

August 28, 2023

Administrator Chiquita Brooks-LaSure  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1784-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

**RE: Comments on the CY2024 Physician Fee Schedule proposed rule (CMS-1784-P)**

*Submitted electronically on regulations.gov*

Dear Administrator Brooks-LaSure:

As the only organization completely focused on advancing telehealth, the American Telemedicine Association (ATA) and ATA Action, the ATA's advocacy arm, are committed to ensuring that everyone has access to safe, affordable and appropriate care when and where they need it, enabling the system to do more good for more people. The ATA and ATA Action appreciate CMS's continued work to expand access to care for all patients, and we are pleased to submit the following comments in response to the calendar year (CY) 2024 Physician Fee Schedule proposed rule (CMS-1784-P).

In the proposed rule, CMS looks beyond the now-expired COVID-19 public health emergency (PHE) to continue the expansion of telehealth services, providing much needed clarity for physicians and other stakeholders across the country. We appreciate the opportunity to work with CMS to expand access to telehealth within its statutory authority and based on its clinical judgment, while we also work with Congress to expand said statutory authority appropriately. The ATA and ATA Action strongly support enhanced access to telehealth and digital health services and provide our comments to this CY2024 Physician Fee Schedule proposed rule as to how CMS can continue that trajectory.

**Medicare Telehealth Services**

The ATA and ATA Action commend CMS for extending Medicare telehealth flexibilities through CY2024 in alignment with the 2023 Consolidated Appropriations Act passed into law last December ([P.L. 117-328](#)). These flexibilities include waiving the geographic and originating site restrictions, maintaining coverage for audio only services, allowing for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to be reimbursed for rendering telehealth services, delaying the telemental health prior in-person requirement, and maintaining the expansion of the Medicare Telehealth Provider list to include physical therapy, occupational therapy, and speech therapy (PT/OT/ST) to ensure those providers can be reimbursed for providing telehealth services. We appreciate CMS's commitment to expanding access to care to all Medicare beneficiaries, including those in underserved and rural communities.

### *Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List*

Looking beyond the COVID-19 PHE, CMS proposes a new process to add, change, or delete codes to the Medicare Telehealth List. CMS states that this process is simpler and would help alleviate confusion stemming from the distinction between services that were added to the telehealth list on the basis of COVID-19 PHE-related authorities versus services that were added temporarily on a Category 3 basis, which does not rely on any PHE-related authority. The proposal would simply classify and consider additions or codes currently on the Medicare Telehealth Services List as either “permanent” or “provisional.” In 2024, any services that are on a category 1 or 2 basis would be on the list as a permanent category, while any services added on a temporary category 2 or category 3 basis would be assigned to the provisional category. Going forward, to consider a request to add a service to the Medicare Telehealth Services List permanently, CMS proposes a four- to five-step process requiring evidence that supports how the telehealth service is either clinically equivalent to a telehealth service already permanently on the list, or evidence that presents studies where findings suggest a clinical benefit sufficient for the service to remain on the list to allow time for confirmative study.

The ATA and ATA Action are supportive of this simplified process and believe it will help provide clarity for providers moving forward. We emphasize the importance of the “optional” step 5 if a code meets all the other criteria but is not analogous to service that is already on the permanent list. While we recognize that “Medicare Telehealth Services” has a specific definition under 1834(m) and includes only face-to-face visits and not the full universe of services that can be delivered virtually, we strongly support coverage of all services that can safely and effectively be delivered face-to-face virtually, regardless of whether they’ve been covered in the past. We are also strongly supportive of other non-face-to-face services like remote monitoring to be covered elsewhere in the fee schedule.

### *Additions to the Telehealth Services List for CY2024*

The ATA believes that telehealth, when utilized in accordance with health equity principles, can eliminate disparities and inequities in health. For more, see ATA’s [framework for eliminating health disparities using telehealth](#). CMS proposes to permanently add HCPCS code GXXX5 (Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5-15 minutes) to the Medicare Telehealth Services List. This will allow practitioners to obtain information about patients’ life circumstances such as their age and conditions they were born in as well as live, grow, and work in. This will give practitioners the ability to more appropriately and accurately diagnose and treat a patient. Additionally, CMS proposes to add three health and well-being coaching codes 0591T, 0592T, and 0593T on a temporary basis until the end of CY2024. The ATA and ATA Action support these two proposals and the intention to give providers more tools to address health disparities.

