The Honorable Mehmet Oz
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

RE: ATA Action Comments in Response CY2026 Medicare Physician Fee Schedule (CMS-1832-P)

On behalf of ATA Action, the advocacy-focused affiliate of the American Telemedicine Association, we commend the Centers for Medicare and Medicaid Services ("CMS" or the "Agency") for its continued commitment to modernizing the Medicare program via the CY2026 Physician Fee Schedule (PFS) proposed rule. We strongly support the Agency's efforts to make the COVID-19 public health flexibilities for virtual care permanent, where permissible under current authority. We also applaud the Agency's efforts to further evaluate opportunities to prevent disease and leverage technology to enhance patient outcomes and care delivery. Below we have outlined ATA Action's comprehensive comments in response to the draft proposals and urge CMS to address important flexibilities that have been left out of the draft rule.

Notable Policies Not Addressed in CY 2026 Medicare PFS Proposal

Collaborate With Congress to Ensure Continuation of Medicare Telehealth Flexibilities

In March, Congress extended the following flexibilities through September 30, 2025:

- Waiving originating and geographic sites
- Audio-only coverage
- Expansion of Medicare telehealth list to include therapists
- Allowing Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to serve as distant sites
- Temporary waiver of telemental health in-person requirement
- Continuation of Acute Hospital Care at Home Program

ATA Action kindly requests CMS to work alongside Congress to make permanent or extend these flexibilities for as long as possible before the end of September. Following an extension, it is critical that CMS releases aligning regulatory guidance as soon as possible to reduce confusion amongst the industry.

Make Telehealth Provider Address Location Flexibility Permanent

A critical flexibility that ATA Action and many industry stakeholders continue to urge CMS to make permanent is the policy allowing providers who deliver telehealth services to list their affiliated practice address, rather than their home address, on Medicare billing and enrollment forms. This flexibility has supported provider retention, expanded access to after-hours care, and helped to grow telehealth capacity across the country. However, this policy is set to expire on December 31, 2025. If CMS reverts to requiring home addresses or other locations of care, it will raise serious privacy and safety concerns for clinicians and significantly increase administrative burdens for providers and health systems alike.

Such a change would impact multiple stakeholders. For providers, it could discourage telehealth participation, exacerbate burnout, and reduce overall capacity. Health systems would face added labor costs and operational complexity. For CMS, the proposed shift would likely increase processing demands and staffing needs. Most importantly, patients could face longer wait times and reduced access to care due to fewer available providers, counter to the goals of expanded telehealth utilization. Failing to make the provider access flexibility permanent would be a significant step backwards for health care access.

We applaud CMS for incremental progress, such as the updated CMS-855i form and the allowance of P.O. boxes for enrollment. **However, this change does not address billing forms and the CY2026 Physician Fee Schedule draft rule does not address this important issue. ATA Action urges CMS to finalize and formalize the current flexibility, allowing providers to permanently use their affiliated practice addresses for billing.** For virtual-only providers without a physical practice location, we encourage CMS to explore secure, privacy-respecting alternatives that avoid mandatory home address disclosure (see here for a previous stakeholder letter to CMS outlining potential solutions for virtual-only providers). Without a permanent fix, this change risks creating unnecessary costs and complications for the Medicare program and the patients it serves.

Facilitate Diagnostic Testing By Virtual Care Providers

To further the significant progress made by the CMS in improving access to care for Medicare beneficiaries, we suggest the Agency consider coverage and payment policies that enable a patient or their care-giver to collect specimens and perform diagnostic tests in their home. Further, we suggest that CMS appropriately reimburse for the time spent and cost incurred by health care providers in connection with a patient's in-home specimen collection and testing. Such changes would help facilitate diagnostic testing by virtual care providers, expanding access to care and addressing many of the barriers Medicare beneficiaries face when seeking care.

For example, the PFS generally treats CPT Code 99000 *Handling and/or conveyance of specimen for transfer from the office to a laboratory* as a bundled service with no associated RVU time. For in-home testing, physicians may not be performing the other services that are bundled CPT Code 99000. In order to ensure fair and appropriate reimbursement we suggest

the Agency allocate separate RVU time to providers for CPT Code 99000 when a patient self-collect samples or performs a diagnostic test at home when provided by their health care practitioner.

