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March 3, 2022

Representative Mariannette Miller-Meeks
Representative Mike Kelly
Representative Morgan Griffith
Modernization Subcommittee
Health Future Task Force
U.S. House of Representatives

Sent via email to: Kendyl.Willox@mail.house.gov

RE: Healthy Future Task Force Modernization Subcommittee Request for Information – Digital Technologies

Dear Representatives Miller-Meeks, Kelly, and Griffith:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to provide comments to the Modernization Subcommittee of the Healthy Future Task Force in the U.S. House of Representatives in response to the Subcommittee's Request for Information (RFI) regarding the "utilization of wearable technologies, the expansion of telemedicine, and the digital modernization efforts in the United States."

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's member pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

In recent years, AMCP has taken a leadership role in the emerging field of digital therapeutics (DTx) by convening thought leaders across the healthcare industry to determine the role that DTx play in patient care, and how to ensure that patients are better able to access this new frontier of medical science. DTx have the potential to revolutionize population health management and help patients live healthier lives, and managed care pharmacists have the knowledge and skills necessary to play a primary role in their management.

Background on DTx

Over the past several years, AMCP has convened stakeholders across the healthcare industry to develop a working definition of DTx.[1] Based on these discussions, DTx describes a "**high-quality digital intervention, making a medical claim, that is driven by software programs to prevent, manage, or treat a medical disorder or disease**." DTx also "**require approval and third-party validation of efficacy and safety claims**" by a regulatory or equivalent national body, such as the Food and Drug Administration (FDA), or a recognized accreditation or health services organization. For instance, the FDA is increasingly approving DTx with indications to prevent, manage, and treat conditions ranging from diabetes and asthma, to depression and substance use disorder. Moreover, some, but not all, DTx may involve a requirement that they must be dispensed only pursuant to a prescription.

Our discussions with stakeholders have also considered whether the most suitable coverage pathway for DTx is under the medical or pharmacy benefit. Depending on how the DTx is furnished, such as whether it is administered by a physician in a healthcare setting or self-administered by the patient in their home, there does not appear to be a "one-size-fits-all" approach to coverage of DTx, and thus both pathways should be accessible to ensure patient access to this emerging class of technologies.

Medicare's Rigid Statutory Framework Poses Significant Barriers to Access for DTx

As alluded to above, coverage and payment for the emerging class of DTx technologies continues to evolve, and depending on the nature of the specific technology, coverage may be most suitable under payers' medical or pharmacy benefit. In the case of Medicare, however, the overlay of the federal healthcare program's rigid statutory framework on top of the evolving coverage and payment environment for DTx has significantly stalled Medicare beneficiary access to DTx as a result of the lack of a clear statutory benefit category. Absent legislative action, beneficiaries are likely to lack access to the full scope of DTx.

Below we outline key challenges associated with DTx under the Medicare program:

- **Lack of a clear benefit category.** Medicare fee-for-service is a defined benefit federal healthcare program, meaning that the benefits available to beneficiaries are defined by statute. Given that the Social Security Act was enacted in the 1960s, it is no surprise that DTx lack a clear benefit category. This has forced DTx to try and "force" themselves into existing benefit categories to access Medicare coverage or forego the Medicare market entirely.

- **Potential disruptions to contracting and business practices.** Because DTx are forced to squeeze themselves into existing benefit categories, stakeholders are often required to develop and implement contracting arrangements that are inefficient and otherwise not used in the commercial space. This is particularly true in the current environment where contracting arrangements are being developed primarily for the commercial market (due to

[1] AMCP Partnership Forum *Digital Therapeutics: What Are They and Where Do They Fit in Pharmacy and Medical Benefits?* (Sept. 2019) and AMCP Partnership Forum *Digital Therapeutics 2.0* (Sept. 2021)

the statutory limitations of the Medicare program) and rely on supply chains that may not be transferrable to the Medicare program.

- **Lack of coding infrastructure.** Coding is the language of the healthcare system, yet DTx currently lack a robust coding infrastructure. In part, the significant lag in the creation of codes (either CPT or HCPCS codes) to describe the specific technology of DTx is attributable to the challenges in securing consistent coverage and payment, which would otherwise require an adequate coding infrastructure to facilitate claims processing.

    - It is worth noting that CMS created the first HCPCS code in mid-February 2022 for prescription digital therapeutics that provide cognitive behavioral therapy. The AMA has also created various CPT codes for remote patient monitoring (RPM) and remote therapeutic monitoring (RTM). However, all of these codes have their limitations, including but not limited to the scope of technologies that the codes encompass, and the entities that are eligible to bill for the codes. In most cases these codes include none, or very little, reimbursement for the actual DTx itself.

- **Lack of payment pathway that adequately ensures access.** Even if manufacturers are successful in accessing Medicare coverage (such as through Medicare Advantage as supplemental benefits or certain benefit categories under Part B, like durable medical equipment), the payment methodologies that would apply may not be suitable for the relevant DTx. For instance, under the durable medical equipment (DME) benefit category of Medicare Part B, Medicare historically pays DME pursuant to a fee schedule based on payment amounts established in the 1980s, and there are very clear "payment categories" that DME must fall into in order to be reimbursed. Depending on the applicable payment category, payment could be made over a certain period of time, on a lump-sum basis, etc. These business models may not be suitable for certain DTx, thereby limiting their feasibility under the Medicare program and adversely impacting beneficiary access as a consequence.

AMCP Supports Both Agency and Congressional Action to Ensure Access to DTx in the Medicare Program

AMCP supports CMS' efforts to creatively exercise its existing authority to respond to the rapid pace of technological innovation that is increasingly straining the existing Medicare regulatory framework. Consistent with our support of CMS' creative problem-solving, we supported the Medicare Coverage of Innovative Technology (MCIT) policy that was finalized by the prior Trump Administration and would have established a 4-year transitional coverage period for Breakthrough devices with the possibility of permanent coverage following the transitional period via a National Coverage Determination. Although the MCIT pathway was formally withdrawn by the Biden Administration, CMS has expressed its continued interest to facilitate access to novel technologies and has indicated it will issue a new proposal via rulemaking under the title "Transitional Coverage for Emerging Technologies."

That being said, we acknowledge that CMS cannot facilitate access to the full potential of DTx under the agency's existing authority; Congress must weigh in and expressly authorize the coverage of DTx (through the creation of a new Medicare benefit category) and provide the agency with sufficient

direction to fill out critical details (e.g., payment methodologies, coding stipulations, eligible billing entities, etc.) through rulemaking.[2]

AMCP appreciates the opportunity to comment on the Modernization Subcommittee of the Healthy Future Task Force's RFI. We are committed to being a valuable resource to Congress on directing the digital revolution in a way that improves access to innovative digital health interventions for vulnerable federal healthcare program beneficiaries. If you have any questions regarding AMCP's comments or would like further information, please contact Jennifer Mathieu at 703.284.2654 or jmathieu@amcp.org.

Sincerely,

Susan A. Cantrell
Chief Executive Officer

[2] We believe that the Medicaid program currently has substantial flexibility to cover and pay for DTx by virtue of being a State-Federal partnership that is not as constrained by federal statutory/regulatory requirements as its Medicare counterpart. However, it would undoubtedly facilitate access to DTx if Congress were to expressly establish a benefit category for DTx under the Medicaid program, thereby eliminating any potential doubt among state Medicaid programs that they may cover DTx without forgoing federal financial participation (FFP).