As offered in previous comments, we continue to recommend the following codes be added permanently: inpatient hospital care services (99221–99223); observation admission services (99218–99220); same-day inpatient/observation admission and discharge services (99234–

99236); new patient domiciliary, rest home services (99324–99328); and home-visit new-patient services (99341– 99345). The ability for hospitals to provide some care via telehealth can help alleviate staffing shortages we see in hospitals around the nation and can reduce delayed admissions and improve care coordination.

Another set of codes we would like to particularly flag for permanent consideration is ophthalmologic services (92002, 92004, 92012 and 92014). These codes are generally covered via telehealth by other insurance plans, including Medicare Advantage plans and the Veterans Health Administration, and should also be available to Medicare beneficiaries. The [National Association of Vision Care Plans \(NAVCP\)](#) published its ocular telemedicine policy in 2020. That policy clarifies that ophthalmological services that are typically covered under benefits administered by managed vision care (MVC) plans may be provided using telemedicine that meets the standards established in the policy. Those services are self-referred routine (aka “wellness”) examinations performed by participating optometrists and ophthalmologists in the MVC provider networks. Such services are typically billed to the MVC plan using the codes noted above. In addition to noting the appropriateness of the use of ocular telemedicine for self-referred regular eye care, the NAVCP also noted that the use of telemedicine for patients presenting with complaints or symptoms suggestive of active ocular pathology would be appropriate when, in the eye care provider’s professional judgment, an initial examination by telemedicine would best serve the patient. There are also a number of peer-reviewed studies supporting the effectiveness of telemedicine for these services.

This year, CMS proposes to add marriage and family therapists (MFT) and mental health counselors (MHC) as telehealth practitioners allowed to practice Medicare telehealth services as of January 1, 2024, in accordance with the 2023 Consolidated Appropriations Act. We are supportive of these providers’ ability to offer Medicare telehealth services. We believe all practitioners should have the option to utilize virtual care when clinically appropriate and be reimbursed for the services rendered.

The ATA and ATA Action believe that physical therapy, occupational therapy, and speech therapy (PT/OT/ST) services can be delivered effectively via telehealth. We urge permanent coverage of the therapy codes even though physical therapists, occupational therapists, and speech therapists are not currently permitted by statute to provide telehealth services after CY2024. Congress has shown interest in changing this statutory requirement either by explicitly adding these providers or by continuing to give CMS the authority to determine other appropriate providers to deliver telehealth services. We do not believe that a static list written into statute can keep pace with clinical best practices. We urge both Congress to provide, and CMS to use, all flexibility possible to make clinically appropriate services accessible in Medicare.

### *Telehealth Reimbursement*

CMS addresses reimbursement rates for providing telehealth services through CY2024 and beyond in this proposed rule. Claims billed with Place of Service (POS) code 10 (telehealth provided in the “home”) will continue to be reimbursed at the higher non-facility rate. Whereas, claims billed with POS code 02 (telehealth provided outside the home), will be reimbursed at the

lower facility rate beginning in CY2024 as they were pre-pandemic. We appreciate CMS' recognition that many providers maintain both a physical office and may conduct telehealth from another location, but the value of their service is the same. We also appreciate that per the CY2022 PFS, CMS defines "home" broadly to include temporary lodging or a place where the patient chooses for privacy or other personal reasons to travel a short distance from the actual location of their home. We support CMS' approach.

As outlined in previous comments, we believe in the concept of fair payment for telehealth services. The time a clinician spends with a patient for a particular service does not vary whether provided in person or virtually. However, other time and costs can vary significantly, particularly infrastructure costs (whether brick and mortar or technological) and administrative time. Using virtual options can save administrative costs and time. Additionally, reductions in payment rates under the fee schedule could disincentivize the adoption of telehealth or the ability of providers to adequately invest in technological infrastructure or incorporate it into their workflow. Fair payment should reflect these factors. Therefore, we urge CMS to continue seeking stakeholder feedback on telehealth reimbursement rates in future fee schedule rules to ensure these reimbursement rates are appropriate as technology continues to advance.

#### *Extending Outpatient Therapists' Ability to Bill for Telehealth*

CMS extended the flexibility that would allow hospital-employed PT, OT, and SLP providers to continue billing for telehealth services through the end of 2024, aligning with the other main telehealth flexibilities and providing much needed clarity. The ATA and ATA Action applaud CMS for making this clarification. "Telerehabilitation, when used to enhance or replace conventional therapy, has demonstrated that it is beneficial to overcome geographic, physical, and cognitive barriers."<sup>1</sup> Numerous studies have shown the clinical and cost effectiveness of telerehabilitation.<sup>2</sup> The American Speech-Language-Hearing Association recognized back in 2005 that teletherapy is a valid means of service delivery for speech therapy disorders.