ATA Action Responses to CY 2026 PFS Proposed Rule

We applaud the Agency's efforts to modernize Medicare and understand how to better treat and manage chronic conditions and improve access to care for Medicare beneficiaries. ATA Action agrees that CMS should continue to look for ways to expand its integration of telehealth and digital health tools across the Medicare program to better support the prevention, management, and self-management of chronic diseases. Chronic diseases like diabetes, hypertension, COPD, and heart failure account for the vast majority of Medicare spending and disproportionately impact older adults and underserved populations. Digital tools and other innovative prevention approaches offer a critical opportunity to address these conditions more proactively and efficiently.

Finalize Proposed Modification of the Medicare Telehealth Services List and Review Process

Through the CY2024 PFS cycle, CMS implemented a five-step review process to add, remove, or change the status of services on the Medicare Telehealth List. However, in response to significant stakeholder feedback highlighting confusion and a lack of clarity around some steps in the process, CMS is now proposing to eliminate Step 4 (*considering whether the requested service maps to service elements of those already granted permanent status in previous rulemaking*) and Step 5 (*evaluating whether there is evidence of clinical benefit comparable to in-person care when delivered via telehealth from a distant site to a patient at an originating site*). CMS has determined that removing these steps would streamline the process and reduce administrative burden. We agree that this is an important step towards the President's goals of unleashing prosperity and reducing regulatory burden. Importantly, it would also allow providers greater discretion in determining when a service should be delivered via telehealth. **ATA Action supports this proposal and believes strongly that providers should be empowered to practice at the top of their license and, more importantly, determine when virtual care is clinically appropriate.**

Currently, services on the Medicare Telehealth List are categorized as either "permanent" or "provisional." CMS proposes to eliminate both the "provisional" and "permanent" categories. If finalized, all services on the current Medicare Telehealth Services List and added in the future would be designated permanent, with CMS retaining the authority to remove services based on internal review or stakeholder feedback. **ATA Action applauds this forward-thinking shift and is encouraged to see CMS move beyond temporary pandemic-era policies toward a modernized, lasting framework for virtual care.**

Lastly, CMS proposes adding five new telehealth services to the Medicare Telehealth List including: multigroup-family psychotherapy (90849), group behavior counseling for obesity (G0473), infectious disease add-on (G0545), and auditory osseointegrated sound processor

(92622-92623). **ATA Action is supportive of adding these codes,** specifically the addition of the group for behavioral counseling for obesity (G0473) to the Medicare Telehealth Services List. Expanding access to this service via telehealth directly supports ATA Action's Virtual Foodcare Coalition efforts, which focus on integrating nutrition and behavioral support into virtual care models to address obesity and other diet-related chronic conditions. This proposal will help more patients access timely, effective care regardless of location or mobility limitations.

Make Removal of Telehealth Frequency Limitations Permanent

Historically, when CMS added certain services (hospital, nursing facility, and critical care visits) to the Medicare Telehealth List, they included certain frequency restrictions on how often physicians and other practitioners may furnish the service via telehealth. These frequency limitations were temporarily removed at the beginning of COVID-19 pandemic in March 2020. This year, CMS proposes to permanently remove these frequency limitations. **ATA Action strongly supports this and urges CMS to finalize this proposal, which removes unnecessary regulatory burdens on telehealth delivery**. ATA Action opposes arbitrary and outdated requirements such as in-person mandates, frequency limits, or brick-and-mortar location rules, all of which create unnecessary barriers to care and undermine the value of telehealth.

Expand and Clarify Proposed Virtual Direct Supervision Changes

CMS is proposing to permanently adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services, except for services that have a global surgery indicator of 010 or 090. Noting, virtual direct supervision may not be appropriate in every setting, but the physician or practitioner should use his or her complex professional judgment to determine the appropriate supervision modality on a case-by-case basis. **ATA Action is strongly supportive of this proposal.**

Additionally, CMS proposes not extending the current virtual direct supervision policy for teaching physicians. Under this proposal, for services provided within Metropolitan Statistical Areas (MSAs), teaching physicians must be physically present during the critical portions of all resident-furnished services to qualify for Medicare payment, not just in-person services, to ensure consistent oversight standards. However, CMS would maintain flexibility for services provided outside MSAs; in rural settings, teaching physicians could continue using real-time audio/video technology to meet the presence requirement, as long as they actively observe and participate in the service.

