

### September 1, 2021

Administrator Chiquita Brooks-LaSure Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1751-P, P.O. Box 8016, Baltimore, MD 21244-8016.

## RE: Comments on the CY 2022 Physician Fee Schedule proposed rule (CMS-1751-P)

Submitted electronically on regulations.gov

Dear Administrator Brooks-LaSure:

As the only organization completely focused on advancing telehealth, the American Telemedicine Association (ATA) is 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 appreciates CMS's work to expand access to telehealth, both during the current COVID-19 public health emergency (PHE) and after and is pleased to submit the following comments in response to the CY 2022 Physician Fee Schedule (PFS) proposed rule (CMS-1751-P). In the proposed rule, CMS looks to make access to some telehealth services permanent even after the PHE ends, which is a top priority of the ATA and its members and which further safeguards a "glide path" to post-pandemic care for beneficiaries. The ATA supports this effort and appreciates CMS's intent to ensure that Medicare beneficiaries continue to have access to quality health care when and where they need it.

The ATA recognizes that CMS is limited in its regulatory authority by restrictive federal laws. As such, the ATA will continue to work with bipartisan members of Congress to provide the agency with the needed flexibilities to ensure access to clinically appropriate care. In the CY2022 Physician Fee Schedule proposed rule, CMS uses its existing but unnecessarily limited authority to propose telehealth services covered and reimbursed under the physician fee schedule. The ATA's comments largely focus on a few key issues, including access to telemental health services, extension of Category 3 services, remote physiologic monitoring, remote therapeutic monitoring, and additional topics.

## **Telemental Health Expansion**

The ATA commends Congress for taking action at the end of calendar year 2020 to pass the Consolidated Appropriations Act, which included a provision in Section 123 to allow for permanent access to telemental health services post-pandemic regardless of a patient's geographic or physical location. This expansion is a necessary step in the right direction to ensuring that Medicare beneficiaries have access to all appropriate telehealth services after the PHE ends.



In-Person Requirement for Certain Telemental Health – In late 2020, Congress changed the Social Security Act to create a requirement for an in-person exam before an eligible telehealth individual can receive a telemental health service when at home. This in-person exam requirement is not contained anywhere else in the Social Security Act for telehealth services, nor does it apply to telemental health services when the patient is located at a qualifying originating site such as a medical clinic. The new language does not take effect until after the PHE expires. In the CY 2022 Physician Fee Schedule proposed rule, CMS looks to implement this statutory policy. The ATA understands that CMS is simply following Congress's lead, though we are hopeful Congress will correct this wrong in the statute. There is no clinical evidence for an arbitrary in-person requirement before a patient can access telehealth services. However, in the proposed rule, CMS considers requiring an in-person visit, not only within the "6-month period prior to the first time" the provider furnishes telehealth to the individual, as stated by law, but also within 6 months prior to subsequent telehealth visits. This effectively creates a new, arbitrary requirement for the patient to have an in-person mental health visit every 6 months should the patient plan to seek telehealth services with that provider. In response to CMS's request for comment on this new policy, the ATA asks CMS to remove the continual 6-month in-person visit requirement. The law gives CMS ample flexibility to expand that time period or eliminate it altogether. The law reads that these visits could occur "at such times as the Secretary determines appropriate." As such, the ATA urges CMS to use the given regulatory authority and establish that no additional in-person visits are required for a provider to furnish telehealth services to an eligible Medicare beneficiary.

Additional Providers — Further, CMS seeks comments on how to address scenarios when a different practitioner in the same practice may need to offer services to the eligible telehealth individual. The ATA urges CMS to use its regulatory authority to ensure a patient does not lose access to care because of their provider's unavailability, whether due to the provider's being temporarily unavailable or even retired. As such, the ATA recommends that CMS, at minimum, allow a provider in the same practice to offer services to the patient should the provider be unavailable or if the patient would like to change providers in the practice. CMS should further ensure providers are empowered to use locum tenens when they are individually unable to care for their patients. Generally, a Medicare patient should not be penalized because of a provider's lack of availability, so CMS should further use every authority possible to ensure these patients can access care, including by going outside the practice if necessary.