#### *Virtual Direct Supervision*

CMS proposes to allow PHE flexibilities for direct supervision to continue through the end of CY2024 but continues to seek comments on whether those flexibilities should be made permanent. The ATA and ATA Action continue to urge CMS to make direct supervision via telehealth a permanent option. As mentioned in previous comments, we believe that CMS should work with stakeholders to identify which services would be the most appropriate for direct supervision via telehealth and that patient safety, as always, should be a top priority for providers, stakeholders, and regulators. We believe physician and nonphysician providers should have the autonomy to determine when direct supervision via telehealth is clinically appropriate and in line with the relevant standard of care and that CMS should avoid adding additional provider requirements that do not otherwise exist for in-person services. The American Medical Association's position on virtual supervision was clear in their letter sent in May 2023 to the

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<sup>1</sup> DeFre Galea, M. (2019, May 1). Telemedicine in Rehabilitation. *Physical Medicine and Rehabilitation Clinics of North America*, 30, (2), 473-483.

<sup>2</sup> Ibid.

CMS Administrator. The association encouraged CMS to permanently allow residents in teaching settings to be supervised through audio/visual real-time communications technology regardless of where they live and work.<sup>3</sup> This position is in alignment with the Accreditation Council for Graduate Medical Education standards. The main reason these organizations urge CMS to make virtual direct supervision permanent is to assist with the ongoing physician shortage crisis.<sup>4</sup>

### *Remote Monitoring for RHCs and FQHCs*

First, we applaud CMS for allowing RHCs and FQHCs to be reimbursed for providing remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM) services. This will ensure better treatment and monitoring for these underserved populations. However, we are unclear on how billing will work for these specific clinics and whether HCPCS code G0511 will be allowed to be billed more than once per month. We urge CMS to clarify how the billing will work for RHCs and FQHCs.

### *16-Day Data Collection Requirement*

The requirement to collect 16 days of data in a 30-day period in order to be eligible to bill remote monitoring codes has been a major concern for many stakeholders. Last year, the industry was hopeful that CPT would address and reconsider this requirement, but unfortunately that did not happen. With the industry still seeking this change and the PHE ending in May, CMS is now reinstating the 16-day data requirement for all beneficiaries. ATA and ATA Action are disappointed to see that CMS did not address this issue more substantively in the 2024 proposed rule.

As noted in previous comments, we disagree in principle with the concept that 16 or more days of data needs to be collected to effectively provide remote monitoring services (both RPM and RTM). We urge CMS to consider the foregoing while contemplating the proposal to condition all payments on 16 days of data. The ATA and ATA Action describe below several different clinical scenarios for which 16 days of monitoring data is not the appropriate amount. As outlined in our CY2021 and CY2022 comments, rather than keep an arbitrary requirement for days of data generated by the patient, we recommend that the requirement be consistent with physician or clinical staff orders as detailed in a patient's treatment plan for each patient. This ensures that the days of data collection over a 30-day period is clinically appropriate.

- Some clinical scenarios where remote monitoring is beneficial, but 16 days of monitoring is not the appropriate number in a 30-day period include:
  - A patient needing to be monitored for a continuous short-term period following surgery. This could include, for example, a patient prescribed a narcotic for pain whose breathing could be monitored while on the medication. This could also include patients who could benefit from remote monitoring to prevent

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<sup>3</sup>Henry, T.A. (2023, June 26). Virtual supervision of resident physicians should be here to stay. American Medical Association. <https://www.ama-assn.org/medical-residents/residency-life/virtual-supervision-resident-physicians-should-be-here-stay>



- readmission;
- A patient with a chronic condition like diabetes may have their weight monitored over a longer period of time, but it is not clinically relevant to have the patient step on a scale 16 or more times in a month;
  - A patient whose blood pressure or oxygen levels are monitored during physical therapy may not necessitate 16 days of monitoring. Physical therapy is often ordered twice weekly, which would result in fewer than 16 days of monitoring in a month;
  - Patients who wear heart monitors to measure palpitations may wear the monitor continuously, but the data only needs to be collected when the individual is experiencing symptoms;
  - Heart monitors to measure palpitations may be worn for 30 days, but data may only be needed when the patient is experiencing symptoms; and
  - Patients with hypertension are often monitored for long-term management of their condition on more of a weekly basis, only needing more frequent data collection for active monitoring with changes in medication or dosages.