ATA Action urges CMS to extend this virtual supervision flexibility within MSAs as well. Urban areas face significant provider shortages (about 29% of designated primary care Health Professional Shortage Areas (HPSAs) are located in non-rural areas, including Metropolitan Statistical Areas) meaning nearly a third of these shortage designations affect urban and suburban regions. Academic medical centers in these areas often rely on virtual tools to expand supervision capacity and manage high patient volumes. Maintaining virtual presence flexibility

across all geographies ensures continued access to care, supports clinical training, and allows teaching physicians to provide timely oversight without compromising patient safety or care quality.

Lastly, ATA Action is seeking urgent clarification on a proposed supervision policy change that appears to introduce a more restrictive standard for Medicare payment of resident-furnished services, particularly when telehealth is involved. In the proposed rule, CMS states *"Physicians must maintain physical presence during critical portions of all resident-furnished services to qualify for Medicare payment."* We are concerned that this language may significantly alter longstanding supervision norms, especially for Evaluation and Management (E/M) services. The proposed phrasing suggests that the attending physician must be physically present and concurrently perform or observe the "key and critical portions" of the service in real time, effectively requiring a side-by-side or "over-the-shoulder" model during the entirety of the critical service delivery. This interpretation, if enforced, would impose a stricter requirement than what is currently applied in-person, and could create confusion, compliance risk, and operational disruption for academic medical centers, teaching hospitals, and digital health programs - many of which rely on telehealth to extend supervisory reach. **We urge the Agency to clarify in the final rule that it does not intend to alter longstanding supervision norms for resident-furnished services.**

Clarify, Finalize, and Extend Medicare Diabetes Prevention Program (MDPP) Proposals and Ensure Fair and Accurate Payment

The Medicare Diabetes Prevention Program (MDPP) represents a holistic, lifestyle-based intervention aimed at preventing the progression to type 2 diabetes among at-risk beneficiaries. Unlike approaches that rely solely on medication, MDPP focuses on sustained behavior change through structured health coaching, dietary education, physical activity promotion, and long-term support. However, despite its strong clinical foundation, uptake has remained remarkably low—with CMS reporting that fewer than 5,000 Medicare Fee-for-Service (FFS) beneficiaries participated in the program over its first six years[1]. This underutilization highlights the urgent need to modernize the program to better meet beneficiaries where they are.

ATA Action strongly believes that telehealth and digital health tools are essential to expanding access and increasing participation in MDPP, particularly for older adults who may face barriers to in-person care such as transportation, mobility limitations, or caregiving responsibilities. Studies show that digital diabetes prevention programs can be as effective as in-person interventions, with several demonstrating comparable or better outcomes in weight loss and glycemic control. For example, digital diabetes prevention programs demonstrate clinical effectiveness and have significant potential for widespread dissemination and impact, particularly considering the growing demand for telemedicine in preventive healthcare services[2]. While a UK-based evaluation of the National Health Service (NHS) DPP found that patients who

[1] CMS Evaluation Report
[2] ScienceDirect – American Journal of Preventive Medicine

were offered a choice and opted for digital experienced better weight loss, compared to patients offered face-to-face only[3].

To improve access and boost engagement, CMS proposes a suite of forward-thinking policies that place digital tools at the center of MDPP modernization, including:

- Allowing asynchronous delivery through December 31, 2029, enabling participants to engage with program materials and sessions on their own time;
- Extending Public Health Emergency-era flexibilities through December 31, 2029, including support for synchronous (live) virtual delivery;
- Clarifying that MDPP suppliers are not required to maintain in-person delivery capability through the same period, further enabling fully virtual models of care.

ATA Action, with a few clarifications and exceptions outlined below, strongly supports all of these proposals and urges CMS to finalize them, while also evaluating opportunities to make these flexibilities permanent beyond 2029. If designed effectively and supported with digital infrastructure, MDPP has the potential to scale significantly, helping millions of at-risk seniors avoid type 2 diabetes and improve their quality of life. To further increase participation in this program, ATA Action urges CMS to update Medicare.gov and other beneficiary-facing materials to clearly promote Online MDPP options, including supplier directories with zip code search functionality and enrollment guidance.