Interactive Telecommunications Systems – CMS has long held the regulatory authority to determine appropriate technologies that can be used as interactive telecommunications systems. The ATA is a technology- and modality-neutral organization and thus supports patients' ability to use any clinically

<sup>&</sup>lt;sup>1</sup> ATA Overview of In-Person Requirements, June 2021; <a href="https://www.americantelemed.org/wp-content/uploads/2021/06/ATA-Overview-of-In-Person-Requirements-1.pdf">https://www.americantelemed.org/wp-content/uploads/2021/06/ATA-Overview-of-In-Person-Requirements-1.pdf</a>

<sup>&</sup>lt;sup>2</sup> United States Code; <a href="https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1395m&num=0&edition=prelim">https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1395m&num=0&edition=prelim</a>

<sup>&</sup>lt;sup>3</sup> United States Code; <a href="https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1395m&num=0&edition=prelim">https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1395m&num=0&edition=prelim</a>



appropriate technology to access telehealth services from their providers. The ATA supports CMS's proposal in the proposed rule to allow for the use of audio-only technologies, because a provider's attention to a patient and ability to care for the patient does not change with the technology. Audioonly technologies have been essential for helping patients, especially those with limited internet connectivity, to continue to access their providers. The ATA believes that as CMS looks to expand access to audio-only services it is appropriate to consider the patient's preference and technology limitations when considering applicability of audio-only care. That being said, the ATA also encourages CMS to consider other services outside of mental health, such as behavioral health services, that could be appropriately delivered via audio-only technology, especially in cases in which the patient does not have access to audio-visual technologies. In response to CMS's question about the need for additional documentation in the patient's medical record to support the clinical appropriateness of audio-only telehealth, the ATA urges CMS to avoid creating new paperwork burdens on providers that could unnecessarily detract from the provider's ability to care for a patient. Further, the ATA believes that audio-only telehealth should not be limited to only certain services such as level 4 or 5 Evaluation and Management (E/M) visit codes or psychotherapy with crisis as proposed. Instead, audio-only should be available, at a minimum, to all Medicare beneficiaries needing mental health services regardless whether the patient is "established" or not.

Federally Qualified Health Centers and Rural Health Clinics – Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) are critical safety-net providers who care for some of the most underserved patient populations in our country. The ATA supports policies to empower these providers to expand access within their communities through technologies such as telehealth. The ATA commends CMS for considering the importance of these providers and for recommending FQHCs and RHCs offer mental health services through interactive, real-time telecommunications technology. The ATA believes this policy change is an important step to ensuring health equity for all Medicare patients, a key policy priority of the ATA. The ATA supports CMS's decision to align FQHC and RHC patient access with other telemental health services provided under the PFS by enabling these patients to use audio-only services. In the proposed rule, CMS specifically requests feedback on whether the agency should further align FQHC and RHC telemental health services with telemental care that is covered under the PFS by replicating the problematic in-person requirement that is statutorily required for PFS services. The ATA emphatically urges CMS to avoid adding an unnecessary in-person requirement to remote services for these patients. The ability for RHCs and FQHCs to offer mental health services remotely is a great step in the right direction, and the ATA urges CMS to consider in future rulemaking what additional services beyond mental health could be offered via real-time telecommunications technology to RHC and FQHC patients, such as Health Behavior Assessment and Intervention services.

As CMS considers other ways to expand all-inclusive care furnished by FQHCs and RHCs, the ATA urges consideration of additional services, including Remote Physiologic Monitoring (RPM) as part of, and included in the calculation for HCPCS G0511 – general Care Management Services for FQHCs and RHCs, as is currently being considered by CMS. Specifically, general care management furnished by these



providers should include not only chronic care management, principle care management, and general behavioral health integration, but also RPM services.

## **Category 3 Services**

Category 3 Extension – The ATA continues to support CMS's decision to use the newly created Category 3 codes for temporary telehealth services. The creation of Category 3 in the CY 2021 Physician Fee Schedule was a practical way for CMS to use its regulatory authority to ensure continued coverage for Medicare beneficiaries. The ATA greatly appreciates CMS's recognition in the proposed rule that a post-pandemic "glide path" is essential to ensuring that Medicare beneficiaries do not immediately go over the telehealth cliff. The ATA commends CMS for extending the Category 3 telehealth service list until December 31, 2023, and further believes Category 3 could be a useful framework to maintain even beyond 2023 and the COVID-19 pandemic. Category 3 has proven to be a helpful pathway during the pandemic through which CMS covers new telehealth services on a temporary basis, allowing for the collection and review of utilization data. The ATA agrees with CMS that this pathway should continue at least through the end of 2023 and further recommends that CMS consider allowing Category 3 to remain permanently to allow the agency a process through which new telehealth services can be temporarily added as CMS continues to collect evidence to support making additional services permanent.

