Near-Term Policy Solutions to Bolster the Youth Mental Health Workforce Through Digital Technology

FINAL REPORT

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Executive Summary

Issue: Mental illness among America's youth is at a crisis point, and our overstretched workforce is unable to meet the demands of this growing public health crisis. While workforce training, redeployment, and task-shifting solutions are being designed to relieve pressure, digital mental health technology (DMHT) can be deployed now, with even more deployed over the short-to-medium term to bolster the existing workforce and support improved quality of care through better detection, monitoring, and treatment of mental health concerns and conditions. However, regulatory and reimbursement obstacles are impeding the adoption and scaling of DMHT, and Medicaid has a critical role to play given that Medicaid insures nearly 40% of children and youth.

Goal: Identify opportunities for the executive branch of the federal government to leverage existing authorities to accelerate the adoption of safe and effective DMHTs. When integrated into existing provider delivery systems, DMHTs have the power to offset the current public health crisis in youth mental health.

Methods: We conducted a rapid cycle series of key informant interviews with leaders and experts across Health and Human Services (HHS), in Medicaid, at Medicaid Managed Care Organizations, and in academia and industry to identify common themes.

Key Findings: While many questions and opportunities for regulatory and reimbursement support for DMHT remain, there are several near-term opportunities for the executive branch to accelerate the adoption of safe, evidence-informed DMHTs and bolster the existing clinical workforce to drive improved access and quality of care for children and youth with mental health needs.

Policy Recommendations: The near-term opportunities for the executive branch of the federal government to improve access to high-quality DMHTs to increase mental health service capacity include:
1. CMS should issue an informational bulletin to clarify existing avenues to support the adoption of DMHT.
2. FDA/ONC/SAMHSA should partner to define more precise categories of DMHTs and clarify regulatory pathways for each to facilitate their safety, dissemination, and appropriate use.
3. ONC should develop data security, interoperability, and privacy standards to ensure safe and optimal use of DMHTs.

Introduction

Mental illness among America's youth is at a crisis point and our overstretched workforce has been unable to meet the demands of this growing public health crisis.[1,2] While critical initiatives to increase the number of trained mental health providers, redeploy them in teams or within primary care for more efficient and effective practice, better define roles to make optimal use of the full range of workforce capacities through task-shifting, and other strategies can address these issues over time, these efforts will unfold over decades. A comprehensive approach employing multiple strategies is required to better meet the needs of youth and address the mental health workforce crisis sooner. Digital mental health technology (DMHT)—technology used to better detect, monitor, and treat mental health challenges—has an important role to play within that comprehensive approach. This brief identifies near-term actions for the executive branch of the federal government to leverage existing evidence-informed digital solutions to bolster the workforce and better address the youth mental health crisis through safe and effective DMHT.

While increasing investments in the development of DMHT has led to a proliferation of products and offerings,[3] a myriad of obstacles slow and even prevent scaling of DMHT to fill gaps in traditional workforce capacity. DMHTs do not easily fit into regulatory systems and reimbursement categories that have existed for decades (and sometimes centuries). There is confusion among consumers and providers about which tools are effective and safe, as well as which can be trusted to protect privacy and sensitive data. Additionally, without reimbursement through public insurance, DMHTs are only available to people with commercial insurance coverage or who can otherwise pay for access. With nearly 40% of children and youth in the U.S. receiving their behavioral health care through Medicaid, DMHT is out of reach for many youth.[4] And health systems that serve children and youth cannot responsibly scale solutions as large numbers of the people they serve are not eligible.

Based on key stakeholder interviews with leaders across Health and Human Services - Office of the National Coordinator (ONC), Substance Abuse and Mental Health Services Agency (SAMHSA), the Centers for Medicare and Medicaid Services (CMS), the Agency for Health Research and Quality (AHRQ) - Medicaid experts, Medicaid Managed Care organizations, academia, and industry, this brief identifies opportunities for the executive branch of the federal government to leverage existing authorities to accelerate the adoption of safe and effective DMHTs to bolster existing provider capacity and improve quality of care to address the current youth mental health crisis.

Workforce Shortage Has Stark Impacts on Youth Medicaid Beneficiaries

As the Surgeon General warned in December 2021 with America's first ever public health advisory focused on mental health:[5] Even before the COVID-19 pandemic, mental illness among

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America's children and youth was already at a crisis point, and the pandemic has made it much worse. Suicide is the second leading cause of death among youth,[6] and continues to rise.

Yet, severe behavioral health workforce challenges leave vast gaps in access to services. This is particularly true for children and youth living in rural areas and youth of color—populations with a high number of Medicaid beneficiaries. In more than half of U.S. counties, there is not even one single psychiatrist, and only one in 10 practicing psychiatrists are people of color or Hispanic.[7]

The need to expand the workforce is particularly acute for youth Medicaid beneficiaries. Medicaid insures almost 40% of children and youth in the U.S.[8] and is the single largest payer for mental health care in the U.S.;[9] however, many mental health providers do not accept Medicaid,[10] and as few as 35% of psychiatrists accept new patients with Medicaid.[11]

Expanding the Toolbox: 21st Century Tools for Bolstering Clinical Care

To offset today's crisis, we must find ways to integrate existing solutions to bolster the workforce and so children and youth receive the mental health support they need. DMHT is one such category of potential solutions. Importantly, DMHT can increase the impact of our limited youth mental health workforce in the following ways.

1. **More effectively and efficiently match patient needs and providers' expertise:** To optimize the existing workforce at the highest and best potential, DMHT, powered by data science, can help match provider specialties with patient diagnoses and acuity levels, cultural fit, and insurance. It can also help overcome geographic barriers.

