake and utilization of DMHT. Then, we engaged DMHT vendors, congressional staff, administration officials, advocates, and other cross-sector experts to better understand how federal statutory authorities and regulations are being utilized and where gaps or opportunities exist for new or improved legislative or regulatory actions.

The research, interviews, and listening session provided insights from multiple perspectives on how stakeholders view the existing framework and how it affects innovation, business models, and access to such products among patients, health care professionals, businesses, and other end users. Based on this research and stakeholder engagement, we identified the following key findings:

- **Regulatory authorities have limitations and may not be complementary across the USG.** Most applicable federal statutory authorities and regulations are not specific to DMHT and may reflect an outdated understanding of the components of DMHT and the product development model. Keeping pace with the rapid development and evolution of digital technologies and devices remains a challenge for policymakers and regulators, especially with continual innovation and advances like machine learning (ML) and artificial intelligence (AI). Torous and colleagues observed, "[T]o fully realize the benefits of novel digital offerings, concomitant innovation in regulatory pathways is necessary."[3] Though many agencies are taking steps to leverage their distinct roles and authorities to advance DMHT, and some coordination is occurring, many stakeholders believe a more cohesive approach to regulating DMHT would further advance access and adoption.

- **Payment and reimbursement issues are central to DMHT development and access, but challenges persist.** Addressing reimbursement is critical to ongoing access to DMHT in MH/SUD care. Stakeholders noted that only a small portion of DMHT clearly falls under current federal regulations addressing consumer access, reimbursement, and use. We found that the experiences of companies that took their products through the FDA review process but then went out of business because of limited uptake following authorization served as warnings to other vendors and affected product development considerations. For example, some companies determined that the cost of pursuing FDA approval was a disincentive to develop DMHT subject to FDA regulation. Consequently, some vendors intentionally designed products to fall under the gray area of regulatory discretion to avoid the costs associated with submitting a product for FDA clearance. Insurers, employers, and other purchasers require strong evidence on real-world effectiveness and impact on health outcomes and costs, which FDA review does not address. In early November, Centers for Medicare & Medicaid Services (CMS) announced the final rule for the Calendar Year 2025 Medicare physician fee schedule (PFS) that includes new billing codes for professional services related to DMHT. Though limited to DMHT with FDA clearance for use in treating mental health conditions, this policy update has potential for broader impacts across the industry.
- **Considerations and concerns related to data privacy and security were voiced across sectors, especially in the context of growing use of AI.** Clarifying how data are used is important to boost consumer confidence in DMHT products. In particular, there are concerns that data, including sensitive information, in DMHT may be used in ways that may not be clear to patients and providers. Stakeholders expressed particular confusion over whether the Health Insurance Portability and Accountability Act (HIPAA) federal privacy and security rules related to protected health information apply to DMHT. A DMHT might be covered under HIPAA if the application is controlled by a covered entity (provider or plan), but if it is a consumer-facing application controlled by the vendor, HIPAA does not apply. The Federal Trade Commission (FTC) provides resources to support DMHT developers in understanding their compliance responsibilities related to privacy and personal information, but further clarification would be helpful.[4]
- **DMHT has the potential to help reduce health disparities in access to MH/SUD care, though stakeholders noted funding and access to technology as potentially limiting factors.** Unmet demand and access challenges are particularly acute for low-income populations. These access challenges are felt by racial and ethnic minorities as well as individuals living in rural or medically underserved areas. Some vendors are designing their products with the intention of addressing disparities in access to mental health care, focusing on certain subpopulations and making the products available in different languages and with appropriate cultural references. Stakeholders noted that limited access to smartphones, generous data plans, broadband internet, and other technology may be barriers to the use of DMHT, but some stakeholders believe these challenges are surmountable.

Based on our findings, we identified several recommendations for advancing DMHT.

- **A multi-stakeholder group should lead a consensus-based process to develop a modern regulatory framework to advance access and adoption of DMHT.** Stakeholders, in consultation with federal policymakers should develop a consensus-based modern regulatory framework for DMHT. A more modern framework that accounts for the realities and potential of DMHT could be accomplished through targeted changes to the current law or through the development of a new, more comprehensive, regulatory framework. Any changes should specifically address the distinctions between general wellness technologies and those intended to screen, diagnose, support, treat, and monitor a mental health condition or SUD, which currently fall under FDA's device authorities. A coordinated federal approach could include a more strategic and complementary use of existing authorities across agencies to address concerns and confusion regarding safety and quality, as well as the requirements to which a specific technology is subject. The framework should address innovation and AI, but also manage the potential for overregulation. Strategic and coordinated planning across agencies would align expectations and foster innovation and more certainty in this field.
- **Public and private payers should provide DMHT vendors with more clarity and guidance on evidence requirements for use and payment to provide more certainty and predictability for vendors while improving consumer access to DMHT.** Patient groups and vendors need additional information on how agencies, such as CMS, state Medicaid programs, the Health Resources and Services Administration (HRSA), and Substance Abuse and Mental Health Services Administration (SAMHSA), approach the use of such technologies in programs that they support, the evidence required for these purposes, and how these policies align with one another across the USG. There are opportunities to leverage existing authorities to support wider adoption of DMHT, such as 510k pathway for substantially equivalent tools, and flexibility for states to cover DMHTs under Medicaid.
- **The federal government should provide more clarity and awareness regarding data privacy and security requirements. Vendors and others should take steps to improve consumer awareness of data privacy and security requirements.** Depending on how the DMHT product is used, it may fall under the HIPAA privacy and security rule and/or FTC requirements. The health information ransomware data breach in early 2024 heightened attention to data security issues, after which the FTC finalized the Health Breach Notification Rule (16 CFR Part 318) first proposed in June 2023.[5] In the wake of this incident, increasing consumer awareness about the privacy protections to which specific products are subject will help bolster confidence and trust in the technology. The administration and vendors should consider whether sensitive information may be collected and/or shared as part of a DMHT product that falls outside these means of protection. The administration could partner with private sector organizations to increase consumer awareness of data privacy and security requirements.

- **The U.S. Department of Health and Human Services (HHS) should assess and act on the potential for DMHT to address health disparities.** The department may consider developing new strategic priorities, modifying existing agency strategic plans, such as those of HRSA, SAMHSA, and the Agency for Healthcare Research and Quality (AHRQ), or other relevant activities to more fully leverage DMHT to address health disparities, including with respect to access, use, and reimbursement. These approaches may focus on research and evidence gaps and opportunities, how the use of such products can help address or alleviate workforce constraints, and how to resolve remaining access barriers contributing to such disparities. Consultation with non-governmental partners, such as vendors, researchers, MH/SUD advocacy groups, health care professional associations, and others, will be important to successful analysis of the gaps and opportunities with the use of DMHT to address health disparities.

The DMHT field continues to rapidly expand and evolve and requires a USG regulatory framework that keeps pace with innovation. This area of digital technology has the potential to advance access to MH/SUD care and support improved outcomes in a field where advancements have often been incremental. Consumers and health care professionals need to be able to determine what DMHT is relevant to the MH/SUD condition they are seeking to address and to understand the evidence and quality behind it for that condition. A number of steps can be taken under the existing authorities that would provide meaningful clarity and certainty to vendors and consumers. Our findings support the conclusion that an updated, modern regulatory framework would help address confusion among stakeholders and provide additional certainty. Such a framework could be developed through strategic use of existing authorities or updates to certain authorities or regulations, as well as exploration of targeted new authorities. Now is the ideal time for stakeholders to come together and develop consensus proposals, as the start of a new administration and Congress next year presents an opportunity to assess actions that could be taken under existing authorities and to develop an updated, coordinated approach to DMHT. DMHT presents a key area for bipartisan engagement to address long-standing barriers to care and to retain U.S. leadership in innovation.