Furthermore, in its proposed rule, CMS seems to have (perhaps unintentionally) expanded the scope of the 16-day requirement beyond the supply of equipment and patient education codes, making the requirement even more untenable by linking it to the treatment management codes as well.

As a reminder, the 16 days of data transmission requirement for billing CPT codes 99453 and 99454 was articulated by CMS in its 2021 MPFS, and it explicitly did NOT apply to CPT codes 99457 and 99458 for treatment management services. The proposed 2023 MPFS initially implied that the 16-day requirement would apply to the RTM treatment management services codes 98980 and 98981, the analogous codes to RPM codes 99457 and 99458; however, the 2023 Final MPFS declined to adopt changes to the RTM codes. Thus, the 16-day requirement has never applied to – and should never apply to – the treatment management codes. The AMA CPT Manual supports this position, referencing the 16-day requirement ONLY for CPT codes 99453, 99454, 98975, 98976, and 98977, NOT for 99457, 99458, 98980, and 98981.

The way the proposed rule is written makes it seem as though the requirement is applicable to both the supply of devices as well as 98980 and 98981 or the RTM treatment management codes. We believe CMS did not intentionally expand the scope, but we urge CMS to clarify as the requirement should not apply to the RPM treatment work codes 99457 and 99458, or the RTM treatment work codes 98980 and 98981. Applying this new requirement to the treatment management services codes would have a significant negative impact on the ability for practitioners to utilize the RPM and RTM code sets.

### *Billing for Remote Monitoring Services*

CMS proposes that practitioners may bill RPM or RTM, concurrently with the following care management services: Chronic Care Management (complex, non-complex), Transitional Care Management, Principal Care Management, Behavioral Health Integration, and Chronic Pain

Management. The ATA and ATA Action are fully supportive of this policy and applaud CMS for this proposal.

However, CMS states that RPM and RTM may not be billed concurrently. We believe RPM and RTM should be allowed to be billed together as these are two completely different metrics, and in some circumstances are needed to be utilized concurrently to ensure appropriate treatment.

Furthermore, CMS notes that “[i]n instances where the same patient receives RPM and RTM services, there may be multiple devices used for monitoring, and in these cases, we will to [sic] apply our existing rules, which we finalized when establishing the RPM code family, meaning that the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected.” This proposed clarification seems contradictory unless CMS suggests that RPM and RTM may be billed for the same patient when ordered by different practitioners.

We urge CMS to reconsider its policy regarding concurrent billing of RPM and RTM services in general. RPM is focused on physiologic metrics relevant to a patient. RTM, on the other hand, is focused on therapeutic monitoring, which may include, for example, adherence and/or response to a medication regimen, a physical therapy program, a cognitive behavioral therapy program, etc. Therapeutic metrics and physiologic metrics are separate and distinct, and both can play a critical role for the same patient. For example, a patient with hypertension might justifiably be on a program for RPM to monitor blood pressure AND for RTM to manage medication adherence for that hypertension. The ATA and ATA Action are supportive of the ability for various specialties and specialists to monitor and bill for different illnesses. The current policy creates many barriers that could prevent practitioners from providing effective and appropriate treatment.

#### *Remote Monitoring: New vs Established Patients*

During the COVID-19 PHE, remote monitoring services were allowed to be furnished to both established and new patients. This flexibility expired with the PHE on May 11 and reverted back to only established patients. But CMS clarified that those who received services during the PHE are considered established patients. The ATA and ATA Action appreciate this grandfathering-in approach as we want to ensure that patients who received care during the PHE do not lose access to these critical monitoring services. However, we strongly believe providers should be allowed to provide RTM and RPM services to both new and established patients, particularly because both services are allowed to monitor patients suffering acute or chronic conditions. Restricting remote monitoring only for established patients would potentially disallow many patients with acute conditions to be remotely monitored during the time they need it most.