2. **Enable universal screening for early identification:** Interventions work best when administered close to symptom onset and *before* symptoms reach a crisis point,[12,13] ideally before the patient even knows they are ill. As such, early identification and treatment are key for expanding access to care and treating conditions when they are more manageable and require less and less credentialed clinical intervention. DMHT can be transformational in achieving earlier and increased universal screening by removing labor-intensive paperwork and by cutting through problematic workflows and staffing bottlenecks. Further, by integrating measurement directly into electronic health records (EHRs), assessments are easier for providers and patients to access when and where they want them.

3. **Improve clinician care by enabling outcomes monitoring:** DMHT can be deployed to facilitate measurement-based care, the use of validated assessments that are completed by patients and reviewed by clinicians to assess the effectiveness of treatment and adjust treatment to improve outcomes.[14] It can also be used to enable implementation of other evidence-based models, such as maintaining a registry and tracking symptoms for the Collaborative Care Model in integrated care settings.

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4. **Increase engagement with evidence-based practices:** Rather than replacing traditional therapy, integrating DMHT into clinical care can increase patients' access to proven evidence-based practices (EBPs). DMHT can be used to increase engagement with homework between sessions (an integral component of many EBPs) as well as engagement with accepted therapy and interventions generally.[15] DMHT can be simply layered on top of sessions to extend the therapeutic process or, in some cases, used to reduce the amount of time or frequency of sessions.[16]

Prioritizing DMHTs With the Most Evidence for Integration Into Clinical Care

There are many different competing definitions of digital mental health solutions and different ways that people define and categorize existing tools. DMHTs exist across multiple mediums and can expand access to well-established evidence-based therapy models through new means—essentially acting as "digital translations of psychosocial interventions,"[17] such as cognitive behavioral therapy or acceptance and commitment therapy.[18] Or DMHTs can be based on entirely new and emerging technologies, including some that use artificial intelligence. They can be integrated with clinician care or be completely self-guided.

Table 1. Categories of Digital Mental Health Technologies

	Category	Description
Telehealth+	Telehealth +	Teleconference or videoconference tools that use data science to assist in matching patients to the best-fit provider, simplify the insurance process, and/or integrate digital measurement-based care to assist in providing the most appropriate and effective provider care.
Screening & Monitoring	Screening & Measurement-Based Care	The use of repeated and validated assessments to track symptoms and outcomes that can be provided digitally in a provider's office or remotely.
Treatment	Clinician Supported DMHT	Patient-facing digital clinical interventions that are integrated into clinician's treatment. The clinician may integrate it fully into care or recommend it to a patient as homework and may discuss the patient's use of the tool in therapy.
	Non-Clinician Supported DMHT	A peer or other non-licensed individual, who is overseen by a clinician, provides advice in real-time through an app, text, or web-based chat that may or may not connect to a teletherapy provider.
	Self-Guided DMHT	Self-guided digital clinical interventions that an individual uses on their own. No clinician oversight is involved.

Note: For the purposes of the research and policy recommendations included in this brief, non-clinician and self-guided tools are not included.

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Technologies that have the **most near-term opportunities** to leverage existing authorities, bolster the workforce, and accelerate adoption of digital mental health are:

1. Used in conjunction with **clinician care** so that clinicians can ensure their safety and efficacy.
2. Primarily comprised of **digital translations of established practices** that are not dependent on new and emerging technologies.
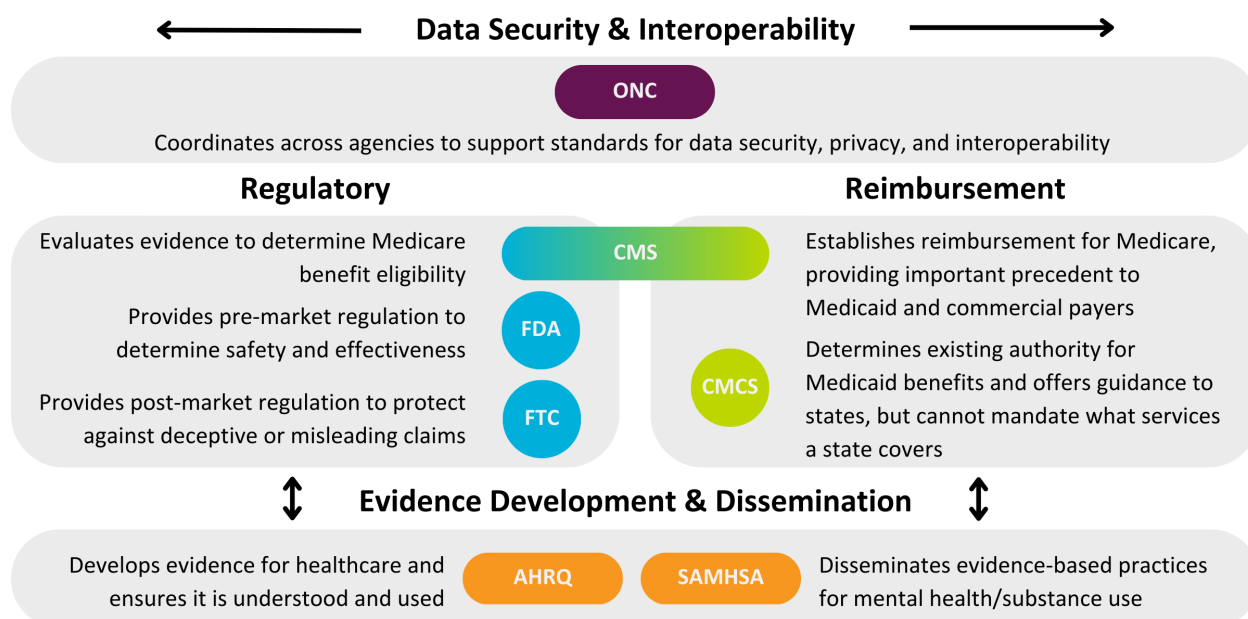
Challenges and Opportunities for DMHT Regulation and Reimbursement

