DIGITAL THERAPEUTICS ALLIANCE

September 6, 2024

Via www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid
Department of Health and Human Services
Attention: CMS 1807-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (CMS-1807-P)

Dear Administrator Brooks-LaSure:

The Digital Therapeutics Alliance ("DTA") thanks the Centers for Medicare & Medicaid Services ("CMS" or the "Agency") for the opportunity to provide comments on the Calendar Year ("CY") 2025 Physician Fee Schedule Proposed Rule ("Proposed Rule"). Our comments focus on our support and recommendations for proposed digital mental health treatment ("DMHT") codes GMBT1-GMBT3 (the "DMHT Proposal").

For background, the DTA is a global non-profit trade association of industry leaders and stakeholders with the mission of broadening the understanding and adoption of digital therapeutics ("DTx") into health care. Headquartered in the United States, DTA works across numerous geographic regions to enable expanded access to high-quality, clinically evaluated digital therapeutics for patients, clinicians, and payors to improve clinical and health economic outcomes.

DTA and its members are grateful to CMS for their careful evaluation of the ability to reimburse DTx under existing Medicare benefit pathways and are excited to work with the Agency in the implementation of its DMHT Proposal.

DTA Supports the DMHT Proposal

DTA applauds the Agency's DMHT Proposal, which is a groundbreaking first step towards Medicare coding and payment for software driven therapeutic interventions under existing Medicare benefit categories.

Recent research indicates that individuals who are seeking but unable to access mental health services experience significant wait times and dissatisfaction with the available resources.[1] We believe the Agency's proposal of paying for DMHT (i.e. physician services and the device supply) is critical in light of these issues and the growing mental health crisis in the United States. These products have been shown to be safe and effective and can be scaled to help increase access to evidence-based first-line mental health services relatively quickly.

As discussed in more detail below, we are strongly supportive of the proposal to begin paying for DMHT, and interpret the proposal to allow any qualified health practitioner to bill the proposed codes when they prescribe or order a covered DMHT device ("DMHD") for patients with mental health conditions consistent with Medicare's "incident to" requirements and state scope of practice law. [2]

The implementation of the DMHT Proposal will allow CMS to evaluate the value of greater Medicare beneficiary access to DTx products, their resource costs (including the practice expenses that qualified practitioners face in acquiring them), and the associated cost savings from their use. All of these learnings could help the Agency as it considers future proposals to code and pay for additional DTx for other health conditions in the near future.

As described above, **DTA fully supports the adoption of new codes for DMHT including DMHDs**, which are therapeutic interventions that are software driven (i.e. software only platforms, software/hardware platforms, or software in and/or connected to hardware), and stands ready to assist CMS by providing information and working with industry to implement the DMHT Proposal. As further discussed below, **DTA supports the proposed codes going into effect in 2025, encourages CMS to continue to evaluate DMHD coding and pricing for purposes of future rulemaking, and recommends further**

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[1]Buck, B., Kadakia, A., Larsen, A., Tauscher, J., Guler, J., & Ben-Zeev, D. (2024). Digital interventions for people waitlisted for mental health services: A needs assessment and preference survey. *Practice Innovations. Advance online publication.* https://doi.org/10.1037/pri0000250)

[2] Concerns have been raised by several of our members about the DMHT Proposal only allowing the physician who diagnosed the patient with a mental health condition to prescribe or order a DMHT, but given the practitioner shortage we do not believe this was the Agency's intent.

evaluating and clarifying the types of devices that may be reimbursed under the GMBT-1 code.

GMBT-1 Valuation Considerations

As further explained below, we note that there are a variety of factors that contribute to the cost of a particular DMHD to the health care professional who furnishes DMHDs to their patients. DTA strongly encourages the Agency to consider health economics data and the potential for use of DMHDs to decrease overall medical spending,[3] as well as the cost of bringing FDA regulated products to market to understand how these factors affect pricing of DMHDs that are purchased by health care professionals in establishing payment rates, and evaluate the spectrum of products and corresponding pricing variance for DMHDs as part of the valuation process.

DTA emphasizes that valuation of GMBT1 should be based on data inputs specific to DMHDs and supplied by DMHD manufacturers. As further explained below, DTA strongly encourages CMS (and if relevant, its contractors) to consider pricing data specific to DMHDs when evaluating and establishing a payment rate for DMHDs, including the cost of DMHD research, development, and regulatory compliance as these factors can influence the prices paid by health care professionals to acquire a particular DMHD.