BACKGROUND AND APPROACH TO RESEARCH

Digital tools designed to improve mental health have ballooned over the past decade, along with development of DMHT that can be leveraged address health disparities and improve access to mental health services.[6] Fueled by private equity investment, DMHTs have proliferated and created a confusing array of choices for health care payers, providers, and consumers.[7,8] DMHT—technology with the potential to detect, monitor, and treat mental health challenges—can support clinicians in providing care through screening platforms, diagnosis and outcome analysis, or provide evidence-based therapy through a health care workforce shortage when adopted and integrated into treatment plans (see Table 1).[9,10]

Table 1. Digital Mental Health Tools

Category	Type	Definition
Patient-Facing Context: Clinician supported, non-clinician supported, and self-guided	Digital Screening	Digital tools and software that screen for a specific MH, SUD, or medical condition.
	Digital Diagnostics	Validated digital tools and software that deliver a diagnosis or prognosis for a specific MH/SUD or medical condition.
	Care Support	Digital solutions intended to help patients better manage their care for a specific MH/SUD or medical condition.
	Digital Therapeutics	Health software intended to treat or alleviate a specific MH/SUD or medical condition by generating and delivering a medical intervention.
	Patient Monitoring	Digital solutions intended to monitor specific health data, which may be interpreted by a physician for clinical management.
	Health and Wellness	Disease-agnostic digital health solutions that primarily capture and store general health data and promote healthy living.
Not Patient-Facing	Health System-Clinical	Tools that physicians and other health care professionals primarily to assist in delivering clinical care (e.g., measurement-based care, decision support, telehealth).
	Health System-Operational	Tools less likely to be used day-to-day by physicians but that are essential for hospitals and health systems to operate efficiently and minimize the costs of delivering care (e.g., training, supervision).
	Non-Health System	Tools that support non-hospital stakeholders involved in the health care ecosystem, such as payers, employers, and industry (e.g., referral, navigation).
Other technologies	Artificial intelligence approaches	Software tools that "analyze and contextualize data to provide information or automatically trigger actions without human interference."[11]

Sources: Meadows Mental Health Policy Institute. (n.d.). Near-Term Policy Solutions to Bolster Youth Mental Health Workforce through Digital Technology. Meadows Mental Health Policy Institute. https://mmhpi.org/topics/policy-research/near-term-policy-solutions-to-bolster-youth-mental-health-workforce-through-digital-technology/; Wade, B., Abraham, J., Coder, M., Makhijani, V., Pezzulo, S, and Conforti, C. (June 2023). Guidance to Industry: Classification of Digital Health Technologies. Health Advances, LLC. https://dtxalliance.org/wp-content/uploads/2023/06/Guidance-to-Industry-Classification-of-Digital-Health-Technologies-2023Jun05.pdf

During the COVID-19 pandemic, as large numbers of Americans experienced symptoms of mental conditions, payers sought new ways to meet demand, and federal requirements were subsequently relaxed to expand access to telehealth services. Although there has been an increase in product development and distribution, obstacles to scaling, confusion among market populations, privacy concerns, and reimbursement pathway ambiguity has limited the adoption of DMHT despite demand. For ongoing utilization, continued development and innovation, and access, regulatory frameworks must modernize to ensure improved outcomes for patients with MH/SUD. However, confusion regarding regulations and the lack of a clear regulatory framework has limited the adoption of DMHT.[12]

This project was undertaken to develop a detailed federal regulatory landscape for DMHTs, including development of specific recommendations for actions that could be taken under current authorities and serve as a resource to policymakers and industry stakeholders, such as developers, payers, and end users of DMHTs. Through detailed review and analysis of the regulatory landscape, curated interviews with DMHT experts, and a facilitated listening session with a diverse set of stakeholders, the team arrived at key findings and recommendations intended to generate public discussion and stakeholder engagement, inform a new Congress and/or administration about the immediate regulatory and legislative options, and lay a foundation for a consensus-based, multi-stakeholder process to develop a modern framework and long-term policy solutions.

Approach

The team assessed the DMHT landscape through three main workstreams: review of regulatory and statutory authorities, key informant interviews, and a guided listening session with multi-sector stakeholders, including payers, vendors, and patient organizations. Through these analyses and interviews, the team sought to gather multi-stakeholder input to understand how current authorities and regulations are being used and where gaps or opportunities exist for new or improved legislative or regulatory actions. Interviews were tailored with questions applicable to the agency, Congress, or developer. Key research questions assessed the interviewees' priorities related to DMHT; engagement and coordination with either the federal government, vendors, or other relevant entities; feedback on landscape assessment key takeaways and opportunities; and perspectives on AI and health disparities.

Workstream 1: Analysis of Current Regulatory and Statutory Authorities

In Workstream 1, the team characterized DMHT across a number of categories, then outlined how a typical intervention may interact with federal regulatory authority from development to implementation and use (e.g., the life cycle). The team conducted a targeted gray literature search, used key search terms related to DMHT to identify relevant federal authorities, and examined the U.S. code and regulations for broader authorities, such as how the Food and Drug Administration (FDA) regulates medical devices and software as a medical device. We also examined guidance documents, where applicable. Leavitt Partners staff reviewed and synthesized the information into a landscape of authorities, which informed the interviews and listening sessions conducted in Workstreams 2 and 3.

Workstream 2: Key Expert Interviews

In Workstream 2, the team conducted 30- to 45-minute virtual interviews with 20 vendors, Congressional staff, administration officials, and other experts. Vendors represented different categories of DMHT and a range of sizes and stages of funding in their product development. Questions across key themes were tailored with questions applicable to stakeholder expertise. The purpose of the targeted interviews was to gather multi-stakeholder input regarding use of current authorities and regulations, gaps and opportunities, and feedback on key takeaways and opportunities. Input was deidentified and key takeaways from the interviews were tested in the listening session.

Workstream 3: Multi-Stakeholder Listening Session

In Workstream 3, the information compiled in Workstream 2 set the stage for the listening session with a broad group of cross-sector stakeholders to comment on the interview findings. One 90-minute virtual listening session was conducted with 14 attendees from multi-stakeholder organizations, with representatives from two organizations attending as observers. Participants held diverse perspectives and positions across vendors, providers, plans, employers, and advocates. Pre-read material was provided to session participants, and the group was provided with a brief, high-level presentation of the landscape assessment and interview findings. The group was then divided into three multi-sector breakout groups for 30 minutes, moderated and facilitated by Leavitt Partners senior staff. During the breakout sessions, the team sought to test key takeaways and discuss any gaps or opportunities in the research for this report. Once the breakout group period ended, groups reconvened, and a readout was provided to the group at large by a designated participant.

ANALYSIS AND KEY FINDINGS

Federal Authorities Across the DMHT Life Cycle

Leavitt Partners assessed federal authorities across the DMHT life cycle, from research and development through compliance, considering the authorities and agencies that may be involved in each stage—from development to implementation and use (see Table 2).