There are two significant facets of digital mental health that makes its regulation and reimbursement particularly challenging. Like other digital health tools, new technologies, particularly software, do not clearly fit into regulatory frameworks created in eras before computers and the internet even existed, and the rate of tech development far outpaces the ability of regulatory bodies to provide adequate oversight. In a recent patient engagement symposium, FDA Commissioner Dr. Robert Califf admitted that the agency is struggling to keep up with the pace of digital health tool development.[19] Mental health technology faces additional challenges because the line between mental healthcare (e.g., anxiety disorders) and the broader category of wellness (e.g., mindfulness) is not always clearly demarcated, sometimes leaving open questions about what is in the purview of various agencies.

The complexity in regulation and reimbursement pathways also adds to the slow pace of DMHT uptake and investment for the Medicaid population; each state has different rules and provides different benefits. Most federal agencies and state Medicaid programs are only recently determining how to develop regulations and processes to navigate digital health tools generally—and the learning curve on DMHT is much further behind. Adding to the complexity, many federal agencies touch upon the regulation of DMHT (see **Table 2 and Figure 1**).

Table 2. Federal Agencies' Roles in Digital Mental Health Oversight and Reimbursement

	Overall Agency Role	**Agency Role in DMHT & Medicaid**
Agency for Healthcare Research & Quality (ARHQ)	Helps produce evidence to improve health care quality and access, and to ensure evidence is used and understood.	Assists in evidence evaluation frameworks for the general public and for CMS reimbursement, such as Coverage of Evidence Development.
Center for Medicaid & CHIP Services (CMCS)	Determines if there is existing authority for state Medicaid programs to allow new benefits. Offers guidance to states, but in general cannot dictate what states can offer as a benefit.	Determines authority for states to offer DMHT as a benefit and may offer guidance on how to do so.
Center for Medicare & Medicaid Services (CMS)	Establishes code and payment for Medicare. Evaluates evidence to determine if items or services are "reasonable and necessary" for the Medicare population.	The Medicare benefit process is an important precedent for many commercial plans and state Medicaid programs; however, it does not directly set policy for Medicaid payment.
Federal Trade Commission (FTC)	Provides post-market regulation for consumer protection against deceptive or misleading conduct or claims.	Regulates DMHT post-market across all payers.
Food & Drug Administration (FDA)	Regulates certain DMHT products to determine "reasonable assurance of safety and effectiveness for the intended use."	Regulates some DMHT as "software as a device." Due to approval for some digital mental health treatments, some states offer specific DMHTs as a benefit. Approval does not obligate payment. Applies to all payers.
Office of National Coordinator (ONC)	Coordinates across Health and Human Services to develop and create standards for data security, privacy, and interoperability.	Can help develop standards for data security, privacy, and interoperability for DMHT. Applies to all payers.
Substance Abuse & Mental Health Agency (SAMHSA)	Establishes and disseminates mental health evidence-based practices.	Supports broader understanding of the DMHT field and evidence-based practices. Does not directly affect Medicaid.

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Figure 1. Federal Regulatory and Public Reimbursement Landscape for Digital Mental Health*

← **Data Security & Interoperability** →

ONC

Coordinates across agencies to support standards for data security, privacy, and interoperability

Regulatory		**Reimbursement**
Evaluates evidence to determine Medicare benefit eligibility	**CMS**	Establishes reimbursement for Medicare, providing important precedent to Medicaid and commercial payers
Provides pre-market regulation to determine safety and effectiveness	**FDA**	Determines existing authority for Medicaid benefits and offers guidance to states, but cannot mandate what services a state covers
Provides post-market regulation to protect against deceptive or misleading claims	**FTC**	**CMCS**

↕ **Evidence Development & Dissemination** ↕

Develops evidence for healthcare and ensures it is understood and used	**AHRQ** **SAMHSA**	Disseminates evidence-based practices for mental health/substance use

Note: Figure is a conceptual framework and does not represent any hierarchy among the organizations.

Helping Clinicians and Consumers Find DMHT That Works

Research has shown that most clinicians are interested in integrating digital tools into the care system to increase access and exposure to evidence-based practices.[20] Youth across the socioeconomic spectrum also have a high level of acceptance of digital services.[21,22]

It is important to realize that regulation is not the only barrier. When the Obama Administration and Congress prioritized universal access to EHRs, both regulatory changes and financial incentives (including technical assistance) were enacted and national implementation was scaled in just a few years.[23] A recent review of implementation barriers for the Collaborative Care Model (CoCM) found that health systems face significant costs in retooling workflows and overcoming inertia.[24] While telehealth for mental health care was generally allowed from a regulatory perspective prior to the COVID-19 pandemic, there was broader access facilitated by the need to financially survive during the pandemic along with additional regulatory relief.[25]

While major gaps exist in the regulation of DMHT are impeding uptake, opportunities exist to help clinicians and consumers find the DMHT that works best. And, short of regulation, various agencies with HHS can help to define the categories of DMHT and develop guidance and standards on what constitutes a sufficient evidence base to deem a technology effective; what apps are safe; and what the standards for privacy, data security, and data interoperability should be. Additionally, there are opportunities to:

- Develop private/public partnerships to draft these standards.
- Evaluate the large number of DMHT being developed
- Create financial incentives and technical assistance to help overcome non-regulatory implementation barriers.