CMS should not finalize the requirement for live lifestyle coaching interactions in order to receive payment for asynchronous, online delivery of MDPP.
While CDC standards require that live interactions be offered, participants may complete lessons without engaging with a coach despite outreach. Denying payment in these cases adds unnecessary billing complexity and penalizes providers who have delivered services. As an outcomes-based program, MDPP should adopt a modality-neutral, least-burdensome approach that allows beneficiaries to focus on weight loss without mandating live interactions.

Finally, **CMS should ensure that the MDPP payment model for online delivery accurately reflects the real costs of providing the program.** Although virtual care has the potential to improve outcomes at lower overall cost, online providers still face significant upfront expenses, such as technology platform costs and supplying each participant with a medical-grade, cellular-enabled weight scale so that beneficiaries can track their weight reliably at home. We strongly encourage CMS to further evaluate the costs to MDPP providers and establish fair and accurate payment for MDPP services.

Expand the Advanced Primary Care Management (APCM) Codeset to all Providers

ATA Action appreciates CMS for establishing coding and payment under the CY2025 PFS for a new set of APCM services described by three new HCPCS G-codes. However, **we would ask that CMS consider expanding this code set to allow for other specialties** and renaming

[3] BMC Health Services Research

these codes as “Advanced Specialty Care Management Codes.” As a simple solution, we recommend that CMS make HCPCS code G0556 available to all healthcare providers, rather than restricting it solely to primary care providers. This would ensure a more inclusive approach to managing advanced specialty care.

Adopt New Remote Monitoring Codes but Reconsider Valuation

Remote monitoring devices play a critical role in prevention and in managing chronic conditions by enabling early detection of health issues, supporting proactive care, and reducing avoidable hospitalizations and emergency department visits. Historically, ATA Action has advocated for the elimination of the arbitrary 16-day remote monitoring data requirement within a 30-day period, urging CMS to adopt the pandemic-era flexibility that allows for as few as 2 days of monitoring. The rigid 16-day threshold can be excessive in certain clinical scenarios and has, at times, led to inappropriate or delayed treatment. Since then, the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Committee accepted a proposal last year in 2024 that added and revised codes for remote physiologic and therapeutic monitoring (RPM and RTM), including device supply codes for 2–15 and 16–30 day periods and time-based treatment management services (first 10, 20, and each additional 20 minutes). These updates also included new RTM codes for respiratory, musculoskeletal, and cognitive behavioral therapy, along with revised remote monitoring guidelines. **We strongly support CMS adopting these codes but urge CMS to clearly state the agency is adopting these codes as described by the AMA in the final rule.**

Additionally, CMS contemplates payment rates for the new and revised remote monitoring codes, with some proposed rates falling below RUC recommendations. We are deeply concerned that continued reimbursement reductions for remote therapeutic monitoring (RTM) and remote physiologic monitoring (RPM) risk further undermining the adoption and sustainability of these technologies, despite their demonstrated clinical value.

RTM and RPM treatment management codes remain significantly undervalued compared to similar services like Chronic Care Management (CCM), which have received appropriate upward adjustments. To ensure continued access to high-quality care and support the long-term viability of remote monitoring, **we urge CMS to update these code valuations accordingly and ideally align RTM and RPM reimbursement rates with those of CCM, given the comparable time, complexity, and value involved in delivering these services.**

Lastly, many of our members request clarification around Place of Service (POS) code usage for remote monitoring services. Specifically, we are asking the Agency for guidance explaining when the POS 10 code should be utilized rather than POS 11 code, and whether one code is always applicable to remote monitoring services versus the other. **ATA Action would greatly appreciate clarification and specific examples in the final rule.**

Expand Digital Mental Health Treatment Code Proposals and Codes

Through the CY2025 Physician Fee Schedule (PFS) proposed rule, CMS established Digital Mental Health Treatment (DMHT) codes, introducing three new HCPCS G-codes to support coverage and reimbursement for certain digital therapeutics (DTx) used for mental health treatment. When the codes were finalized, confusion remained regarding whether the diagnosing practitioner had to be the prescribing/ordering practitioner of the DMHT device. ATA Action is grateful that the Agency has clarified that the ordering/prescribing practitioner need not be the diagnosing practitioner, which is consistent with real-world care delivery.