Broad, flexible authorities address DMHT across the life cycle but generally are not specific to DMHT. An example are the authorities addressing basic and advanced research, as well as development of evidence related to the quality and function of the DMHT. The Public Health Service Act (PHSA) provides broad authority for the U.S. Department of Health and Human Services (HHS) to support, conduct, and coordinate research and development for a range of health issues, including DMHT and evidence development. Other statutes provide authorities related to coordinating cross-government federal research policy objectives, such as the Office of Science and Technology Policy (OSTP) and advancing early-stage research of novel technologies. We identified several ways that agencies are currently using authorities related to DMHT:

- **Supporting Research Initiatives:** The National Institute on Mental Health is using its authorities to support digital health interventions to advance mental health treatment access, including for suicide risk, postpartum depression, and post-traumatic stress disorder.
- **Identifying Research Priorities:** OSTP, in coordination with the White House Domestic Policy Council (DPC), developed scientific research priorities across USG agencies related to the prevention, diagnosis, and treatment of mental health and issued a report. The report identified three cross-cutting research priorities, the second of which was to improve "understanding and leveraging digital mental health interventions."[13] They noted significant growth in digital health platforms for a range of mental health challenges and disorders, with varying evidence to support efficacy. The report identifies two key priorities: 1) development and assessment of digital mental health interventions, and 2) establishment of digital data standards.
- **Supporting Development of Technical Briefs:** The Agency for Healthcare Research and Quality's (AHRQ) Evidence-Based Practice Centers supported development of a technical brief on the use of mental health mobile applications and a framework by which to assess them. The framework is comprised of:
    - Risk assessment and mitigation strategies to determine the risk profile of the app;
    - Function, characterized by accessibility, costs, organizational credibility, evidence and clinical foundation, privacy and security, usability, remote monitoring functions, access to crisis services, and AI; and
    - Mental health app features, such as mood tracking or journaling.[14]

Table 2. Federal Authorities across the DMHT Life Cycle

	Research and Development	Consumer Access	Reimbursement	Utilization	Data Usage, Storage, and Transfer	Compliance
Key Federal Statutes and Agencies	PHSA (NIH, ARPA-H, AHRQ, FDA); Federal Food, Drug, and Cosmetic Act (FDA)	Federal Food, Drug, and Cosmetic Act (FDA)	Social Security Act (CMS); Public Health Service Act (CCIO, USPSTF); Internal Revenue Code; Employee Retirement Income Security Act (Department of Labor)	Public Health Service Act (HRSA, SAMHSA, CMS); Social Security Act (CMS, HRSA); Communications Act of 1934 (FCC); Ryan Haight Act (DEA); Digital Equity Act (NTIA); Health Information Technology for Economic and Clinical Health Act (ASTP); Indian Health Care Improvement Act (IHS); National Defense Authorization Act (DHA); Title 38 (VHA)	HIPAA (ASTP); Patient Safety and Quality Improvement Act (OCR); Public Health Service Act-42 CFR Part 2 (SAMHSA)	Federal Food, Drug, and Cosmetic Act (FDA); Federal Trade Commission Act (FTC); HIPAA (OCR, DOJ); Opioid Addiction Recovery Fraud Prevention Act (FTC); American Recovery and Reinvestment Act (FTC)
Example	USG has authority to provide support for the research and development of DMHTs throughout their life cycle, including basic through advanced research, as well as development of evidence related to the quality and function of the product.	Certain DMHT that meet the definition a medical "device" are subject to FDA regulation, which in some cases includes pre-market review. For those that don't meet this definition there is no similar authority related to consumer access.	There is no benefit mandate for DMHT across federal health programs or in federal regulations governing commercial health insurance. Each program and market segment is making efforts, albeit relatively uncoordinated, to assess how DMHTs fit in the current reimbursement framework. DMHTs may also be eligible for indirect coverage or incorporated into value based and alternative payment models.	DMHT utilization may be impacted by integration or use in federal health care services programs and access to infrastructure, including to address health disparities. DHA and VHA have programs dedicated to the use of digital health technology, including support for development and assessment of and access to mobile applications and other digital health technologies.	Federal laws on health information privacy, security, and breach apply to DMHTs only to the extent they create, maintain, or transmit PHI on behalf of a covered entity or business associate. In addition, federal efforts to develop a national health data infrastructure have largely left the needs of behavioral health providers and patient needs.	FTC generally has authority to prohibit false or misleading claims about a DMHT's safety or performance. It also has the authority to require certain businesses to provide notifications following breaches of personal health record information.

Acronyms: Advanced Research Projects Agency for Health (ARPA-H); Agency for Healthcare Research and Quality (AHRQ); Assistant Secretary for Technology Policy/Office of the National Coordinator (ASTP); Centers for Medicare & Medicaid Services (CMS); Consumer Information and Insurance Oversight (CCIO); Defense Health Agency (DHA); Department of Justice (DOJ); Drug Enforcement Administration (DEA); Federal Communications Commission (FCC); Federal Trade Commission (FTC); Food and Drug Administration (FDA); Health Resources and Services Administration (HRSA); Health Savings Account (HSA); Indian Health Service (IHS); Dept. of Commerce's National Telecommunications and Information Administration (NTIA); HHS Office for Civil Rights (OCR); Substance Abuse and Mental Health Services Administration (SAMHSA); National Institutes of Health (NIH); Veterans Health Administration; U.S. Preventive Services Task Force (USPSTF).

Only a small portion of DMHT clearly fall under current federal regulations addressing consumer access, reimbursement, and use. The Federal Food, Drug, and Cosmetic Act (FFDCA) statute and related regulations and guidance are generally based on a medical device product development model that does not take into consideration digital technologies and the rapid pace of their development. Certain DMHTs that meet the definition of a medical "device" are subject to FDA regulation, which in some cases includes pre-market review. FDA further categorizes devices and regulatory controls into risk-based classes dependent on intended use of the device and indications for use. A DMHT meets the definition of a "device" and is subject to FDA regulation based on a risk classification framework if it is:

- "[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory" intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals;
- Intended to affect human or animal structure or any function of the body; and
- "[W]hich does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes" (21 USC 321(h)).

However, for those that do not meet this definition there is no similar authority related to consumer access; certain software functions, including those intended for maintaining or encouraging a healthy lifestyle that are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, were excluded from the definition of "device" in Sec. 3060(a) of the 21st Century Cures Act. A company that wants to market a Class I, II, or III device for human use for which a Premarket Approval application (PMA) is not required must submit a 510(k) pathway (21 CFR 807) and must receive a letter, or order, from FDA which finds the device to be substantially equivalent and that it can be marketed in the U.S.[15] There is also a De Novo pathway for lower-risk Class I or II devices that requires "reasonable assurance of safety and effectiveness for the intended use."[16]

FDA acknowledged the need for new statutory authorities in the summary of findings from the Pre-Certification Pilot Program, noting that, "For digital health technologies that meet the definition of a device in section 201(h) of the [Federal Food, Drug, and Cosmetic Act], FDA identified not only the potential for these devices to improve public health, but also that FDA's regulations are not optimally suited to the manner in which these devices are designed, validated, and improved over time."[17] The report notes that the current statutory framework is "not well suited to the faster cycles of innovation and the speed of change" needed to assure safety and effectiveness in rapidly evolving devices.[18]

Additionally, there is no benefit mandate for DMHT across federal health programs under current law or federal regulations governing commercial health insurance. Once a DMHT is cleared or approved by FDA, evolving pathways for Medicare coverage of and payment for DMHT are not always clear. CMS is taking steps to address this for certain subsets of DMHT, as is noted in the in focus on the 2025 Medicare physician fee schedule DMHT proposal on page 13.