Safety and Efficacy

The FDA is the primary agency tasked with ensuring the safety and efficacy of consumer products in the country. While the FDA has struggled to keep pace with the rapid development of digital health tools,[26] to its credit, the agency has made significant headway in developing processes to regulate and review digital health products. However, the vast majority of digital *mental* health technology falls outside of what FDA has chosen to *actively* regulate. When FDA regulates DMHT, it is regulated as "Software as a Medical Device (SaMD)." SaMD is defined as "software intended to be used for one or more medical purposes," including diagnosis, mitigation treatment, and prevention of disease, but the software is not part of a medical device.[27]

An unknown number of DMHTs are considered SaMD and are considered to pose a low risk to consumers. FDA has taken a hands-off approach to these apps; DMHTs in this category do not require FDA review before going to market. Only a handful DMHTs have undergone review and are FDA "cleared" or "granted." The FDA views most DMHTs as health and wellness apps and therefore they are entirely outside of the scope of FDA approval (See **Table 3**).[28,29] In 2021, there were 20,000 mental health apps available on the Apple App Store or Google Play Store to download, with only five of them granted FDA approval.[30]

Table 3. Potential FDA Regulatory Pathways for DMHT[31,32]

	Types of Products	Functional Oversight	Quantity
FDA Review Required	Digital tools that meet the definition of SaMD and are typically used for novel low-risk medical devices. Often referred to as "prescription digital therapeutics."	Must go through FDA pre-market review.	Less than 10 DMHTs have received this approval.*
FDA Enforcement Discretion	Used for products deemed to pose a low risk to patients or products used to manage disease without providing a specific treatment.	Hands-off approach: stipulations on labeling, safety, and quality, but there is no clearance process.	Tens of thousands of DMHTs fit these categories.
Outside Scope of FDA Enforcement Discretion	Consumer health and wellness apps not considered SaMD.	No FDA oversight.	

Note: Because there are not clear categories for DMHT or digital mental health therapeutics, the exact number is unknown.

From a consumer and provider perspective, the line between fostering wellness and treating clinical mental health conditions is blurry. Companies may position their technologies to be outside of the scope of FDA oversight because they claim to promote "activities generally related to a healthy lifestyle or wellness." Were these apps to claim they focus on behavioral health techniques, they would require a minimum level of FDA enforcement discretion.[33] This leaves providers and patients on their own to decipher which apps are safe and of high quality within a rapidly evolving and oversaturated market of DMHTs claiming to improve mental health.[34]

It is critical for the executive branch to engage to help both providers and consumers select quality DMHTs, while also allowing innovators to build viable business models to support the workforce needs. However, FDA regulation is not necessarily the solution. While the lack of FDA oversight leaves a gap in regulation, based on our interviews, the FDA approval process does not appear to offer a viable or scalable pathway for many DMHT companies. Our research determined that DMHT based on a "previously validated DMHT method," rather than a "novel intervention or new technological medium" should focus on "a minimum evidence standard, which would not necessarily require FDA approval."[35] Other agencies, including SAMHSA and ONC, may be better positioned to engage with digital mental health experts to define minimum evidence guidance and the types of DMHT the guidelines would apply to, focusing on the tools most ready for near-term action and those with the greatest potential for impact.

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Privacy and Data Security

Unfortunately, patient and clinician concerns about privacy and data security are not unfounded. Currently, very few protections are in place to safeguard the privacy and data security of consumers; numerous privacy violations have occurred.[36] One commonly cited example is Crisis Textline, a suicide hotline service, which was found to have shared personal data with a for-profit entity without user consent.[37,38] Moreover, DMHT often require users to review lengthy forms written in a legal language incomprehensible to most.[39] Minors, people with low literacy levels, or people with cognitive impairment may be particularly vulnerable.[40] The Health Insurance Portability and Accountability Act of 1996 (HIPAA), amended in 2009 by the Health Information Technology for Economic and Clinical Health (HITECH) Act, governs health privacy and data security rules in the U.S. However, it does not adequately cover the range of new digital health tools as it is limited to "covered entities," defined as health plans, provider organizations, and clearinghouses.[41] As such, many DMHT companies fall outside of HIPAA's scope.

Data Sharing and Interoperability

The sharing of data between EHRs and DMHT is important to maximize their benefit and allow DMHTs to integrate into clinical workflows. Ideally, clinicians receive data about a patient to inform care, something crucial for measurement-based care. To reach this ideal, DMHTs need to follow standards of data interoperability.[42] However, such standards are not always clear. As pointed out in several stakeholder interviews, behavioral health was largely left out of the HITECH Act that helped the rest of the healthcare system build its IT infrastructure over the last few decades. In particular, many local health authorities and community health centers, which provide a large share of mental health care for Medicaid and rural populations, lack the data infrastructure to support many DMHTs.

Without a well-suited regulatory process that will both foster innovation and provide the consumer with appropriate protection and guidance, many digital mental health experts have advocated for outside entities, such as non-profits, to take up the task of creating evidence standards to vet digital mental health companies and products to create "digital formularies" (i.e., lists) to help providers and patients know what tools are safe and effective, including the appropriate privacy and data protection.[43,44] Non-governmental agencies, such as One Mind with One Mind PsyberGuide and American Psychiatric Association with its App Advisor, have begun creating evidence standards and vetted search tools. Just last year, AHRQ developed an evaluation framework founded on tools like these while adding in important evaluation elements such as cultural competence and accessibility. Focusing on DMHTs that already have a strong evidence base, along with creating clear guidelines on privacy, data security, and interoperability can go a long way in helping these entities identify appropriate tools for clinician and consumer use.