CMS proposes expanding DMHT code applicability to devices authorized under 21 CFR § 882.5803, digital therapy devices for ADHD, pending FDA clearance and validated effectiveness measures. Currently, the DMHT codes are limited to software as a medical device (SaMD) under a specific FDA classification that are used to treat insomnia, substance use disorder, and depression. As multiple stakeholders mentioned in response to last year's DMHT proposal, there are a variety of digital therapeutics that could be appropriately furnished "incident to" a practitioner's professional services to treat a much broader range of mental and physical health conditions. **ATA Action agrees with these comments and supports CMS's proposal to expand coverage to include digital therapy devices for Attention Deficit Hyperactivity Disorder (ADHD),** a common and often undertreated condition, particularly among adults.

Last year commenters also noted that DMHT codes could be appropriately expanded to DTx that treat the behavioral health component of a more complex condition, such as irritable bowel syndrome (IBS) and chronic pain from various conditions such as fibromyalgia and migraine. As further explained below, ATA Action supports the expansion of DMHT coverage to include a broader range of devices.

While we appreciate the Agency's reasoning in expanding the DMHT codes to other classes of devices with the same special controls as existing DMHT devices under 21 C.F.R. 882.5801 (specifically, clinical performance testing of the behavioral therapy in general and as delivered by the device, software description and software verification, validation, and hazard analysis, and patient and physician labeling requirements) and agree that DMHTs should be FDA classified devices, we note that similar controls exist under the following classifications:

- Computerized Behavioral Therapy Device for Treating Symptoms of Gastrointestinal Conditions classified under 21 C.F.R. 879.5960 requires clinical data demonstrating the model of therapy delivered by the device and any adverse events, Software verification, validation, and hazard analysis, software usability assessment, and physician and patient labeling requirements.
- Digital Therapy Device to Reduce Sleep Disturbance for Psychiatric Conditions (e.g., nightmare disorder, PTSD, etc.) classified under 21 C.F.R. 882.5705 requires clinical performance testing and validation of the device's ability to provide therapy and the worsening of any symptoms, software description and software verification, validation, and hazard analysis, and patient and physician labeling requirements.

- Computerized Behavioral Therapy for the Treatment of Fibromyalgia Symptoms classified under 21 C.F.R. 882.5804 requires clinical data demonstrating an improvement of symptoms and any adverse events, software description and software verification, validation, and hazard analysis, and patient and physician labeling requirements.

While the above controls are not exactly the same, they are substantially similar to 21 C.F.R. 882.5801. **ATA Action strongly encourages the Agency to administratively manage and evaluate the DMHT supply codes by FDA classification and expand the supply codes to include the above FDA device classifications for CY 2026.** These additions are critical, as they reflect the growing clinical evidence supporting the effectiveness of DTx across a broader range of chronic and comorbid conditions. ATA Action strongly supports these proposed expansions and urges CMS to continue broadening the list of eligible conditions to reflect both clinical need and innovation in the digital health space.

ATA Action recognizes, however, that expansion of the classes of devices that qualify for coverage under the existing DMHT codes will further complicate the valuation process for DMHT devices. As the Digital Therapeutics Alliance (DTA) noted in its comments supporting the DMHT codes for CY 2025, there are a wide range of mental 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).[4] As further discussed below, we are also aware of variability in price between the DMHT devices that currently qualify for coverage under G0552. This may be partially explained by the different mental health conditions treated under one device classification (e.g. depression, SUD, and insomnia).

Due to the variability between devices, many of our members would prefer to see codes specific to each device rather than by device classification. We understand such an approach may not be viable at this point, ATA Action recommends CMS consider multiple pathways to improve DMHT code valuation. In the near term, we support creating new supply codes for additional FDA classifications and using modifiers to distinguish between conditions treated under the same classification. Additionally, we recognize the value of a longer-term strategy that structures pricing by therapeutic indication to reflect differences in clinical complexity, regulatory burden, and evidence standards.

In the near term, we strongly urge CMS to create new supply codes for the four additional FDA device classifications discussed above and that the Agency consider modifiers for such codes if necessary to distinguish between mental health conditions treated by the same device class to allow for more specific analyses of treatments and pricing. For example, CMS could keep the G0552 code and create modifiers for each mental health condition treated by the 21 C.F.R. 882.5801 device class and create new DMHT supply codes for ADHD, GI, sleep disturbance, and fibromyalgia treatment devices. If this is not possible,

[4] DTA CY 2025 PFS DMHT Comments Final .docx

adding these 4 additional FDA product classifications to the existing G0552 code is still an important step forward that we support for CY 2026.