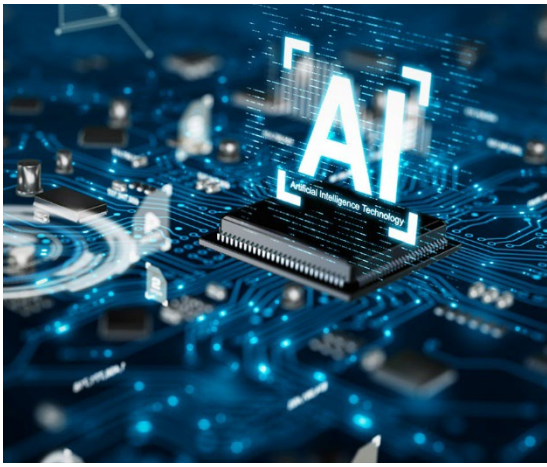
Agencies are leveraging authorities in various ways to address consumer access, reimbursement, and utilization.

- **Regulatory Support for DMHT Innovators:** FDA has developed several resources that could support DMHT innovators, including those supported by the FDA Digital Health Center of Excellence to accelerate digital health advancements, the Digital Health Policy Navigator to help product developers understand whether a software function is potentially subject to or the focus of FDA's regulatory oversight as a device, and the Software Precertification Pilot Program (2017 to 2022).
- **Regulatory Discretion:** FDA issued guidance to "communicate how the Agency intends to apply its regulatory oversight to certain software, including device software functions and mobile medical applications (MMA) intended for use on mobile platforms or on general-purpose computing platforms."[19] The agency indicated it intends to apply its regulatory oversight to those device software functions that meet the definition of a medical device and which could pose a patient safety risk if it did not function as intended.
- **Medicare Reimbursement:** The CMS 2025 Medicare Physician Fee Schedule Proposed Rule included a provision for new reimbursement code for DMHT to treat or alleviate a mental health condition that are approved or cleared by FDA.

Additionally, as described in the in focus on artificial intelligence (AI) on this page, agencies are exploring issues related to the risks and benefits of development and use of AI, which has the potential to impact DMHT.

There are specific rules applicable to DMHT for use of personal health information. Federal laws on health information privacy, security, and breach apply to DMHT only to the extent they create, maintain, or transmit protected health information on behalf of a covered entity or business associate. Many DMHT do not meet the definition of a covered entity or business associate and are therefore not subject to HIPAA rules; however, other federal laws and regulations may apply. Additionally, the 21st Century Cures Act required the National Coordinator for Health Information Technology to establish the Trusted Exchange Framework and the Common Agreement (TEFCA) to establish a floor for interoperability in the U.S. TEFCA supports data exchange between health care and other entities. We found that the administration has taken a number of actions related to personal health information, including:

- **Privacy Protections:** TEFCA requires participating entities that are not covered by HIPAA to protect individually identifiable information in substantially the same manner that a HIPAA covered entity protects protected health information.[20]



ARTIFICAL INTELLIGENCE IN FOCUS

Key Statutes

- The National Artificial Intelligence Initiative (15 U.S.C. Ch. 119)
- General agency authorities related to innovation and technology

Executive Order (E.O.) 14110

- Calls on federal departments and agencies to address key issues raised by the potential uses of AI, including management of security and privacy risks and promotion of innovation.
- Followed by establishment of a White House AI Council comprised of lead officials from departments and agencies. The administration has also established an AI Task Force at HHS.

Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. October 30, 2023.

DMHT may be subject to FDA and/or FTC compliance regulations. If a DMHT meets the definition of a medical device under the FFDCA, then it is subject to all of the compliance provisions applicable to medical devices. The FTC generally has the authority to prohibit false or misleading claims about a DMHT's safety or performance under the Federal Trade Commission Act, and it also has the authority to require certain entities to provide notifications following breaches of health information in a personal health record or related technology. FTC has used its authorities to pursue action against companies that make specific claims regarding their product with insufficient evidence, and which use health information in a manner for which users did not provide consent.

- **Compliance Support:** The FTC provides tools to help support DMHT developers in understanding their compliance responsibilities.

Key Findings

Based on our research and stakeholder engagement, we identified four key findings:

1) Regulatory authorities have limitations and may not be complementary across the USG.
2) Payment and reimbursement issues are central to DMHT development and access, but challenges persist.
3) Considerations and concerns related to data privacy and security were voiced across sectors, especially in the context of growing use of AI.
4) DMHT has the potential to help reduce health disparities in access to MH/SUD care, though stakeholders noted funding and access to technology as potentially limiting factors.

Finding 1: Regulatory authorities have limitations and may not be complementary across the USG.

Federal authorities governing DMHT activities (i.e., the applicable Federal Food, Drug, and Cosmetic Act (FFDCA) statute and related regulations) do not always take into consideration digital technologies and the rapid pace of their development. Increasingly DMHT are employing artificial intelligence (AI) methods that require frequent updates. In addition, DMHT vendors often update tools to support ease of use. Certain DMHTs that meet the definition of a medical "device" are subject to FDA regulation, which in some cases includes pre-market review; however, for those that do not meet this definition there is no similar authority related to consumer access. It was estimated that in 2020, more than 90,000 new digital health apps were released,[21] with the majority focused on "wellness management," which means they are not subject to FDA oversight. Even though the FDA medical device authorities do apply to some DMHT, in its 2022 report, "The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle (TPLC) Approaches and Key Findings," which also reflected stakeholder concerns, FDA acknowledged the limitations of current law:

- "Ultimately, the approach to regulating novel, swiftly evolving medical device software must foster, not inhibit, innovation, while continuing to provide reasonable assurance of safety and effectiveness. These aspects are not mutually exclusive. A flexible, risk-based approach to regulation could allow FDA to tailor regulatory requirements more efficiently for devices based on the latest science, the benefits and risks posed by devices, their real-world performance, and their contribution to promoting health equity. It could leverage the capabilities of evolving medical device software so that health care providers, patients, and users can benefit from advancement and innovation, and so that risk for such devices can be reduced through swift software and cybersecurity updates throughout the TPLC, when needed. New legislative authority establishing such an approach could be supplemental to, and not replace, the established regulatory pathways."[22]

In addition to FDA, there are other federal agencies with broad, flexible authorities that generally support DMHT across the life cycle, including basic and advanced research, development of evidence related to the quality and function of the product, data and privacy protection, and reimbursement. Each of these agencies have different legal authorities, objectives, and missions that may necessitate different data and approaches, which may make it challenging for vendors to understand how to engage with each agency. Participants noted that policymakers should consider how to modernize statutory and regulatory requirements, so they adapt with technology. Additionally, it was noted by at least one participant that in the substance use disorder space, the Drug Enforcement Administration drives the approach to care, which federal health agencies then follow.

- An additional complication stems from the fact that many policies related to DMHT are more general authorities related to digital health tools and do not take into consideration the unique data and use cases that differentiate MH/SUD needs from those of medical and surgical needs. While some stakeholders noted that there are more similarities than differences between MH/SUD needs and those of medical and surgical needs from a DMHT perspective, others noted FDA expertise in psychosocial interventions and the need for recognized evidence-based data will be integral to advancement of DMHT.

