



September 24, 2020

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-801

Re: Comments on the CY 2021 Physician Fee Schedule Proposed Rule (CMS-1734-P)

Submitted electronically on regulations.gov

Dear Administrator Verma,

As the only organization completely focused on advancing telehealth, the 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 is pleased to submit the following comments to CMS on the CY 2021 Physician Fee Schedule proposed rule (CMS-1734-P).

The ATA appreciates CMS's efforts to expand access to telehealth. With Congressional authority, CMS has led the way in expanding access to remote care during the COVID-19 public health emergency (PHE). With this proposed rule, CMS seeks to make some of those regulatory flexibilities permanent. The ATA strongly supports increased access to telehealth services in the Medicare program in order to increase access to clinically and cost-effective care, particularly for underserved populations. Our comments focus on three areas: expanding access to more **telehealth services** and more **telehealth providers**, changes to **remote patient monitoring** services, and telehealth in **federally qualified health centers and rural health clinics**.

Additionally, we are pleased that telehealth is further integrated into reporting and beneficiary assignment requirements in the Quality Payment Program. Telehealth will be particularly effective in value-based care arrangements as it can produce better outcomes at lower costs. While this rule focuses on fee-for-service Medicare, the ATA looks forward to continuing to work with CMS on transforming our system from one that rewards volume to one that rewards value, and we believe telehealth is an integral part of that effort.

Medicare Telehealth Services

Proposed permanent coverage of additional Category 1 codes

In this rule, CMS proposes to add nine codes that were temporarily covered during the COVID-19 PHE to the telehealth services list on a permanent basis (GPC1X,



90853, 96121, 99XXX, 99483, 99334, 99335, 99347, and 99348). The ATA supports adding these codes for group psychotherapy, neurobehavioral status exam, and evaluation and management (E/M). As CMS notes, home visits are allowed for patients with a substance use disorder or a co-occurring mental health condition under Social Security Act Section 1834(m) as amended by the SUPPORT for Patients and Communities Act. The ATA supports the addition of home and domiciliary visits for patients with substance use disorder or a co-occurring mental health condition as Category 1 services.

Additionally, the ATA recommends the following codes be added to Category 1. Please see our February 10, 2020 Telehealth Review Process submission for more detail:

- Inpatient hospital care services (99221-99223);
- Observation admission services (99218-99220); and
- Same day inpatient/observation admission and discharge services (99234-99236).

Creation of Category 3 codes

CMS recognizes that the timing of its normal review process for adding codes to the telehealth services list may not align with the end of the PHE. Therefore, to fully assess codes that were temporarily added during the PHE without interrupting coverage, CMS proposes to create a third category of temporary coverage while the review process is underway. The ATA believes CMS is exercising its authority in a practical way to ensure the safety and clinical effectiveness of coverage of specific services while not arbitrarily limiting care due to unfounded concerns. The ATA supports the creation of Category 3 and the inclusion of domiciliary, rest home, or custodial care services for established patients (99336, 99337), home visits for established patients (99349, 99350), emergency department visits (99281-99283), nursing facilities discharge day management (99315, 99316), and psychological and neuropsychological testing (96130-96133) on that list. The ATA recommends that the COVID-related flexibilities for Category 3 codes should remain in place until the end of the calendar year *following* the year in which the PHE ends. This should be done in order to give added certainty to patients and providers.

CMS also requests comments on additional services that were temporarily added to the list during the PHE and whether they should be a part of Category 3. The ATA supports adding the codes CMS is considering to Category 3, aside from the abovementioned codes that should be added to Category 1. This includes:

- Higher level emergency department visits (99284-99285)
- Hospital, Intensive Care Unit, Emergency care, Observation stays (99217, 99224-99226, 99484-99485, 99468-99472, 99475-99476, and 99477- 99480)
- Radiation treatment management services (77427)
- End-stage renal disease (ESRD) services (99052-99053, 90959, 90962)



- Psychological and Neuropsychological Testing (96136-96139)
- Physical and occupational therapy services (92521-92524, 97161-97168, 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761)
- Initial and final observation and discharge day management visits (99234-99236, 99238, 99239)
- Inpatient neonatal and pediatric critical care (99468, 99469, 99471-99473, 99475)
- Initial and continuing intensive care services (99477-99480)
- Critical care services (99291, 99292)
- Therapeutic activities to improve functional performance (97530)
- Orthotic and Prosthetic Management (97763)

Audio-only

During the COVID-19 PHE, CMS recognized the need to perform E/M services remotely, including using telephones and cell phones for audio-only services. This is particularly important in rural and underserved areas that do not have access to reliable broadband and for communities that may not have access to smartphones or other video-enabled technology. While some types of services will still be permitted to be done using audio-only, CMS notes in the rule that it does not intend to permanently cover audio-only telephone evaluation and management (E/M) services (99441, 99442, 99443) due to the definition of a telecommunication system as audio and video. CMS seeks comments on whether to expand upon the existing virtual check-in code (G2012) that can be done audio-only.