In the longer term, **ATA Action urges CMS to pursue a structure of differential pricing primarily by therapeutic indication, consistent with regulatory and clinical practice frameworks.** While recognizing that variation in complexity and return on investment can exist within indications, indication-based categorization provides a transparent and practical foundation. Within each indication, CMS may incorporate secondary adjustments to reflect substantial differences in development complexity, evidence base, or treatment models, thus balancing clarity and flexibility while avoiding overly burdensome complexity metrics.

Expand Coverage for Digital Therapeutics with New Codes

While there are a small number of DTx available in the U.S., they already cover many different therapeutic categories including diabetes, musculoskeletal, respiratory, mental and behavioral health, women's health, oncology, and more will continue to enter the U.S. market. **ATA Action strongly supports CMS expanding Medicare coverage for DTx under existing benefit categories (i.e. incident to a practitioner's services and as DMEPOS).** As DTA noted in its comments to the CY 2025 PFS, there are a wide range of health conditions (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). ATA Action agrees and recommends that CMS consider ways to differentiate between DTx products that have substantially different practice expense inputs, clinical applications and hardware types as it expands Medicare coverage for DTx. As discussed above with respect to DMHTs, creating new codes for new classifications of devices (preferably with condition specific modifiers as necessary) to further specify the type of devices and treatments involved could allow the Agency to describe and price different classifications of DTx products with more specificity.

Address and Anticipate Complexity for Digital Therapeutics and Other Digital Tools

<u>Lessons Learned from G0552 Implementation: CMS Guidance Necessary</u>

CMS notes that a small number of claims for DMHTs have been submitted and mentions the business model (e.g. physician buys and bills) could be to blame. While there are various challenges, they are not insurmountable, and ATA Action is asking for the Agency's assistance in addressing them. One hurdle to adoption is practitioner unwillingness to use codes if there is a lack of clarity on documentation requirements for claims submission or if claims are not processed and paid in a timely manner or denied, and another concern is regarding fair and accurate pricing. Practitioners cannot be expected to invest in new health care technologies without having information about what the financial impact will be on their practice.

Unfortunately, the MAC pricing process has been slow, and the MACs are questioning DMHT coverage. Furthermore, there are concerns about fair and accurate pricing for DMHT devices which seem to be driven by a continued lack of understanding between various types of technologies (e.g. unregulated wellness apps, remote monitoring devices, and DTx) and when DMHT use is clinically indicated. The MACs do not seem to appreciate that DMHTs deliver clinically validated cognitive behavioral therapy (CBT), and thus treatment using a DMHT device would be clinically indicated in the same circumstances as other forms of CBT. Skepticism regarding the use of invoices for pricing and the value of FDA required special controls for DMHTs also contributes to pricing and claim processing difficulties. ATA Action is concerned that the current MAC-determined rates are insufficient to support provider adoption and patient access. We urge CMS to direct MACs to establish rates that reflect true acquisition costs of DMHT devices by collecting and analyzing manufacturer invoice data.

We emphasize that while the professional DMHT treatment management services may have physician work and practice expense inputs that are like the treatment management services for remote therapeutic monitoring (RTM- CPT codes 98980 & 98981), DMHT devices are substantially different from devices used for RTM. Regarding code valuation, DMHT devices 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. Furthermore, it is not appropriate to crosswalk DMHT devices which have gone through the FDA process to technologies that are reimbursed but are not subject to the same level of regulatory requirements. It is our understanding that the MACs may not appreciate these distinctions, resulting in unfair and inaccurate pricing for devices that qualify for coverage under G0552. Failure to adequately reimburse physicians for DMHT device costs will hinder adoption and Medicare beneficiary access to clinically proven mental health treatments.

For these reasons, **ATA Action continues to suggest that the Agency provide guidance to the MACs regarding the implementation of the DMHT codes, and suggests taking the following steps:**

- **Explain to the MACs the rationale for coverage of specific FDA classifications of devices (e.g. what is required to meet special control requirements) and what level of clinical evidence review is appropriate in light of the specific controls required by FDA and the relatively low level of risk posed by DMHTs as Class II devices;**
- **Instruct the MACs to use DMHT device invoices reflecting the cost to physician practices for purposes of establishing fair and accurate DMHT device pricing;**
- **Direct the MACs to communicate the documentation required for G0552 device coverage; and**
- **Instruct the MACs to develop a timely and transparent process for G0552 device claims review.**

Address Variations in Regulatory Burden When Establishing Coding and Payment Policies

CMS is soliciting feedback on reimbursement models for digital tools not subject to FDA clearance or authorization, including options to create lower-intensity billing codes and valuation methods. The digital health ecosystem encompasses products that span the entire patient experience and care continuum beginning with self-care and through diagnosis and treatment including direct to patient care and ongoing patient support and monitoring. These products pose varying levels of risk to consumers and thus are subject to different degrees of regulation.