While there is some coordination among agencies, stakeholders in the private sector are not always aware or satisfied with the level of coordination. An example of coordination occurring within the USG is the White House Report on Mental Health Research Priorities, which was led by the Office of Science and Technology Policy (OSTP) in partnership with the Domestic Policy Council (DPC).[23] Working with experts across a number of departments and agencies, the report identifies a number of research priorities, including related to DMHT. Specifically, the report:

- Identified three cross-cutting research priorities, the second of which was "understanding and leveraging digital mental health interventions."
- Noted that significant growth has occurred in digital health platforms for a range of mental health challenges and disorders with varying evidence to support efficacy.
- Identified two priorities related to DMHT: 1) developing and assessing digital mental health interventions, and 2) developing digital data standards.
- Noted that DMHT should align with HHS's National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care.

2025 MEDICARE PHYSICIAN FEE SCHEDULE DMHT IN FOCUS

CMS announced the 2025 Medicare PFS final rule on November 1, 2024. The final rule includes three new Healthcare Common Procedure Coding System (HCPCS) codes related to digital mental health treatment devices used as part of a behavioral health treatment plan of care. Specifically, the final rule:

(1) Requires that eligible tools must be cleared under section 510(k) of the FDCA or granted De Novo authorization by FDA for mental or behavioral health treatment;

(2) States that physicians or other practitioners authorized to diagnose, evaluate, and treat mental health disorders may prescribe or order a digital mental health treatment device in accordance with State prescribing laws and then report HCPCS code G0552; and

(3) Adds two HCPCS codes to reimburse providers for time managing the patient's treatment with a digital mental health treatment device.

Calendar Year 2025 Medicare Physician Fee Schedule Final Rule. November 1, 2024, scheduled for publication December 9, 2024.

Some participants noted that this coordinated effort for the research component of the DMHT lifecycle was well-received, but the other components of the life cycle, particularly FDA approval and reimbursement, were not addressed.

During the course of the interviews and listening session, vendors identified a number of challenges related to the current DMHT regulatory framework, including the costs of applying for FDA approval and questions about data requirements, including for products that frequently require updates. The listening session also unearthed a common theme from stakeholders that more alignment of objectives across the federal government would help support additional DMHT investments, development, and usage. Additional clarity on enforcement and limiting the gray space in which vendors operate would also make it easier for them to navigate the different agency requirements.

There are models for a complementary approach that acknowledge product innovation and evolution, several of which were identified by stakeholders.

- The United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE) are partnering, with support from Wellcome, to address key challenges related to regulating and evaluating DMHTs.[24] FDA is engaged in the project as well, with Dr. David McMullen, Director of the Office of Neurological and Physical Medical Devices in FDA's Center for Devices and Radiological Health, noting "that successful international harmonization will require the integration of ideas and perspectives from key stakeholders, including other regulatory authorities to facilitate improved patient access to safe and effective digital mental health technologies."[25]

- Several participants cited Germany's Digitale Gesundheitsanwendungen ("DiGA") digital health fast-track process as a potential example of a lower-barrier approach to regulation and reimbursement.[26] Established as part of Germany's Digital Healthcare Act, the assessment procedure is intended to facilitate more rapid market access for digital health. Products classified as certain medical devices are eligible to apply for Fast Track, after which the Federal Institute for Drugs and Medical Devices must evaluate the product within three months based on a defined a set of requirements. These requirements assess security, functionality, quality, data protection and security, and interoperability, as well as effects on care related to medical benefit and structural and procedural improvements. A product can be granted admission into the DiGA directory or receive preliminary admission into the DiGA directory, which requires additional evaluation before a final determination is issued. The DiGA directory provides information about qualities and services of the devices. Once listed, physicians receive an additional reimbursement as well.

- Some participants noted that technology readiness levels (TRLs) used by both the Biomedical Advanced Research and Development Authority (BARDA) and the National Aeronautics and Space Administration (NASA) may provide a means of applying standardized criteria to assess DMHT development stages. BARDA uses TRLs for medical countermeasure products and product development tools like reagents and assays.[27] NASA uses nine TRLs to assess hardware and software and provide criteria required to move to the next readiness level. TRLs provide a common set of definitions to determine research and development progress.

- Numerous non-governmental efforts are under way to provide evidence-based assessments of DMHT. Below are some examples that arise during research and participant discussions:
    - The American Psychiatric Association's App Advisor provides information on how to evaluate an app and suggested criteria to consider when assessing apps for personal and professional use.[28]
    - The Peterson Health Technology Institute (PHTI) assesses evidence related to digital health technologies with the goal of improving health care outcomes and lowering costs.[29] To provide feedback on the approach used to assess digital health technologies, PHTI created a Purchaser Advisory Council that includes members from health plans, employers, and health systems to provide perspectives on key metrics.

We also heard from participants that the emergence of AI, with its potential risks and benefits in the DMHT field, generates urgency in the need for a framework that addresses these factors, and that AI also makes such a framework more complicated.

Finding 2: Payment and reimbursement issues are central to DMHT development and access, but challenges persist.

Addressing reimbursement is critical to ongoing access to DMHT in MH/SUD care. The relationship between FDA approval and pathways for payment and reimbursement is not always straightforward. Many DMHT have multiple functions, addressing screening, clinical intervention, care management, and others, and vary with respect to the intended user. FDA approval is a key factor in prescribing, but the pathway to a viable business model can be less clear. If a product meets the FDA's definition of software as a medical device, the FDA pathway (de novo pathway for lower risk devices, 510k pathway, or "enforcement discretion") has relevance to consumers, providers, and purchasers. Some vendors will pursue FDA approval as a means of demonstrating quality to support reimbursement from public and private payors. Many others assert that their DMHTs are not devices, are low risk, or are intended to help patients manage their condition without providing specific treatment and thus should fall under FDA's regulatory discretion.

A major issue raised by the vendor community was the concern that at least one company that took a DMHT through the FDA review process but then went out of business due to reimbursement challenges and low uptake once the product was on the market.[30] Regardless of whether a vendor seeks FDA approval or positions its product as a "general wellness" DMHT, it is clear that stakeholders view reimbursement or payment from public and private payors as necessary to further develop the DMHT market. In addition to payment for the product, some vendors and providers noted that reimbursement for clinician time spent in educating patients and using the product is an important factor.

CMS recently included in the final rule for the Medicare Physician Fee Schedule (PFS) for Calendar Year 2025 three billing codes for professional services related to DMHT, as described in the in focus section on page 14.[31] Though limited to DMHT with FDA clearance for use in treating a subset of mental health conditions, these billing codes could have broader impacts across the industry. Participants generally viewed the initial proposal as progress, but some noted the scope of prescription DMHT for treatment as overly narrow and expressed concern that a new code will not guarantee uptake.

This message was consistent with discussions with stakeholders regarding legislation that would require Medicare and Medicaid coverage of prescription digital therapeutics. Some participants noted that requiring a prescription for FDA-cleared DMHT can limit access and that having a non-prescription DMHT product could allow vendors to make the product available through a number of trusted touchpoints, such as therapists, social workers, and even peer navigators, which could have a positive impact on access to care and health equity. Further, providing direct to consumer access DMHT was viewed as a potential means of providing care when people live in areas that are experiencing health professional workforce shortages. Others noted, however, that in the absence of other indicators of evidence, limiting the scope to prescription DMHT provides assurance that certain factors related to safety and evidence have been met.