The extension until the end of 2023 at minimum will allow CMS time to work with patients and stakeholders to determine which telehealth services should be permanently added to the telehealth list once the COVID-19 PHE ultimately expires. While the ATA recognizes this reasonable and essential step, we also must acknowledge that without congressional action, any telehealth service added to the permanent telehealth service list will only be available to certain Medicare beneficiaries once the current statutory telehealth flexibilities expire. For this reason, the ATA continues to urge CMS to work with policymakers to ensure the agency has the maximum flexibility to continue to allow Medicare beneficiaries access to health care services. The extension of Category 3 services through the end of 2023 is a good policy decision, and the ATA urges Congress to also recognize the need for telehealth services to continue for a period not dependent on the COVID-19 PHE, as has been recommended by the nonpartisan Medicare Payment Advisory Committee.<sup>4</sup>

Codes Included – The ATA is concerned that CMS is proposing to remove some telehealth services from the Category 3 list prematurely and further recommends that CMS retain at least through the end of CY 2023 all appropriate telehealth services that have been listed at any point as Category 3. These should include, at minimum, the codes listed in table 11 in the proposed rule.

<sup>&</sup>lt;sup>4</sup> MedPAC Report to Congress: Medicare Payment Policy, March 2021; <u>medpac.gov/docs/default-source/reports/mar21 medpac report to the congress sec.pdf</u>



Additionally, the ATA is disappointed that CMS has rejected requests to permanently add new telehealth services next year. The ATA continues to recommend the following codes be added to Category 1: inpatient hospital care services (99221–99223); observation admission services (99218–99220); sameday inpatient/observation admission and discharge services (99234–99236); new patient domiciliary, rest home services (99324–99328); and home-visit new-patient services (99341–99345).

CMS temporarily added cardiac rehabilitation services (CPT codes 93797 and 93798) to the Medicare telehealth list on October 14, 2020. CMS should add these cardiac rehabilitation codes to the telehealth list on a Category 3 basis. This will promote advancements in equitable access to care because a Category 3 designation will allow for additional data collection and subsequent consideration of permanent placement. Current evidence on cardiac rehabilitation services is sufficient to "foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth." The evidence supports patient safety outside the circumstances of the COVID-19 pandemic. The services do not jeopardize quality of care outside the circumstances of the COVID-19 pandemic. All elements of the services could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology. In short, the current evidence on cardiac rehabilitation services meets the three factors CMS considers for inclusion on a Category 3 basis.

# **Remote Therapeutic Monitoring**

Billing Practices in Proposed Rule — Remote Therapeutic Monitoring (RTM) services can offer providers and patients new tools to monitor non-physiologic data to help manage and adhere to a patient's therapeutic regiment, thus saving lives and taxpayer dollars. The ATA commends CMS's swift action to adopt, cover, and reimburse RTM service codes in the proposed rule. The ATA further appreciates CMS's recognition that the currently proposed coding for RTM services may meet severe challenges during implementation in the field, namely that only a specific set of provider types can bill the codes and that clinical staff time is not able to be billed incident -to physician/nonphysician practitioner services under General Supervision. The ATA welcomes the opportunity to provide solicited comments on this payment challenge and looks forward to working with CMS and providers to help ensure that patient access is not hindered and that the original intent for a broader set of providers to bill RTM codes is upheld.

The ATA agrees with CMS's point raised in the proposed rule that, as currently written, the PFS would limit RTM codes to a specific set of providers. By using exclusively general medicine codes for RTM services, the proposed codes negate the possibility for RTM to be billed by a broader array of providers, and, unlike with Remote Physiologic Monitoring codes, RTM physicians and QHPs providing services under general medicine would be precluded from reporting services performed by clinical staff under general supervision as incident to services. As with E/M codes, a direct consequence is that certain nonphysician practitioners may not be able to bill for RTM services (i.e., codes in the "general medicine"

<sup>&</sup>lt;sup>5</sup> See 86 Fed. Reg. at 39138–39145.