General wellness applications that are marketed to consumers without making specific claims about particular health conditions are subject to regulation by the Federal Trade Commission and unlike SaMD and SiMD are not required to go through the process of validating clinical safety and effectiveness as part of the FDA regulatory process. As a result, these products can be developed relatively quickly and without significant expense when compared to products that meet the FDA definition of a medical device. We distinguish the unregulated wellness apps from products that are considered medical devices but are marketed under pathways other than De Novo and 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 are subject to regulation by FDA but typically have lower development and regulatory costs, which should be taken into consideration.

With the above in mind, we suggest that CMS develop coding and payment policies that prevent including DTx and other digital health tools that are subject to different regulatory requirements from being reimbursed under the same code (e.g. unregulated devices, 510 (k) exempt products, and 510(k) products should all have separate codes), and from inappropriate crosswalking to technologies that do not have the same regulatory burden (e.g. crosswalking DTx to remote patient monitoring discussed above).

Evaluate and Address Complexity Presented by Innovative Technologies

CMS's intent to better understand and potentially capture the costs associated with digital tools including Software as a Service (SaaS) platforms is important, but we urge caution in applying a one-size-fits-all approach. The valuation of digital tools varies significantly depending on the platform, its function, and its developer. As discussed above, some digital tools delivered via a SaaS platform will be subject to FDA regulation as medical devices and thus be subject to significant regulatory requirements and development costs. Other digital tools, particularly those supporting straightforward functions (e.g. administrative), have more predictable and transparent cost structures. Still other forms of digital tools may provide clinical support functions but are not regulated as a medical device. Further, some FDA regulated products utilize SaaS platforms delivering complex solutions including remote therapeutic monitoring (RTM) software and/or DTx, which are far more complex and involve different pricing models depending on design, development, regulatory classification, and clinical integration.

While we appreciate the Agency's desire to address software costs, focusing on the mode of delivery (e.g. SaaS) rather than the software itself can create unnecessary confusion. We

encourage CMS to discontinue use of the term “Software as a Service” when referring to software-based technologies that support clinical decision making or are otherwise regulated by FDA as a medical device. Instead, CMS should use the correct regulatory term of art, “Software as a Medical Device” which is recognized in medical and regulatory contexts. By law, SaMD is considered a medical device and, therefore, should be considered a direct practice expense as medical equipment. It is not “computer software” that should be treated as an indirect non-allocable expense and should not be treated as such for purposes of Medicare reimbursement. **For clarity, we believe that DTx (SaMD), as federally regulated medical devices, should be coded and reimbursed separately and appropriately because they meet an evidence threshold above and beyond mobile health products**.

While some developers may allocate certain amounts toward development and upkeep, others must account for more intensive and ongoing investments in areas like real-time data tracking, algorithm updates, patient safety features, and compliance with evolving regulatory requirements. Importantly, valuation should not focus solely on initial development but also on the costs of maintenance, security, compliance, clinical updates, and operational continuity, all of which are essential to delivering safe and effective care over time. Additionally, outcomes associated with SaMD and other digital tools, such as improved patient engagement, adherence, or reduced hospitalizations, may be difficult to quantify upfront but are central to their value.

The above reasons, among others, are why a single formula for valuing SaaS platforms and other digital tools does not exist. **We encourage CMS to consider flexible methodologies that recognize these variations and allow for tailored payment approaches based on regulatory burden, functionality, clinical utility, and ongoing support needs.** As part of this process, the Agency should consider **establishing a dedicated group focused on AI and SaMD payment and coverage** such as a CMS task force, Federal Advisory Committee, or Technical Expert Panel to address these issues in a predictable, thoughtful, and flexible manner.