Other approaches are available for building a market besides FFS reimbursements. Some vendors position their product under FDA regulatory discretion and seek a market through mechanisms other than FFS reimbursement. Participants indicated that most DMHT are provided through business contracts, such as with plans, employers, or even providers. They also noted that coverage with the option for further evidence development would be another approach to advance access and provide certainty for vendors. Additionally, value-based payment and other coverage options also present opportunities. The Center for Medicaid and Children's Health Insurance Program (CHIP) Services issued an informational brief in June 2024 that outlined opportunities for state Medicaid agencies to receive enhanced federal matching for health information technology expenditures related to increasing access to MH/SUD services, including smartphone and web applications, screening technology, and peer support web platforms.[32]

Different evidence requirements across FDA, CMS, states, and other actors in the health care industry can present a barrier to DMHT advancement for startups and smaller companies. Insurers, employers, and other purchasers seek strong evidence on real-world effectiveness and impact on health outcomes and costs to make a decision on whether to pay for a product. Though the FDA assesses safety and efficacy of a DMHT, health care systems are interested in the broader impacts of DMHT. Health systems and payers will also consider whether a technology is better than the standard of care as they approach payment for these tools. Costs related to meeting FDA safety and efficacy requirements, should a company pursue that path, as well as stakeholder questions regarding return on investment and health impacts, are particularly challenging to smaller or start-up DMHT companies—especially companies that target underserved populations. Some participants noted that the FDA approval requirements and process is geared toward the traditional medical product industry versus DMHT developers. The lack of agreement about required evidence and trial methods for DMHT are also challenging, especially when DMHT incorporate AI tools are frequently updated to support ease of use.

Finding 3: Considerations and concerns related to data privacy and security were voiced across sectors, especially in the context of growing use of AI.

Clarifying how data are used is important to consumer confidence in DMHT products. There are concerns that data, including sensitive information, in DMHT may be used in ways that may be unclear to patients and providers. Recent ransomware and other cyberattacks on health care entities have increased concern and attention regarding sensitive health information across the health care industry and among consumers. A particular concern that stakeholders expressed confusion over is whether HIPAA federal privacy and security rules related to protected health information apply to DMHT.

DMHT are covered under HIPAA, if the application is controlled by a Covered Entity (provider or plan) or business associate. However, if it is a consumer-facing application controlled by the vendor not in a contractual relationship with a Covered Entity, HIPAA does not apply. In these instances, FTC regulations regarding false and misleading claims, general consumer privacy and security, and, potentially, the FTC Health Breach Notification Rule, come into play. It may not be clear to consumers and some health care providers which privacy and security protections apply in a given circumstance. Furthermore, the FTC also provides resources to support DMHT developers in understanding their compliance responsibilities related to privacy and personal information, but further clarification, including for consumers, would be helpful.[33] In addition to federal laws and regulations, actors have to navigate state-required privacy protections.

Some participants noted that the relationship between health systems and federal agencies, including liability concerns, does not facilitate open discussion about issues related to data privacy and security with respect to DMHT. They further noted that there are a lot of requirements about how an app needs to operate, but not many regarding data storage (for example, the requirement for HITRUST certification). We also received varying feedback on coordination among the Department of Justice (DOJ), HHS, and FTC and the extent to which USG officials understood the issues facing DMHT vendors and users. Participants expressed concern that there is a disconnect between the USG and the issues facing vendors and users of DMHT.

While policymakers are weighing the risk and benefit framework for AI and regulatory considerations, participants noted that there should be considerations for how, in what manner, and with what level of consent the use of AI is integrated into DMHT.

Finding 4: DMHT has the potential to help reduce health disparities in access to MH/SUD care, though stakeholders noted funding and access to technology as potentially limiting factors.

DMHT have the potential to increase accessibility of care and help manage workforce challenges. We found that some vendors are considering the potential for DMHT to address health disparities across each phase of research and development, including by designing the DMHT with the intention of addressing disparities in access to mental health care. This may include focusing on certain subpopulations or making the product available in different languages and with culturally appropriate references. Small vendors addressing underserved populations view themselves at a disadvantage compared with large firms due to the amount of funding required for FDA review. Similarly, some vendors are actively engaged in improving diversity of participants in clinical trials, while others seek to do this. Some participants noted the financial cost to make investments into technology that really benefits everyone. Others noted that it is not a first priority as a startup.

Efforts to address health disparities are often considered across a range of subpopulations, particularly individuals with serious mental illness and those in rural areas, as well as racial and ethnic minorities and low-income populations. Each of these populations may have different access and care needs in using the tool. Some vendors are making commitments to address health disparities at the leadership level, including by establishing health equity task forces or diversity boards. As a practical matter, access to technology, like smartphones or one family sharing a phone and broadband internet may present a barrier to utilizing these tools, but some believe these to be surmountable. There are USG activities that seek to address some of these barriers, including collaborations across HHS, the Federal Communications Commission, and U.S. Department of Agriculture to expand wireless broadband services.

RECOMMENDATIONS

Through our assessment and stakeholder engagement, we identified four recommendations to improve predictability and certainty for DMHT innovators, consumers, and health care providers.

1) A multistakeholder group should lead a consensus-based process to develop a modern regulatory framework to advance access and adoption of DMHT.
2) Public and private payers should provide DMHT vendors with more clarity and guidance on evidence requirements for use and payment to help provide more certainty and predictability for vendors while improving access for consumers of DMHT.
3) HHS should provide more clarity and awareness regarding data privacy and security requirements. Vendors and others should take steps to improve consumer awareness of data privacy and security requirements.
4) HHS should assess and act on the potential for DMHT to address health disparities.

Recommendation 1: A multistakeholder group should lead a consensus-based process to develop a modern regulatory framework to advance access and adoption of DMHT.

- A diverse set of health care stakeholders, in consultation with federal policymakers, should develop a consensus-based modern framework for regulating DMHT to fully harness the promise of the latest innovations in mental health research and technology. A flexible, evidence-based approach that adapts for changing science and technology will give vendors and other stakeholders the certainty they need to make further investments in DMHT.
- Such a framework should:
    - Clearly identify the scope of products appropriate for federal pre-market review or approval versus products that may be sold direct to consumer without federal action.
    - Take into consideration factors such as the potential risks and benefits of a DMHT, the proposed use of the DMHT (general wellness or to diagnose, support, treat, and monitor a MH/SUD), the unique data and use cases that differentiate MH/SUD needs from medical/surgical needs, how the DHMT may help to address MH/SUD coverage and care shortages.
    - Provide clear direction to regulated DMHT vendors on the evidence and data needed to support regulatory actions including pre-market review or approval and reimbursement.
    - Recognize that different agencies have unique and complementary authorities and roles that may necessitate different data and approaches.
    - Include recommendations for interagency collaboration and strategic planning to ensure that each agency is best leveraging its authorities to support further development, adoption, use, and reimbursement of DMHT.
    - Ensure the appropriate protections for patient information.
    - Consider the appropriate role of the private sector or third-party certifications in helping to provide better information on a DMHT product to consumers, providers, and payers. This could include on data on quality and real-world evidence, and other factors to help navigate the large number of available DMHTs.

- The proposed framework should be accompanied by an implementation plan that provides specific actions that the federal government and health care stakeholders must take to effectuate the framework. This could include actions that the federal government can take under its current authorities, such as agency-specific actions consistent with their respective authorities and objectives, suggested policy changes that require legislative changes to existing authorities, or the establishment of new interagency initiatives. The implementation plan should also clearly describe who with in the federal government has authority over implementing the framework. The administration could address this recommendation through strategic planning across agencies and offices involved in each aspect of the DMHT life cycle, which would benefit from engagement with stakeholders and consideration of state, private sector, and international activities related to DMHT. There are examples of how government has done this, such as the Cancer Moonshot Executive Order and Maternal Health Initiatives.
- In addition to the federal authorities described, the framework should also identify steps that the private sector can take alone or in partnership with the federal government to achieve these objectives.