In the event that CMS proceeds with contractor pricing, **DTA urges CMS and the Medicare Administrative Contractors ("MACs") to rely on device specific invoices** to determine appropriate payment to a provider under the GMBT1 code.

DTA also recommends that CMS take the following steps in order to ensure timely and accurate claims review, processing, and payment for DMHDs:

1. Provide guidance to the MACs regarding covered DMHDs and valuation of the devices;

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[3] There is a growing body of evidence showing digital mental health products allow health care professionals to use their time more efficiently and can decrease overall health care spending on individuals suffering from mental illness. *See e.g.* Youn SJ, Jaso B, Eyllon M, Sah P, Hoyler G, Barnes JB, Jarama K, Murillo L, O'Dea H, Orth L, Pennine M, Rogers E, Welch G, Nordberg SS. Leveraging Implementation Science to Integrate Digital Mental Health Interventions as part of Routine Care in a Practice Research Network. *Adm Policy Ment Health*. 2024 May;51(3):348-357. doi: 10.1007/s10488-023-01292-9. Epub 2023 Aug 24. PMID: 37615809; Altunkaya J, Craven M, Lambe S, Beckley A, Rosebrock L, Dudley R, Chapman K, Morrison A, O'Regan E, Grabey J, Bergin A, Kabir T, Waite F, Freeman D, Leal J Estimating the Economic Value of Automated Virtual Reality Cognitive Therapy for Treating Agoraphobic Avoidance in Patients With Psychosis: Findings From the gameChange Randomized Controlled Clinical Trial *J Med Internet Res 2022;24(11):e39248.* DTA has asked its members to submit additional health economics data and analysis to the Agency for its consideration.

2. Instruct the MACs to develop a timely and transparent process for DMHT (i.e. GMBT1-3) claims review; and
3. Provide DMHT billing and coding guidance to health care providers.

Utilize Data from Actual DMHDs

There are a variety of digital devices available in connection with health and wellness. It is critical that national pricing for DMHDs be based on adequate and accurate data. To further this goal, DTA has encouraged its members to individually submit mental health DTx pricing data[4] confidentially to CMS as soon as possible in order for the Agency to consider a more accurate and robust data set.

The DMHT Proposal suggests requiring FDA clearance under 21 CFR 882.5801 for DMHDs, but references a Care Patron article[5] when discussing variations in DMHD costs between $0-$140 per year (the "CP Article"). **DTA and its members have significant concerns about CMS relying on practice expense inputs from products that are not medical devices, including those in the CP Article and elsewhere.** To our knowledge all of the products listed in the CP Article are "wellness apps" which are not regulated in the United States as medical devices and thus these products would not be covered by Medicare "incident to" a health care professional's services.

We appreciate that digital mental health is new and CMS is looking for as many data sources as possible to better understand pricing variability. If CMS finds it necessary to conduct further internet searches, we suggest focusing the area of inquiry to specific products based on FDA regulatory requirements for GMBT1. CMS could also utilize other available digital health information such as claims data and federal data sources.

For purposes of avoiding confusion, we also note that there are mental health DTx products that are considered medical devices but are marketed under pathways other than 510(k) due to the low risk presented to patients, such as 510(k) exempt devices, and those operating under FDA enforcement discretion. These types of medical devices typically have lower development and regulatory costs and thus should not be included in valuation for GMBT1 under the DMHT Proposal or other devices that have undergone 510(k), De Novo, or Premarket Approval. That said, these devices can be clinically effective and in the future we encourage the Agency to consider whether

[4] We have asked for data submission beyond the scope of products covered under the DMHT Proposal in order for CMS to better evaluate the variables that could contribute to rate variability.
[5] https://www.carepatron.com/app/cbt-therapy-apps

providing access to these products would benefit Medicare beneficiaries as the Agency continues to evaluate coverage of DTx under existing Medicare benefits.