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Figuring Out How to Pay for DMHT

One of the biggest barriers to accelerating DMHTs is in figuring out how to pay for them. While there is a long pathway ahead, CMS and state Medicaid programs have begun to develop mechanisms to advance reimbursement potential. For instance, CMS is laying the groundwork for a "coverage with evidence development" process—digital tools with some level of evidentiary support can be paid for while research is being conducted to develop a stronger evidence base. A few state Medicaid programs, such as Washington and Louisiana, have also begun to develop coverage determination processes that are more suitable to the rapid development of digital tools. Additionally, when focusing on tools used in conjunction with a clinician, there are additional opportunities for reimbursement within existing codes. These challenges and opportunities are highlighted below.

Potential Pathways for Reimbursement

The U.S. healthcare reimbursement system is very complex. The traditional, fee-for-service (FFS) payment model is challenging for many DMHT to fit. In the long run, value-based payment (VBP) approaches, in which payers align financial incentives and outcomes with the aim of improving care and reducing costs, may be the most logical and compelling payment pathway for many DMHTs.[45] However, as many of our interviewees relayed, VBP still remains challenging in mental healthcare because quality metrics are underdeveloped and underutilized.[46] Thus, VBP is likely not viable for scaling DMHT in the near term.

In the FFS system, Current Procedural Terminology (CPT) codes, synonymous with Healthcare Common Procedure Coding System (HCPCS) Level I codes, cover the cost of medical services and procedures provided by health care professionals.[47] HCPCS Level II codes "are typically assigned to equipment outside of the clinical setting, such as medical devices, consumable supplies and medications."[48] Telehealth, including what we have called "telehealth plus," and universal screening and measurement-based care codes fit readily under existing CPT procedure codes. Yet fitting DMHTs that provide treatments, such as mobile apps, into these reimbursement coding systems is often like fitting a square peg into a round hole, as interviewees described. There have been various efforts to attempt to fit DMHT and other digital health products into these coding systems.

Until recently, there were no codes for DMHT that act as standalone treatments. In 2021, the CPT Editorial Panel of the American Medical Association (AMA) created a CPT code 989X6 for Cognitive Behavioral Therapy (CBT) monitoring services; as of January 2023, local Medicare Administrative Contractors may accept the CPT code and reimburse at their discretion. In 2022, CMS created a HSCPCS Level II code (a device code), A9291 for FDA-cleared digital treatments (or "therapeutics") to "facilitate options for non-Medicare payers to provide access to this

therapy in the home setting," which includes Medicaid.[49] However, neither code has been valuated or put on the Medicare fee schedule.

For clinically guided DMHT treatments, payment can be tied to CPT procedure codes used for clinician services. Several avenues may be possible to cover the device itself, and most CPT codes tie reimbursement to physician effort. Reimbursement rates for CPT codes are based on summation of "Relative Value Units" (RVUs). For each CPT code, there are RVUs for work, malpractice, and practice-expenses, the latter of which includes supplies and associated costs of staff.[50] There may be a possibility to provide enhanced rates based on increasing the RVUs allocated for practice expenses. Specifically for services provided by psychiatrists, "add-on codes" may be applied to cover additional services beyond a regular therapy session if the patient needs extra support.[51] There are also existing codes to account for clinician and support staff time spent on patient education and training, which can be used to cover time spent helping a patient use an app.[52] This includes support provided by peer coaches.

The Role of CMS and Medicare

While very few children and youth are covered by Medicare, Medicare plays a leadership role for both commercial payers and Medicaid nationally. Commercial payers often follow Medicare's lead in setting prices,[53] and many Medicaid programs base their rates on a percentage of Medicare rates.[54] Therefore, CMS' determination of the avenues for coding, evaluating, and pricing codes related to DMHT set an important precedent. CMS' influence is partly due to how it evaluates evidence to provide reimbursement. A key step for long-term, sustainable reimbursement for DMHT is the development of clear evidence standards.

While FDA determines that the item or service (e.g., drug or medical device) is safe and effective for the intended population, CMS has the additional (perhaps higher) requirement of determining whether items and services are "reasonable and necessary to diagnose or treat an illness or injury." CMS strives to provide "timely and predictable coverage of medical devices while at the same time ensuring that coverage is based on scientifically sound clinical evidence," but there are often long delays between FDA approval and CMS reimbursement.[55] Because of the rapid, iterative pace of new technologies coupled with the slow pace of research, CMS has struggled to come up with a Medicare coverage pathway that achieves the balance of efficiency and rigor.[56]
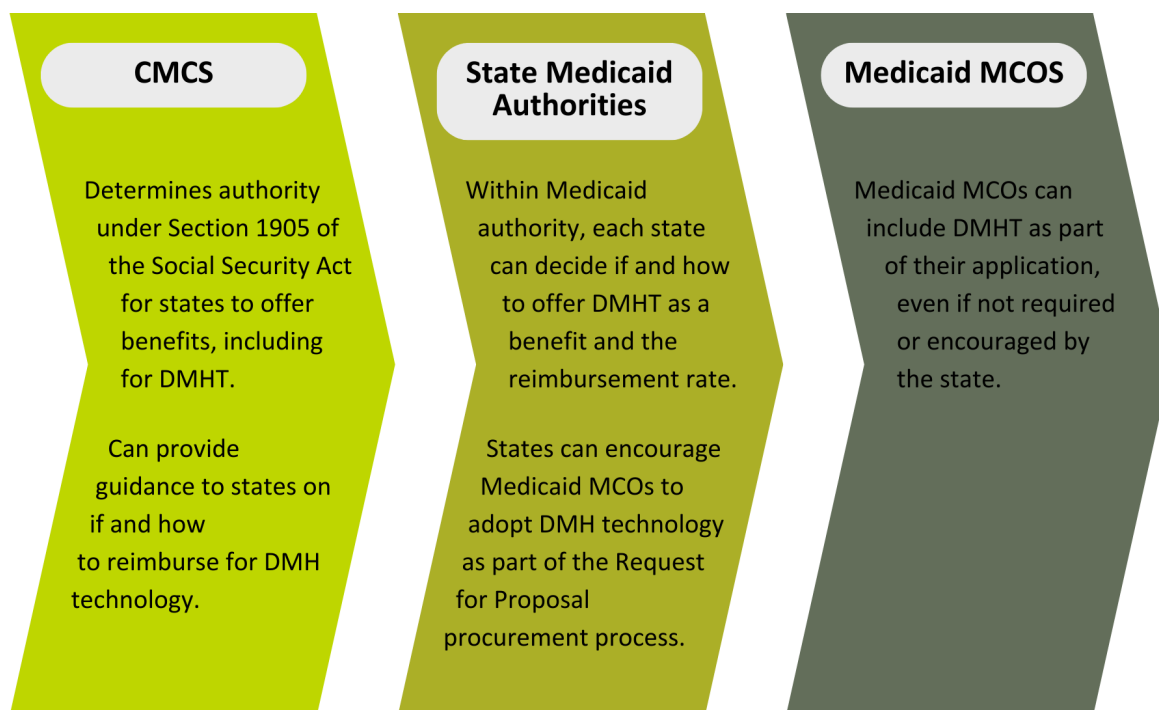
In January 2021, "The Medicare Coverage of Innovative Technology" (MCIT) final rule was established to "accelerate the availability of medical devices" by providing four years of Medicare coverage for devices newly approved through the FDA breakthrough pathway for innovative technologies. However, this rule was later rescinded because it was determined that evidence standards were not strong enough for the Medicare population. Still, CMS/FDA have a parallel review pathway that allows them to collaboratively engage manufacturers during the