Recommendation 2: Public and private payers should provide DMHT vendors with more clarity and guidance on evidence requirements for use and payment to help provide more certainty and predictability for vendors while improving access for consumers of DMHT.

- As part of the initiative above, public and private sector agreement on evidence requirements is needed.
- There is not enough information from regulators and reimbursement experts on what constitutes sufficient evidence and consistency in outcomes. Agencies could improve these efforts by identifying approaches to the evaluation of DMHT. While some private-sector entities are trying to advance approaches to evidence-gathering, there is not yet a uniform approach in the field.
- When it comes to reimbursement, CMS should establish clear policies within Medicare, Medicaid, and ACA markets. There are opportunities to leverage existing authorities to support wider adoption of DMHT, such as flexibility for states to cover DMHTs under their Medicaid benefits. The 2025 Medicare Physician Fee Schedule Final Rule has the potential to influence the DMHT market more broadly in the future, including for MH/SUD care beyond treatment.
- Federal agencies should issue FAQs or other notices to provide insights on how they view DMHT and factors considered in the context of their respective programs. In June 2024, the Center for Medicaid and CHIP Services issued an informational bulletin related to improving access to MH/SUD care and enhanced federal Medicaid matching rates for state information technology expenditures, which included a section on FAQs.[34] Patient groups and vendors need additional information on how agencies, such as the Health Resources and Services Administration and Substance Abuse and Mental Health Services Administration, as well as state Medicaid programs, approach the use of such technologies in programs that they support, the evidence required for use, and how these policies align with one another across the USG.
- Private payors should work with private sector entities or in partnership with the federal government to identify approaches to demonstrating quality, for example, digital health technology accreditation programs. Accreditation programs may also help providers identify products that meet certain metrics and quality standards to help providers navigate the landscape of DMHT.

Recommendation 3: The federal government should provide more clarity and awareness regarding data privacy and security requirements. Vendors and others should take steps to improve consumer awareness of data privacy and security requirements.

- As part of the coordinated framework recommended above, the administration, as well as vendors and experts, should assess and consider the many ways in which the range of DMHT may be used in health care contexts; whether HHS authorities, including related to HIPAA, 42 CFR Part 2, and FTC authorities protect sensitive health information as expected or whether there are gaps in such privacy and security protections; and identify options for addressing such gaps, which may include regulatory or statutory updates. The extent to which health care providers' data is included in the DMHT and implications for the use of their data should be considered as well.

- The administration, vendors, health care providers, and private, non-profit organizations should take steps to increase consumer awareness of data privacy and security requirements in a manner that is consumer friendly and appropriate for a range of digital literacy levels, as well as data privacy and security requirements awareness activities for health care professionals.

    - For example, there are a number of actions the administration or non-governmental partners have taken in the past to improve clarity and awareness on issues related to data privacy and security that could enhance awareness and understanding in this case as well. For example, the HHS Office for Civil Rights has issued fact sheets and guidance on HIPAA and mental health for different audiences, such as parents, families, and health care professionals. These documents clarify how mental health information is treated under HIPAA, what information may be shared and with whom, and the circumstances surrounding disclosures. Such an approach could also be helpful with respect to DMHT.

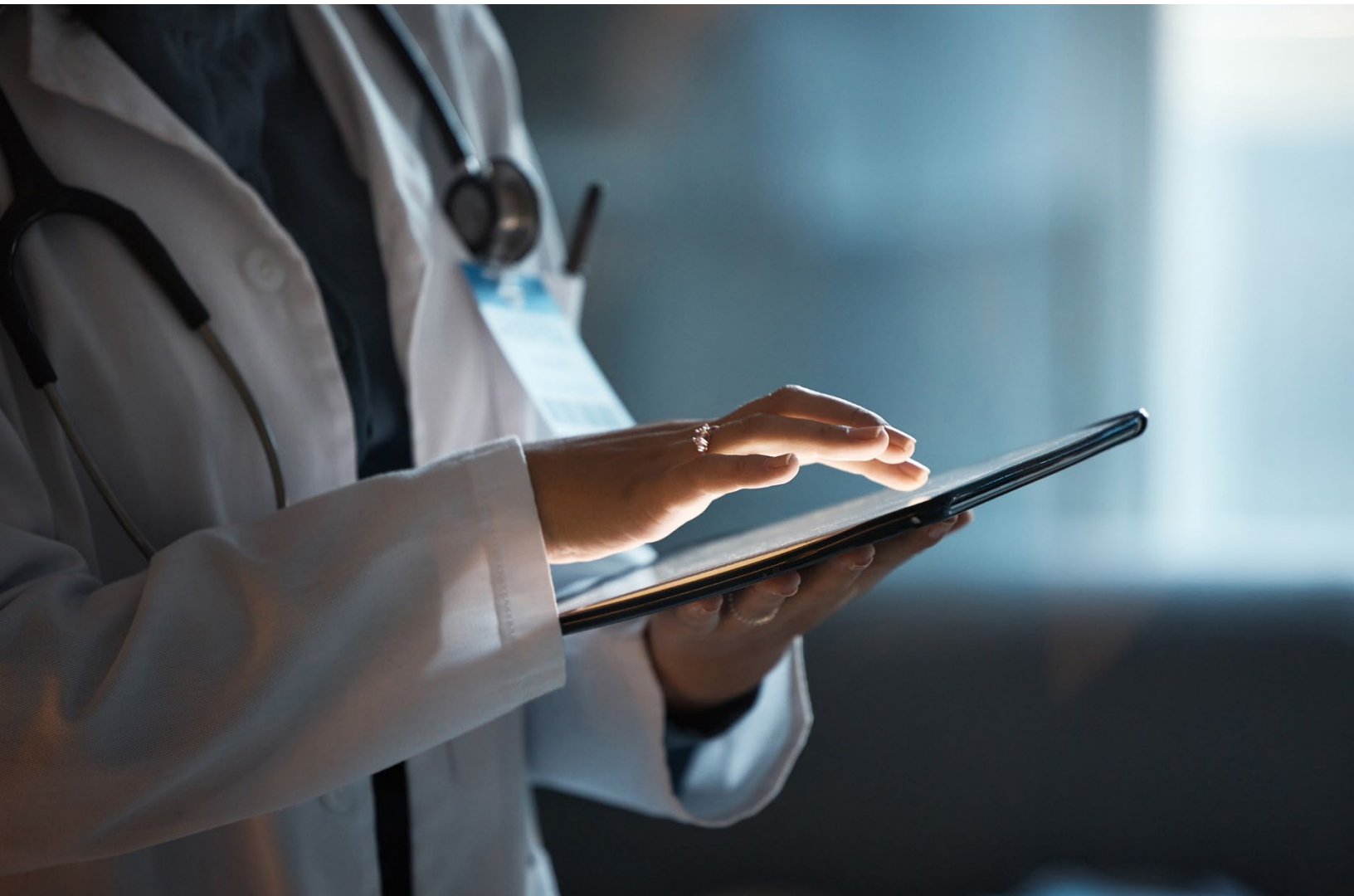
- As consideration of AI in DMHT continues, the administration should engage stakeholders in development of approaches for the use of AI to fully explore the potential risks and benefits of its use in DMHT, particularly associated with data use and privacy. This could be done through stakeholder workshops facilitated by key agencies, such as the NIH, FDA, and ONC or through agency requests for information.

Recommendation 4: HHS should assess and act on the potential for DMHT to address health disparities.