DTA also emphasizes that while the professional DMHT treatment management services (identified by GMBT-2 and GMBT-3) may have physician work and practice expense inputs that are similar to the treatment management services for remote therapeutic monitoring (RTM - CPT codes 98980 & 98981), DMHDs are substantially different from devices used for RTM. **Regarding code valuation, DMHDs have substantially different practice expense inputs which reflect the fact that they are therapies designed to treat, manage or prevent a mental health condition, vs RTM devices which are designed to collect and transmit data back to the treating practitioner.**

Consider Cost of Research, Development, and Regulation

While costs vary by the product's sophistication and risk, **all DMHD manufacturers incur significant research, development, and regulatory costs which companies consider in establishing pricing to health care professionals for DMHDs. As a result, these factors should be considered by CMS when establishing DMHD rates.**

The DMHT Proposal only covers medical devices that are regulated by the FDA. Unlike the products listed in the CP Article, DMHD and other DTx manufacturers are required to present safety and effectiveness data as part of their completion of the relevant FDA regulatory pathway that must be completed in order to be legally marketed in the United States. As a result, DMHD companies as medical device manufacturers must invest in research and development and conduct studies demonstrating the safety and efficacy of the product (which in the case of DMHDs typically involves showing therapeutic benefit through clinical trials) in order to successfully complete the relevant FDA process. Additionally, DMHD companies must comply with FDA regulations applicable to medical device manufacturers on an ongoing basis, which include certain special controls (e.g., software controls and labeling controls) specific to the regulatory classification under which such devices are regulated.

Currently, it can take 6-8 years or more to develop and bring a prescription DTx to market in the United States, at significant cost. For example, Pear Therapeutics reported research and development costs of $37 million in 2021 and $28.1 million in 2020.[6] We urge the Agency (and the MACs) to consider these costs when establishing payment rates.

[6] https://www.sec.gov/ix?doc=/Archives/edgar/data/1835567/000183556722000010/pear-20211231.htm

Multiple organizations have evaluated the investment of time and capital required to bring a prescription DTx to market, and we recommend the Agency review these reports. For example, we understand Evercore ISI, a research organization for investment bankers who originally analyzed prescription DTx investment in 2021, recently released an update to its analysis which found development costs for prescription DTx can typically range from $28 to $63 million.[7]

Additionally, DTA has encouraged its members to confidentially submit their individual research, development, and regulatory cost data directly to CMS so the Agency may conduct its own analyses.

FDA Pathway Considerations

DTA encourages CMS to align the devices covered under the DMHT Proposal with its access, safety, and efficacy goals for behavioral health treatment. The current DMHT Proposal requires devices to be "FDA cleared"[8] for reimbursement, unnecessarily limiting eligibility to devices that have undergone the 510(k) premarket clearance process. This requirement would exclude devices that have completed other FDA processes such as Premarket Approval or De Novo review, for example formerly Pear Therapeutics' reSET (now owned by Pursue Care) and Swing's Stanza.[9]

Additionally, requiring clearance under 21 CFR 882.5801 is unduly narrow, limiting use cases to insomnia, substance use disorder, and depression. This regulation, originally intended as a catch-all for computerized behavioral therapy devices, does not encompass the current diversity of products that could be used as DMHDs. As a result of further innovation, FDA has since established additional regulatory device classifications tailored to different device types or indications for use and their respective patient risks and regulatory needs. Many of these new device classifications may be appropriately furnished "incident to" the services of a qualified health practitioner. These classifications include:

- Digital Therapeutic Software for Attention Deficit Hyperactivity Disorder (21 CFR 882.5803)

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[7] Elizabeth Anderson, Sameer Patel, Joanna Zhou, and Prem Patel, *DTx Download – Digging into PDT Clinical Trials: An Updated Primer + Comparison to Molecular Drug Trials*, EVERCORE ISI HEALTH CARE/HEALTHCARE TECHNOLOGY & DISTRIBUTION, August 20, 2024.
[8] A term of art that refers to completing the FDA 510(k) process.
[9] *See* https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160018.pdf; https://www.accessdata.fda.gov/cdrh_docs/pdf22/DEN220083.pdf

- Digital Therapy Device to Reduce Sleep Disturbance for Psychiatric Conditions (e.g., nightmare disorder, PTSD, etc.) (21 CFR 882.5705)
- Computerized Behavioral Therapy for the Treatment of Fibromyalgia Symptoms (21 CFR 885.5804)
- Computerized Behavioral Therapy Device for Treating Symptoms of Gastrointestinal Conditions (21 CFR 879.5960)