#### *PTs and OTs: The “General Supervision” of PTAs and OTAs During Outpatient RTM Physical Therapy Services in Private Practice*

Lastly, CMS is extending the flexibility that allows physical therapists and occupational therapists in private practice that qualify as a supplier to generally supervise, for RTM services, physician therapist assistants and occupational therapist assistants. ATA and ATA Action

support this decision. However, the [Medicare Benefit Policy Manual](#) (chapter 15) defines the term therapist in a private practice and outlines the qualifications for a supplier, but it's convoluted and arduous. We urge CMS to simplify and clarify this language to ensure that stakeholders understand easily who qualifies.

### *RPM to be Considered "Primary Care services" under the Medicare Shared Savings Program*

CMS is proposing to classify CPT codes 99457 and 99458 as primary care services under the Medicare Shared Savings Program ("MSSP"). While this proposal seems innocuous on its face, its intended purpose is not clear. Is the proposal aimed solely at counting claims for CPT codes 99457 and 99458 as part of the process for attributing beneficiaries to an MSSP ACO? Would reimbursement for 99457 and 99458 count towards the ACO's benchmark for purposes of determining whether or not the ACO is eligible for shared savings? If so, this may be a disincentive for some practitioners to order these services. We encourage all RPM and RTM codes to be reimbursable in the MSSP context without the cost of these care management codes being factored into the determination of eligibility for savings, thereby appropriately incentivizing use of these codes for patients as appropriate.

### **Opioid Treatment Programs**

We applaud CMS for the continued expansion of telehealth within opioid treatment programs (OTPs) over the past few years. This year, CMS proposes to extend the flexibility that allows periodic assessments to continue to be furnished using audio-only communication technology following the end of CY2024 for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs. The ATA and ATA Action are supportive of this flexibility and making audio only services permanent overall.

A study that included 30 Federally Qualified Health Centers (FQHCs) in California that serve 1.3 million patients, found that in August 2022, 1 in 5 primary care visits and 2 in 5 behavioral health visits were audio only.<sup>4</sup> "FQHCs continued to deliver audio-only visits in high volume, likely because of their role in improving access."<sup>5</sup> Satisfaction with audio-only visits are on par with video visits, as shown in a national study (n=200).<sup>6</sup> Researchers also found that audio-only telehealth produced similar benefits and was not inferior when compared to video-based visits; a majority of participants shared that they would recommend an audio telemedicine visit to others and that their medical concerns were addressed.<sup>7</sup> Audio only further promotes equity for individuals who are economically disadvantaged, live in rural areas, are racial and ethnic minorities, lack access to reliable broadband or internet access, or do not possess devices with video capability.

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<sup>4</sup> Uscher-Pines, L., McCullough, C.M., Sousa J.L., Lee, S.D., Ober, A.J., Camacho, D., & Kapinos K.A. (2023, April). Changes in In-Person, Audio-Only, and Video Visits in California's Federally Qualified Health Centers, 2019-2022. *JAMA*;329(14):1219-1221.

<sup>5</sup> *ibid.*

<sup>6</sup> Danila, M.I., Sun,D., Jackson,L.E., Cutter, G., Jackson, E.A., Ford, E.W., DeLaney, E., Mudano, A., Foster, P.J., Rosas, G., Melnick, J.A., Curtis,J.R., & Saag, K.G. (2022, November). Satisfaction with modes of telemedicine delivery during COVID-19: A randomized, single-blind, parallel group, noninferiority trial. *The American Journal of the Medical Sciences*, 364 (5).

<sup>7</sup> *Ibid.*



## **Provider Address**

We are appreciative of the amount of clarity CMS has provided throughout this year's proposed rule, but there is one concern that the telehealth industry needs guidance on moving forward. During the PHE, CMS did not require providers to list their home address on the 1500 claim form when most of the services were provided virtually. Instead, the provider is allowed to list the address of the facility with which they are associated. Within CMS guidance, it notes this flexibility will be continued through CY2023, but does not provide any further guidance after that date. Maintaining the confidentiality and security of the provider's address, especially when they are providing mental health services, is imperative. Additionally, if providers have to list their home address it may disincentivize them from providing telehealth services. We urge CMS to permanently allow providers to bill practice addresses rather than home addresses.

## **Medicare Diabetes Prevention Program (MDPP)**

In this rule, CMS allows the MDPP to be offered virtually through the end of 2027. However, this only applies to MDPP suppliers that have and maintain CDC DPRP in-person recognition. We were disappointed to see that virtual-only suppliers are still not able to participate. The ATA and ATA Action are supportive of allowing virtual providers offering CDC-recognized Diabetes Prevention Programs (DPPs) to enroll in the Medicare DPP.