FDA's premarket review decisions in hopes of shortening the time between FDA clearance and CMS coverage decisions. Additionally, CMS coverage with evidence development (CED) would allow for Medicare coverage of DMHT or other medical devices "on the condition that the product is used in clinical studies approved by the agency." Currently, CMS is working with AHRQ to develop a final rule on the CED process.[57]

The Role of the Center for Medicaid and CHIP Services (CMCS)

Reimbursement in Medicaid is particularly complex as each state makes its own rules and regulations and often contracts with multiple Medicaid Managed Care Organizations (MCOs) that also have some authority to set policy. Unlike Medicare, Medicaid is run by each individual state with CMCS providing federal oversight. One of CMCS's roles is to identify if there is authority to cover certain benefits under the Social Security Act. State Medicaid programs can opt into covering certain health services, while others are required.[58] As several key stakeholder interviewees attested, even though CMCS cannot mandate coverage of new benefits, it is extremely influential and plays a critical role in helping state Medicaid programs understand what is within their authority and how they may go about covering certain benefits.

Figure 2: Pathways to Achieving Reimbursement in Medicaid

CMCS

Determines authority under Section 1905 of the Social Security Act for states to offer benefits, including for DMHT.

Can provide guidance to states on if and how to reimburse for DMH technology.

State Medicaid Authorities

Within Medicaid authority, each state can decide if and how to offer DMHT as a benefit and the reimbursement rate.

States can encourage Medicaid MCOs to adopt DMH technology as part of the Request for Proposal procurement process.

Medicaid MCOS

Medicaid MCOs can include DMHT as part of their application, even if not required or encouraged by the state.

In our interviews, CMCS informed us that it is working to determine if there is existing authority to reimburse DMHT treatments as services, but thus far has been unable to do so. While there is no authority to cover DMHT as a standalone service, CMCS indicated that states may be able to enhance rates for physician service codes to account for the cost of the DMHT (like apps) within the medical services category. This indicates that, while there may be a longer path to

reimbursement for standalone DMHT treatment tools, enhancing rates for current procedure codes may be the most viable outcome in the near term.

State Medicaid Authority

While state Medicaid programs are mandated to cover certain health services, other services are optional.[59] State Medicaid programs can also decide to cover benefits not mandated by Medicaid or covered by Medicare, as long as they are within the Medicaid authority. A few individual state Medicaid authorities have interpreted certain DMHTs as within their purview and have implemented benefit coverage for specific DMHTs that have received FDA clearance or approval. For example, Massachusetts' state Medicaid program authorized member access to reSET and reSET-O—cognitive behavioral therapy smartphone apps for substance and opioid use disorders.[60] Florida's state Medicaid program put reSET and reSET-O on its preferred drug list.[61] One of the challenges of this approach is that devices are administered as a pharmacy benefit that can only be prescribed by a physician. This prohibits psychologists and many other mental health clinicians from giving patients access to these technologies. Other states have struggled with the lack of clarity on if and how they can cover DMHT treatments. Kentucky's legislature passed a joint resolution to seek guidance from CMCS on coverage of prescription digital therapeutics, for example.[62]

Additionally, some states have developed coverage determination processes that shift some of the burden of proof from state Medicaid program staff to the manufacturer or other benefit requestor. These processes have also emphasized working towards transparency and systemization on how evidence is evaluated, including weighting evidence from studies conducted with Medicaid populations more heavily. States such as Washington and Louisiana have pioneered such efforts, and much will be learned from their experiences in the coming years.[63]