As further innovation happens, FDA is likely to create new device categories tailored to new DMHT device types as technology and treatment modalities evolve. **Limiting coding and paying to devices cleared under one specific regulation unnecessarily restricts access to these important devices and does not align with the Agency's goal of expanding access to these valuable behavioral health treatments.**

We are aware of the following products currently marketed subject to 21 CFR 882.5801: Big Health's SleepioRx and Daylight, Pursue Care's reSET and reSET-O, Nox Health's Somryst, Otsuka & Click Therapeutics' Rejoyn, and Curio's MamaLift Plus.[10] All of these products are currently software only medical devices and therefore in the short term could be appropriate under a single G code.[11]

We note that the scope of DMHDs under GMBT1 could potentially be expanded to include a broader range of software only treatments for behavioral health furnished "incident to" clinical services. Examples of products that are software only behavioral health treatments not currently covered by the DMHT Proposal include Swift's Stanza, Mahana Therapeutics' Mahana IBS, and MetaMe Health's Regulora®.[12]

To promote access to safe DMHDs, the agency could modify the reimbursement criteria by requiring a demonstration of reasonable safety and effectiveness through **an appropriate** FDA pathway, **without** specifying a particular regulatory process or regulation.

If the Agency feels more specificity is necessary, we suggest requiring that DMHDs have "clearance, approval, or classification granted" from FDA similar to the Access to Prescription Digital Therapeutics Act's (S.723/H.R. 1458) definition of a prescription digital therapeutic: a product, device, internet application, or other technology that—

[10] We note that Pear Therapeutics developed reSET, reSET-O and Somryst which were sold due to bankruptcy.
[11] However, as discussed earlier, reSET went through the De Novo rather than 510(k) process and thus would not be "cleared" for purposes of meeting the requirements of the DMHT Proposal.
[12] We note that the ownership and availability of these products could change due to financial hardship.

"(1) is cleared or approved under section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act;

"(2) has a cleared or approved indication for the prevention, management, or treatment of a medical disease, condition, or disorder;

"(3) primarily uses software to achieve its intended result; and

"(4) is a device that is exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act under section 801.109 of title 21 of the Code of Federal Regulations (or any successor regulation)."

Considerations for Future DTx Valuation and Coding

DTA reiterates its enthusiastic support of the DMHT Proposal and strongly encourages the Agency to finalize it in November in order to address an existing gap in coding and the growing mental health needs of Medicare beneficiaries.

As we look to the future, DTA recommends that CMS evaluate the reasons for pricing variability and develop a longer-term coding and payment strategy for a broader range of products as DMHDs and other DTx products CMS determines may be furnished "incident to" a clinical service. The software utilized across all DTx products including DMHDs varies in levels of complexity and can be used alone, or connected to or inside hardware to treat a variety of conditions and disorders. For example, Freespira is an FDA-cleared digital mental health treatment device that treats the symptoms of posttraumatic stress disorder (PTSD) and panic disorder.[13] DTA expects that the sophistication of these products and the range of conditions and disorders treated will continue to diversify.

Additionally, there are a wide range of mental and physical health disorders (which have varying degrees of patient risk associated with them) and the products designed to treat them may have varying levels of software complexity (ranging from simple analytics to artificial intelligence), different mechanisms of action, and variations in hardware requirements (e.g. nothing required beyond a smartphone, to software connected to or incorporated into a sensor or other devices such as wearables and VR/AR headsets which can vary greatly in terms of functionality and cost). While we recognize these nuances may not be addressed immediately, **DTA recommends that CMS consider ways in future rulemaking to differentiate between DTx products that have substantially different practice expense inputs, clinical applications and**

[13] Product Class 21 CFR 882.5050, Product Codes HCC and CCK.

hardware types. We note that this may include the development of new and different codes, or ways to better differentiate products underneath codes in order to assign more appropriate and more accurate resource inputs. These actions will help promote beneficiary access, ensure accurate payments, and support better tracking from Medicare. We would be happy to discuss these ideas with you in more detail.

DTA thanks CMS for the opportunity to comment on its DMHT Proposal. If you have any questions about these comments, please do not hesitate to contact our Vice President of U.S. Policy Lara Compton at lara@dtxalliance.org.

Sincerely,

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Lara Compton
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