Finally, we encourage CMS to take an incremental approach to reimbursement for digital health tools, prioritizing products that have been clinically validated and authorized by FDA. As stated previously, confusion surrounding coverage and pricing for a small number of digital therapeutics that qualify for reimbursement under G0552 is hindering implementation. We suggest that CMS focus on implementation of the DMHT codes and reimbursement for other FDA regulated products prior to establishing new payment policies for other digital tools.

CMS Should Create Separate Coding and Payment for Medically Tailored Meals

ATA Action strongly supports CMS’s exploration of separate coding and payment for medically tailored foods (Medically Tailored Meals and Medically Tailored Groceries), particularly when integrated with virtual care and remote patient support services. Access to medically appropriate nutrition plays a crucial role in sustainably improving health outcomes in the short and long-term, especially for individuals with chronic illnesses, recent hospitalizations, high-risk pregnancy, or food insecurity. MTFs can serve as a powerful

complement to medical nutrition therapy (MNT) and digital health tools by supporting care plan adoption and adherence, improving medication effectiveness, reducing hospital readmissions, and sustaining better health outcomes. ATA Action encourages CMS to create HCPCS codes (akin to those S and B codes used for medical foods) for MTMs and MTGs and allow flexibility for providers (e.g., PCPs, Registered Dietitians, and other specialty care providers) to be eligible to bill for the services separately.

This will provide better data for tracking the utilization and impact of MTMs, digital tools and services to enable analysis that is separate from and in addition to home-delivered meals (that are not medically tailored), MNT or other therapeutic program components. CMS should also allow for the inclusion of virtual foodcare services, such as digital screening for adequate access to food, personalized foodcare plans, personalized meal planning, remote medical nutrition therapy, and meal tracking via patient apps.

What is the appropriate description of such services, and under what circumstances?

A potential code descriptor for MTFs could be:

> "Provision of medically tailored foods, including medically tailored meals or medically tailored groceries, food preparation support and home delivery of meals aligned with a patient's chronic condition and care plan."

ATA Action believes MTF prescriptions could be created by a wide variety of medical, clinical or social providers or practitioners as part of foodscripts (dietitian referrals combined with MTF prescriptions).

Do community-based organizations (CBOs) currently employ eligible billing providers?

Many smaller, community-based organizations (CBOs) that deliver MTMs do not employ Medicare billing practitioners (e.g., MDs, NPs, PAs, or Registered Dietitians). These organizations typically focus on food production and delivery, often in partnership with healthcare providers or social service agencies. We recommend CMS ensure their eligibility to be Medicare suppliers that provide MTFs. Providers, including Registered Dietitians, can access MTFs for patients through community-based organizations that prepare and deliver MTFs. CMS should allow flexibility for different types of providers - from RDs to NPs and PAs to MDs, to bill for MTF.

Should CMS allow referrals to CBOs while maintaining general supervision by billing providers?

Yes, CMS could allow referrals from billing providers and direct billing through clinicians that have billing capabilities, with the practitioner maintaining general supervision and care plan oversight as needed. Provider groups can also partner with and support CBOs, and other Food and MTF providers to enable Medicare billing ensuring patients receive clinically appropriate meals while preserving Medicare billing integrity.

Virtual foodcare models, such as those supported and created by ATA Action members, can further enable real-time care coordination, patient engagement, and data sharing across provider settings. This includes the use of digital tools to verify delivery, meal adherence, and patient feedback, enhancing accountability and quality assurance.

How should CMS ensure integrity of the service?

To maintain program integrity, CMS could:

- Require documentation of clinical indication and duration of need within the care plan.
- Mandate that meals meet nationally recognized nutritional standards (e.g., specific sodium, carb, or protein targets).
- Encourage or require participation in quality reporting, such as delivery verification, dietary adherence, and patient satisfaction surveys.
- Allow use of digital reporting and tracking platforms to provide visibility into service delivery and outcomes.
- Ensure the deployment of personalized foodcare plans, personalized meal plans and transition to long-term, affordable grocery and cooking solutions
- Deploy Food-as-Medicine Benefits Management to ensure optimal ROI is achieved

ATA Action appreciates CMS's continued commitment to advancing virtual care and innovation within the Medicare program. We believe this proposed rule takes important steps toward building a forward-looking care model that moves beyond temporary COVID-era policies. We look forward to working together to ensure Medicare beneficiaries can access high-quality care when and where they need it most. Please don't hesitate to reach out with any questions.

Kind regards,

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