As numerous stakeholders reported, the Request for Proposal (RFP) procurement process is one of the primary ways that state Medicaid programs can structure innovation and influence the adoption of DMHT. Forty-one (41) states contract with Medicaid managed care plans, and 81% of Medicaid enrollees are now covered through managed care.[64] In these states, Medicaid authorities contract with MCOs to provide managed care to enrollees, and these contracts are awarded through the RFP process.[65] In the RFP, a state Medicaid authority delineates its priorities, goals, and expectations for MCO contracts.[66] An RFP could require more innovation in youth mental health solutions or digital mental health, for example. It could also focus on achieving universal screening for mental health, which would likely necessitate digital solutions.
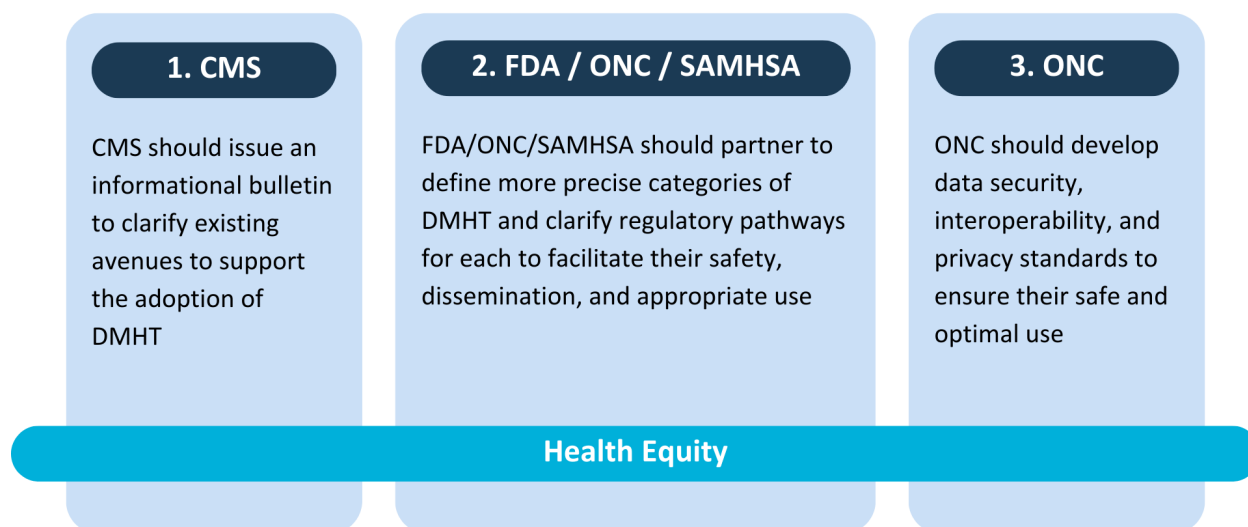
Medicaid MCOs

Even if a state does not specifically call for utilizing DMHT in its RFP, Medicaid MCOs can leverage DMHT and its potential to address child and youth mental health needs to differentiate themselves in the RFP process. Specifically, Medicaid MCOs could offer a DMHT as a value-added service, an extra benefit offered by Medicaid MCOs beyond Medicaid-covered services.[67] Medicaid MCOs often leverage value-added benefits to stand out in the RFP process or to their customers. Medicaid MCOs could pilot DMHT to address youth mental health as a value-added service and, if pilots are successful, ask their Medicaid authorities to include coverage of applicable codes in the benefit fee schedule. For example, AmeriHealth Caritas DC is piloting a DMHT platform, MindRight, that provides coaching by text to youth ages 13–20 as a value-added service.[68] Additionally, Wisconsin's Children's Community Health Plan is also offering a DMHT platform, Freespira, for its members with PTSD and panic disorder.[69]

Near-Term Policy Recommendations

While there is much work to be done to solve the regulatory and reimbursement challenges in the deployment and integration of DMHT comprehensively, there are steps that the executive branch of the federal government can take today to accelerate the adoption of safe, evidence-informed tools to bolster the existing clinical workforce and drive better outcomes in children and youth with mental health needs. Based on our research, we recommend the following policy options to accelerate the adoption of DMHTs designed to help clinicians deliver care more effectively and efficiently and technologies that could help the federal government address some of the mental health needs of youth Medicaid beneficiaries.

Figure 3: Summary of Recommendations

1. CMS	**2. FDA / ONC / SAMHSA**	**3. ONC**
CMS should issue an informational bulletin to clarify existing avenues to support the adoption of DMHT	FDA/ONC/SAMHSA should partner to define more precise categories of DMHT and clarify regulatory pathways for each to facilitate their safety, dissemination, and appropriate use	ONC should develop data security, interoperability, and privacy standards to ensure their safe and optimal use

Health Equity

Recommendation One

Centers for Medicare and Medicaid Services (CMS) and the Center for Medicaid and CHIP Services (CMCS) should issue an informational bulletin to clarify existing opportunities to support DMHT adoption, including how DMHT can be leveraged to support the delivery of behavioral health services for youth and to bolster the existing workforce.

This informational bulletin should:

a. **Explain existing financing pathways for incentivizing and reimbursing DMHT that can be used in conjunction with clinician care and highlight examples of states using DMHT.** Examples of where the guidance may be particularly useful include information on, but not limited to, the following:

   – Reimbursement codes for administering validated instruments (e.g., PHQ-9 or GAD-7) to facilitate screening and follow-up assessments to track improvements in patient outcomes.

   – Incorporating DMHT to support collaborative care and other primary care integration codes for states that have implemented these codes (and recommend implementation of the codes for states that have not already done so).

   – How physician rates may be enhanced to account for the cost of digital tools, such as by incorporating them into the rate calculation/RVUs, using add-on codes or otherwise modifying codes.