<sup>&</sup>lt;sup>6</sup> 86 Fed. Reg. at 39130–31.



category cannot be billed using incident to billing). The ATA appreciates CMS's recognition of this challenge in the proposed rule. The ATA recommends that CMS consider any appropriate mechanism that will allow additional practitioners to supplement a patient's care through the use of RTM, including creating parallel temporary HCPCS G-codes. The ATA suggests that CMS consider creating a set of temporary G-codes modeled after 989X4 and 989X5 that would be considered E/M codes included in care management services, allowing physicians and qualified health professionals (physician assistants, nurse practitioners, certified nurse specialists, and certified nurse midwives) to bill for RTM. These G-codes will allow for incident-to billing and are essential to ensuring auxiliary personnel and clinical staff are able to assist in the provision of RTM services under the general supervision of a billing provider, as correctly questioned by CMS. In addition, CMS should ensure the RTM codes allow all relevant providers, including physical therapists and other qualified health care providers, to bill independently for RTM services. The ATA suggests creating another set of new G-codes for RTM treatment assessment services under general medicine that would allow for nonphysician providers (physical therapists and nurses) to bill directly. In doing so, CMS will allow a greater array of providers to offer RTM services.

Coverage of Use Cases – The ATA's policy principles state, "to effectively leverage and expand telehealth, digital health, and virtual care technologies, federal and state health policy must be technology, modality, and site-neutral." As such, the ATA urges CMS to consider devices other than those currently contemplated for reimbursement via RTM codes. We recognize that other devices and direct patient input may collect important non-physiologic data on metrics such as pain, patient mood, and adherence. These devices, too, should be reimbursable under the CY 2022 PFS. The ATA urges CMS to consider broader use cases for RTM, including but not limited to behavioral and mental health therapies and services addressing vascular, endocrine, neurological, and digestive systems. Further, the ATA supports coverage and reimbursement of a condition-agnostic supply code, including through the creation of a new, temporary HCPCS G-code.

RPM Alignment – Given the success of and the potential value similarities between RTM and RPM services, the ATA urges CMS to consider every opportunity to align RTM and RPM coverage and payment. One way to better align RTM and RPM coverage and reimbursement is to expand the universe of RTM codes beyond the currently proposed use cases. The ATA additionally recommends that CMS extend to RTM the regulatory flexibilities that were recently allowed for RPM to ensure further alignment. These should include flexibilities that are currently temporary during the COVID-19 pandemic, as well as provisions that have recently been made permanent. These policies should include provisions related to acute and chronic patients, obtaining consent at the time of service, general supervision, cost-sharing waivers for COVID patients, and allowing access to new and established patients. Further, CMS should make permanent the currently temporary policy allowing for access to RPM services for new patients and should align this policy with RTM services as well.

<sup>7</sup> ATA Policy Principles, July 2020; <a href="https://www.americantelemed.org/policies/ata-policy-principles/">https://www.americantelemed.org/policies/ata-policy-principles/</a>



Alignment of RTM and RPM must avoid misguided policies of the past, including many recurring concerns with the current RPM payment structure. For example, the ATA urges CMS to not reflect RPM's minimum-days-of-monitoring requirement in new policies for RTM. The ATA also recommends the agency's ensuring RTM services can be used for new as well as established patients, even when the current COVID-19 PHE ends. As detailed below in the RPM section and in the ATA's recent letters to CMS,<sup>8</sup> the ATA urges CMS to consider specific changes to ensure appropriate availability and usage of RPM services through the Medicare program. At a minimum, we ask that these barriers not be repeated in RTM payment policy. The ATA urges CMS to create complementary G-codes to allow for RPM treatment-assessment services, which would allow nonphysician providers to permanently bill for RPM as well. These providers could include but are not limited to physical therapists and other nonphysician providers, who would then be allowed to bill these codes within their benefit categories and scopes of practice.

All of these recommended alignment changes in the final rule would recognize that the same patient in the same month could and should benefit from RTM and RPM combined. The ATA would urge CMS to make that provision clear in the final rule.

### **Remote Physiologic Monitoring**

Telehealth and remote physiologic (or patient) monitoring (RPM) are at the forefront of the new standard of care that must be available to all Americans, especially Medicare beneficiaries. We applaud the important steps previously taken to expand access to RPM services as part of America's COVID-19 response while setting a precedent for greater access after the conclusion of the pandemic. RPM enables beneficiaries to remain safely in their homes where they can be properly supported to manage their conditions while also reducing the strain on the healthcare system. However, the ATA is disappointed that CMS did not consider important changes to ensure access to RPM services in the proposed rule. The absence of RPM in the CY 2022 PFS proposed rule represents a missed opportunity for CMS to continue to expand access to needed care for Medicare beneficiaries by addressing several historical policy barriers. As noted in the ATA's comments in response to the CY 2021 PFS proposed rule<sup>9</sup> and in a May 2021 letter to Secretary Becerra and Acting Administrator Richter,<sup>10</sup> CMS has the authority to correct several policy issues through the PFS to ensure access to appropriate RPM.