- HHS should work with researchers, health care professionals, public health officials, vendors, states, territories, local governments, Tribes, and others to identify how to best leverage DMHT to address health disparities, identify gaps and opportunities, and develop evidence to support the development of evidence-informed and evidence-based uses of DMHT to improve access to care.

- The Department may consider developing new priorities, modifying existing agency strategic plans, or other activities to incorporate DMHT as a tool to address health disparities and improve access to care. These approaches should consider research gaps and opportunities, how the use of such products can help address or alleviate workforce constraints, and how to navigate barriers, such as lack of broadband or smartphone access. The department should take into consideration DMHT research, including research supported by NIH and other agencies, that explores the use of DMHT to address gaps in care.

- HHS and stakeholders should also consider how DMHT can be leveraged in federally funded programs that seek to improve access to care, such as those of HRSA and SAMHSA, as well as Medicaid, to support MH/SUD care delivery and the types of evidence that would be required.
- Stakeholders, including vendors, should additionally consider how their work can address health disparities by leveraging the use of DMHT and supporting the development of evidence-informed and evidence-based practices related to its use. There may be opportunities to obtain support from or to partner with the government to develop this evidence.
- Vendors should conduct their clinical trials in a manner that promotes diversity and inclusion and better reflects the population most likely to use and/or benefit from the DMHT. This may include individuals with different age, sex, race, ethnicity, and language needs characteristics, as well as different mental health conditions and geography.
- HHS and stakeholders should consider how programs could utilize DMHT to improve health outcomes and address equity challenges, including among hard-to-reach populations or in rural areas, as well as whether there is the infrastructure to support such use (*e.g.*, broadband).



CONCLUSION

DMHT is at a pivotal point in its regulatory positioning in the U.S. and has the potential to be an additional tool to advance access to MH/SUD care. Consumers and health care professionals need a way to determine what works and what doesn't from the multitude of products. Further, the U.S. regulatory environment risks falling behind if it does not keep pace with the development of technology such as DMHT. Our findings support the conclusion that an updated, modern federal regulatory framework is needed to address the disparate patchwork of authorities affecting DMHT that perpetuate confusion among stakeholders. Such a framework can also promote innovation and improve access to safe, effective, and equitable DMHTs to support optimal outcomes for people with MH/SUD. This goal could be accomplished through strategic use of existing authorities, as well as strategic updates to existing authorities or regulations. Targeted new authorities could be explored as well. This paper is intended to generate discussion and stakeholder engagement over key issues present in the DMHT industry.

With a new administration and Congress set to convene next year, the timing is ideal to further the discussion related to the use of DMHT to address MH/SUD needs and to take steps to develop an updated, coordinated approach to DMHT. We have identified actions that can be taken to lay the groundwork for a modern framework and a multi-stakeholder consensus-based process to encourage the development of DMHT while addressing disparities and decreasing overall health costs. While advancements in MH and SUD care have often been incremental and siloed, DMHT presents a key area for bipartisan engagement to address long-standing barriers to care and to retain U.S. leadership in innovation.

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ACRONYMS

U.S. Government Department, Agency, and Office Acronyms

AHRQ: Agency for Healthcare Quality and Research
ARPA-H: Advanced Research Projects Agency for Health
CMS: Centers for Medicare & Medicaid Services
CCIO: CMS Center for Consumer Information and Insurance Oversight
DEA: Drug Enforcement Administration
DHA: Defense Health Agency
DOD: Department of Defense
DOJ: Department of Justice
DPC: White House Domestic Policy Council
EBSA: Employee Benefits Security Administration
FDA: Food and Drug Administration
FCC: Federal Communications Commission
FTC: Federal Trade Commission
HHS: U.S. Department of Health and Human Services
HRSA: Health Resources and Services Administration
IHS: Indian Health Service
NIH: National Institutes of Health
NIBIB: National Institute of Biomedical Imaging and Bioengineering
NIDA: National Institute on Drug Abuse
NIMH: National Institute on Mental Health
NSF: National Science Foundation
NTIA: National Telecommunications and Informatio Administration
OCR: HHS Office for Civil Rights
ONC: Office of the National Coordinator for Health Information Technology
OSTP: White House Office of Science and Technolog Policy
SAMHSA: Substance Abuse and Mental Health Services Administration
USDA: U.S. Department of Agriculture
USPSTF: U.S. Preventive Services Task Force
VA: U.S. Department of Veterans Affairs
VHA: Veterans Health Administration

Statute Acronyms

ACA: Affordable Care Act
ARRA: American Recovery and Reinvestment Act
CSA: Controlled Substances Act
COPPA: Children's Online Privacy Protection Act
ERISA: Employee Retirement Income Security Act of 1974
FFDCA: Federal Food, Drug, and Cosmetic Act
FTCA: Federal Trade Commission Act
HIPAA: Health Insurance Portability and Accountability Act
HITECH Act: Health Information Technology for Economic and Clinical Health Act
PHSA: Public Health Service Act
SSA: Social Security Act

Other Acronyms

AI: Artificial Intelligence
BAA: Business Associate Agreement
CFR: Code of Federal Regulations
CMP: Civil Monetary Penalties
DMHT: Digital Mental Health Technologies
DTC: Direct-to-Consumer
EHR: Electronic Health Record
FFS: Fee-for-Service
FSA: Flexible Spending Account
HSA: Health Savings Accounts
IMDRF: International Medical Device Regulators Forum
MH/SUD: Mental Health and/or Substance Use Disorders
PDT: Prescription Digital Therapeutics
SaMD: Software as a Medical Device
USC: United States Code
USG: U.S. government

ABOUT LEAVITT PARTNERS

Leavitt Partners, an HMA Company (LP), has been at the forefront of health policy development for more than three decades. The firm is comprised of professionals whose experience spans the executive and legislative branches of government. As former congressional staff and executive branch political appointees, its team members know the regulatory and legislative processes firsthand and are respected for integrity, expertise, and a record of success. LP helps clients understand and navigate the legislative and regulatory environments to create opportunities, resolve problems, direct action, and build and maintain positive interactions with key federal policymakers.

Our team in Washington, D.C. has deep federal policy expertise, having helped write significant health care legislation and regulation during their time in public service. We have been involved in developing most of the major health care legislation over that time, including Medicare Part D, the Affordable Care Act, the Drug Supply Chain Security Act, the Medicare Access and CHIP Reauthorization Act (MACRA), the Comprehensive Addiction and Recovery Act, the 21st Century Cures Act, the Mental Health Reform Act of 2016, the Bipartisan Budget Act of 2018, multiple FDA User Fee Acts, the SUPPORT Act in 2018, the Pandemic and All-Hazards Preparedness Act and its reauthorizations, multiple COVID-19 relief packages, and the health care provisions of the Consolidated Appropriations Acts of 2021, 2022, and 2023, including the major provisions related to mental health, substance use disorder, and pandemic preparedness.

Additionally, Leavitt Partners is home to expert conveners in the Leavitt Center for Alliances with decades of experience in the private sector and government who have spent years fine-tuning the process for building successful alliances that bring multi-sector stakeholders to the table with a commitment to reaching consensus, real-world solutions. Leavitt Center experts have helped more than 50 alliances achieve impactful outcomes, including the Dual Eligible Coalition, the CARIN Alliance FHIR accelerator, the Helios FHIR accelerator for Public Health Data Modernization, the Pharmaceutical Distribution Security Alliance (PDSA), the COVID Patient Recovery Alliance, and the National Alliance to Impact the Social Determinants of Health (NASDOH).