   – How peer support specialists, case managers, and community health workers can be reimbursed within existing payment structures for time spent supporting patient use of DMHT to further expand provider capacity while supporting health equity.

b. **Issue guidance promoting universal screening for mental health symptoms and reimbursement under Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) periodicity schedules—just like well-checks and immunization—and outlining how DMHT can be leveraged to support these requirements.** Certain types of DHMTs are designed specifically to help clinicians more effectively and efficiently screen and monitor outcomes and should be integrated into care. Encouraging the adoption of DMHT could help programs successfully meet universal screening more rapidly and help promote improved clarity on the youth mental health crisis and which conditions are of greatest urgency. Further, CMCS could encourage state Medicaid programs to collect screening data stratified by race, ethnicity, and language to provide a greater understanding of health disparities experienced by the youth population and drive disparity reduction.

c. **Encourage states to utilize the RFP procurement process to incentivize MCOs to integrate DMHT into mental health services and benefits.** CMCS can encourage states to take advantage of opportunities within the quality measures, performance improvement projects, or value-added services as potential mechanisms for DMHT inclusion. States can encourage MCOs to focus on equitable access to DMHT by considering barriers and facilitators to equitable access, such as tools that utilize more affordable technologies like mobile devices that operate through SMS. In order to mitigate risk related to winner-takes-all approaches, RFPs can be structured thoughtfully to allow MCOs to select more than one DMHT.

d. **Highlight state strategies to adopt evidence-informed technology benefit coverage determination processes and provide a template for states to adopt similar strategies.**[70] This may be particularly important for states to avoid a winner-takes-all approach to contracting and create processes that will be successful for evaluation of DMHTs in the longer-term.

e. **CMCS should encourage states to continue the telehealth advancements made during the COVID-19 public health emergency (PHE) that extended access to care and ensure continuity of care under the current telehealth flexibilities.**[71] Doing so will mitigate disruptions to virtual relationships and care treatment plans established during the PHE, prevent further marginalization of underserved populations,[72] and increase access to care for individuals in rural areas. As noted in CMCS' 2022 informational bulletin on youth behavioral health, telehealth played a crucial role in providing youth access to behavioral health services during the pandemic,[73] particularly for youth living in rural areas.[74] Furthermore, maintaining telehealth advancements supports the broader goal of addressing the national mental health crisis; telehealth is a significant strategy.[75]

f. **CMS should develop a learning collaborative on DMHT for states to share ideas and encourage healthy competition in DMHT adoption.** Much can be learned from creative solutions and pilot programs across the country about the challenges, opportunities, and mechanics of scaling digital mental health solutions.

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Recommendation Two

FDA, ONC, and SAMHSA should partner to define more precise categories of DMHTs and clarify regulatory pathways for each to facilitate their safety, dissemination, and appropriate use.

To achieve this:

a. **Develop more precise definitions and categories of digital mental health technologies**, ensuring inclusiveness of technologies that will reach underserved children and youth. These can then be used to advance target outcome measurement in the longer-term.

b. **Delineate and widely publicize the roles, responsibilities, processes, and ownership within federal agencies for advancing DMHT solutions**, so stakeholders can more easily navigate quality reviews, reimbursement, regulations, and financing opportunities. Ensure offices with oversight of equity are included to ensure knowledge of and priority for equitable and culturally sensitive solutions.

c. **Create guidelines on developing and evaluating DMHT tools for accessibility, cultural competence, and appropriateness for vulnerable populations** (e.g., people with cognitive impairment or severe mental illness).

Recommendation Three

ONC should work across the public and private sectors to develop data security, interoperability, and privacy standards for integrating DMHTs to ensure their safe and optimal use.

To achieve this:

a. **ONC should develop standards on data privacy and security to ensure the protection of consumer data.** These standards should include recommendations that informed consent can easily be provided by users, including the role of parental consent for minors. While Congress will likely need to expand HIPAA and HITECH, clearer data privacy and security standards will provide a gold standard for manufacturers and innovators to follow, while assisting nonprofit entities and professional associations, such as One Mind PsyberGuide and American Psychiatric Association, in evaluating DMHTs to support consumers and clinicians in selecting tools.

b. **Launch a task force of experts across the private and public sector to create standards on interoperability to integrate DMHT into clinician workflows and data systems**, prioritizing the needs of local health authorities and community health centers and the technologies more likely to engage lower-income populations (e.g., SMS).

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c.   **Realize the full potential of the 21st Century Cures Act by requiring all electronic health records (EHRs) to include mental health measurement-based care instruments and data to support clinical decision-making and better patient care.** While this legislation was designed to increase interoperability for patient care across physical and mental health, it has not been leveraged to its full potential. Further, its authorities also called for a revised understanding and clarification of HIPAA, something that could also be leveraged to support ONC in tackling this need.

Conclusion

Stakeholders agree that we have reached a point in the child and youth mental health crisis where we need to identify all the available and emerging tools leaders can deploy in solving the crisis. Further, we can no longer question *if* technology will be used in mental health services in the future, and expert are increasingly realizing the potential of DMHT to support the workforce needs of today and the future. Leaders must choose action over continued inaction on how to leverage innovative solutions to support our workforce needs and help more children and youth access mental health services. The identified actions included in this brief present low risk and high potential value in using DMHT to help our country correct the current trajectory. Without immediate action, the mental health of our most vulnerable youth will continue to suffer.

To offset the mental health crisis we are experiencing in our country, executive branch agencies can take steps today to ensure that DMHT helps to reduce rather than exacerbate mental health disparities by implementing the near-term policy solutions described in this report. These actions will facilitate a step forward in the near term to advance critical screening, diagnosis, and mental health care for youth.

Methods

We conducted semi-structured stakeholder interviews in multiple agencies within Health and Human Services, including the ONC, SAMHSA, CMS, and AHRQ. We also interviewed Medicaid experts, including two former state Medicaid directors, and leaders from Medicaid MCOs, academia, and industry. The FDA was invited to participate in this project but declined due to scheduling.

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