<sup>&</sup>lt;sup>8</sup> ATA Comments on the CY 2021 PFS proposed rule, September 2020; <a href="https://www.americantelemed.org/wp-content/uploads/2020/09/PFS-CY2021">https://www.americantelemed.org/wp-content/uploads/2020/09/PFS-CY2021</a> ATA-comments 9.24.20-FINAL-1.pdf; ATA Letter on RPM for Physician Fee Schedule CY 2022, May 2021; <a href="https://www.americantelemed.org/wp-content/uploads/2021/05/RPM-Letter-on-FY22-PFS-ATA.pdf">https://www.americantelemed.org/wp-content/uploads/2021/05/RPM-Letter-on-FY22-PFS-ATA.pdf</a>

<sup>&</sup>lt;sup>9</sup> ATA Comments on the CY 2021 PFS proposed rule, September 2020; <a href="https://www.americantelemed.org/wp-content/uploads/2020/09/PFS-CY2021">https://www.americantelemed.org/wp-content/uploads/2020/09/PFS-CY2021</a> ATA-comments 9.24.20-FINAL-1.pdf

<sup>&</sup>lt;sup>10</sup>ATA Letter on RPM for Physician Fee Schedule CY 2022, May 2021; <a href="https://www.americantelemed.org/wp-content/uploads/2021/05/RPM-Letter-on-FY22-PFS-ATA.pdf">https://www.americantelemed.org/wp-content/uploads/2021/05/RPM-Letter-on-FY22-PFS-ATA.pdf</a>



### **Additional Topics**

Artificial Intelligence — As technology continues to alter the future of health care delivery across the United States, the ATA looks forward to continuing to work with CMS and other federal partners to ensure that Americans have access to clinically appropriate care and that technology improves and does not hinder provider capabilities. As such, the ATA is glad to see the proposed rule's inclusion of national coverage and reimbursement for artificial intelligence (AI) software used for diabetic retinopathy through CPT code 92229. Further, the ATA commends CMS for the thoughtful set of questions related to AI included in the proposed rule. These important questions introduce concepts that must be addressed by the medical community, including how AI can influence health outcomes for racial minorities and people who are economically disadvantaged. The ATA has prioritized health equity and access for all Americans and looks forward to the opportunity to work with CMS on these pressing issues. However, we do recommend that CMS consider an alternate platform to raise these questions separate from the PFS to ensure appropriate attention is given.

Direct Supervision via Telemedicine – CMS seeks comments on whether to adopt a policy to permanently allow provision of direct supervision via telehealth. The ATA believes that CMS should make this policy permanent by amending the current definition of "direct supervision" (both under 42 CFR 410.27 (a)(1)(iv)(D) for hospital outpatient services and under 42 CFR 410.32(b)(3)(ii) for physician office services). We understand that ATA members and their patients have benefited from direct supervision via telehealth during the pandemic, and we believe providers should continue to have this option moving forward. The ATA believes 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. The ATA believes providers generally 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.

Medicare Diabetes Prevention Program —The ATA recognizes that chronic diseases such as diabetes cost the United States and taxpayers greatly in lives and resources. Since 2018, the Medicare Diabetes Prevention Program has offered behavior change interventions to Medicare beneficiaries at risk of developing type 2 diabetes. Unfortunately, to date, Medicare beneficiaries have been unable to access this intervention program when offered remotely because CMS has not allowed digital providers to be eligible for reimbursement in the MDPP expanded model. As CMS considers future policies, the ATA urges the agency to align payment policy with the decisions of the Centers for Disease Control and Prevention (CDC) and to ensure that CDC-recognized virtual Diabetes Prevention Program providers are able to participate in MDPP.

Merit-based Incentive Payment System and Advanced Alternative Payment Models – The ATA believes telehealth and digital health can help improve health care access, quality, and value. The ATA commends CMS's continued efforts to promote value-based care and encourages the continued



integration of telehealth and digital health tools into the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) to help meet this shared goal. We encourage the agency to use existing authority to incentivize the use of digital health technology through MIPS and support digital health tools in APMs.

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 discuss our recommendations further, please contact Kyle Zebley, Vice President, Public Policy at <a href="mailto:kzebley@americantelemed.org">kzebley@americantelemed.org</a>.

Kind regards,

Ann Mond Johnson Chief Executive Officer

American Telemedicine Association