The MDPP is a structured year-long lifestyle change program focused on preventing the onset of type 2 diabetes in beneficiaries with prediabetes. Four states have no MDPP suppliers and 39% of Medicare beneficiaries live more than 25 miles from the nearest MDPP location. Those in the Teladoc Health CDC-recognized virtual Diabetes Prevention Program (DPP) lost the same amount of average weight as the MDPP in-person program. Given the identical outcomes of the DPP and limited enrollment in the MDPP due to, in part, access issues, some Medicare Advantage health plan partners have elected to offer the virtual DPP as a supplemental benefit<sup>8</sup>. We encourage CMS to work with Congress to improve the accessibility of the MDPP by allowing it to be offered virtually.

## **Community Health Integration (CHI) Services**

CMS has proposed two new G-codes that would enable practitioners to better furnish community health integration services to beneficiaries with the assistance of local community health workers. We applaud these efforts to further expand access to care and convenience for Medicare beneficiaries. Additionally, we strongly urge CMS to align with its recent approach to Medicare telehealth services and ensure these services are modality neutral and allow providers and beneficiaries to choose the most appropriate modality, whether virtual or in person. For example, a practitioner may determine during an initiating CHI visit (virtual or in person) that a beneficiary may be experiencing food insecurity. The practitioner could connect the beneficiary to a community health worker, whether contracted or otherwise, who is familiar with local programs able to help. Connecting to these local programs can be just as easily accomplished via

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<sup>8</sup> Teladoc Health. (n.d.). Expanding Access to the Medicare Diabetes Prevention Program (MDPP) Through High-Quality Virtual Care.

virtual means and studies have shown that community health workers are as effective at addressing gaps in care when working remotely.<sup>9</sup>

### **Telehealth Frequency Limitations - Inpatient and Nursing Facility Settings, and Critical Care Consultations**

The ATA and ATA Action are not supportive of limitations on the quantity of telehealth visits a practitioner can furnish over a period of time or any type of in-person requirement. These are arbitrary barriers that limit access to care. Ultimately, we want the practitioner to be able to practice at the top of their license and allow them to use their clinical judgment to determine the type of visit, how many visits, and the type of treatment that is the best fit for the patient so long as the standard of care is met. CMS proposes to temporarily remove the telehealth frequency limitations for the codes 99231-3, 99307-10 that pay for telehealth services in skilled nursing facilities as well as nixing telehealth frequency limitations for critical care consultation services, G0508-9, until the end of CY2024. We appreciate this extension but urge CMS to eliminate these barriers permanently.

### **Additional Topics**

#### *Payment for Software Algorithms*

The ATA and ATA Action are supportive of the coverage and payment of software algorithms. These are important components within technologies that help to make the healthcare industry more efficient and effective. We applaud CMS for working with the CPT Editorial Committee who approved the new permanent code 7X005 to report non-invasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the dataset from a coronary computed tomography angiography. We are supportive of this code but remain concerned with the way CMS generally accounts for software algorithms in its Practice Expense (PE) methodology. CMS payment methodology does not consider “computer software” as a direct PE, but deem as indirect practice expense which are typically non allocable. Unfortunately, CMS seems to include medical device software or Software as a Medical Device (SaMD) into its general categorization of non-allocable indirect PE “computer software.” That is an incorrect categorization as SaMD is no different from a legal perspective than hardware medical devices. CMS must explain how they intend to expand their existing payment methodology to reflect SaMD as direct PE, and how artificial intelligence algorithms which replace some human tasks as “work performed by a machine” will account for such services as either direct PE clinical staff time or professional work.

#### *Requests for Information on Digital Therapies*

The ATA and ATA Action appreciate CMS for inquiring about these important issues, such as AI and digital therapeutics, but these broad issues have far reaching implications that may even affect other payment systems outside of the fee schedule. We urge CMS to consider an official

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<sup>9</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8274676/>



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standalone request for information on these topics with an associated public meeting to ensure appropriate feedback from all relevant stakeholders into these important future setting issues.

Thank you very much for the opportunity to provide our detailed feedback on this year's Physician Fee Schedule proposed rule. If you have any questions or would like to further discuss our recommendations, please contact Kyle Zebley, Executive Director, ATA Action, [kzebley@ataaction.org](mailto:kzebley@ataaction.org).

A handwritten signature in black ink that reads 'Kyle Zebley'.

Kyle Zebley  
Executive Director, ATA Action  
Senior Vice President, Public Policy, ATA