The ATA supports reimbursement of audio-only services when clinically appropriate, which would include expanding beyond the G2012 code, which is not sufficient to cover all situations in which audio-only is appropriate. We encourage CMS to work with stakeholders to determine which services are clinically appropriate using audio-only modalities long-term. During the COVID-19 pandemic, we encourage CMS to cover audio-only services more widely to ensure patients can maintain critical access to care in a time of social distancing. This should include coverage of telephone E/M services (CPT codes 99441, 99442, 99443) at least until the end of the calendar year *following* the year in which the PHE ends. This should be done in order to give added certainty to patients and providers. Additionally, CMS should consider the adverse impact of only using G2012 for audio-only services on the provision of home health services due to current face-to-face requirements.

Other services outside Section 1834(m)

CMS considers “Medicare telehealth services” to be remote audio/video services subject to the restrictions in Section 1834(m) of the Social Security Act. In recent years, CMS has expanded access to other telehealth services (services using communications technology) that are not considered “Medicare telehealth” under the definition and therefore not subject to the 1834(m) restrictions. These services include virtual check-ins, e-visits (which can be asynchronous), and remote physiological monitoring (RPM). CMS solicits comments on other



telecommunications-based services that should fall outside of the traditional face-to-face visit defined by 1834(m).

The ATA recommends updating the virtual check-in codes (99421, 99422, 99423) to incorporate interactive time spent by the patient providing the clinical information necessary to appropriately diagnose and treat the patient asynchronously. Currently, the time requirement is isolated to time spent by the provider. To fully account for the complexity of the visit and the quality of care delivered, interactive patient time should be included in the time requirement for these virtual check-in codes.

Additionally, the ATA supports coverage for tele-ICU monitoring. Tele-ICU monitoring supports local staff and allows patients to remain in facilities locally, where their family and support networks are, rather than requiring them to be transferred.

Further, CMS recognizes the new CPT code for diagnostic imaging of the retina using artificial intelligence (AI) technology and proposes to pay for that code as a diagnostic test. The ATA strongly supports CMS's recognition of the value of new modalities of care like AI and including them as covered reimbursable services. The ATA encourages CMS to continue to review and add services in this category.

Treating new patients

During the PHE, CMS approved the use of G2010 for new patients rather than only established patients. We encourage CMS to make this exception permanent. We also encourage CMS to open virtual check-ins to new patients, as well as established patients. Overall, the ATA supports removing restrictions on offering telehealth services to new patients and not just existing patients.

Medicare Telehealth Providers

Supervision requirements

Generally, direct supervision requirements require that the supervising clinician be on site with the billing clinician when the service is provided. During COVID, CMS has allowed virtual direct supervision of incident-to and diagnostic services to be done via telehealth. Under the proposed rule, this change would be in effect through the end of 2021, or the end of the PHE, whichever is later. While physician supervision requirements have traditionally been a barrier to the delivery of telehealth services, this new CMS definition of direct supervision opens up more opportunities for telehealth. The ATA supports the ability of supervision to be done remotely using telehealth when the supervising provider does not clinically need to be available in person. ATA recognizes this definition may not be clinically appropriate in complex or high-risk procedures and thus should only be applicable when clinically appropriate. The ATA encourages CMS to make this change permanent beyond the PHE.

Inpatient and Nursing Facility Settings

CMS requires that patients in inpatient residential settings and skilled nursing facilities (SNFs) receive periodic visits by a physician or other practitioner. The initial visit is



required to be in person and subsequent visits can only be done over telehealth once every 3 days in inpatient settings and once every 30 days in SNFs. CMS is proposing to revise the frequency limit and allow these visits to occur via telehealth once every 3 days in SNFs. The ATA supports this proposal as telehealth is a very effective way to maintain continued contact with a health care provider for patients in residential settings. The ATA generally supports removing categorical limitations that restrict a provider's ability to reach patients through telehealth.

PT/OT/ST and other providers

Section 1834(m) of the Social Security Act restricts the type of providers who are allowed to bill Medicare telehealth services to physicians and other practitioners, defined as physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists, certified registered nurse anesthetists (cRNAs), certified nurse-midwives, clinical social workers (CSWs), clinical psychologists, and registered dietitians/nutrition professionals. The ATA supports Congress acting to give CMS further authority to expand access to other Medicare providers not on that list, including physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs). There is mounting evidence and demonstrated need that these services can be done remotely, providing clinical utility to the patient, during and beyond the pandemic. The ATA also supports CMS adding PT/OT/ST service codes to the telehealth list in the case that Congress acts and/or those providers are able to provide these services under supervision or incident to a physician.

CMS does have authority to determine which providers are appropriate to deliver services outside of 1834(m), including for communication-based technology services (CBTS). During the PHE, CMS specifically allowed CBTS to be billed by licensed CSWs, clinical psychologists, PTs, OTs, and SLPs. In this rule, CMS proposes to finalize this policy to allow these providers to bill CBTS services within their scope of practice. The ATA strongly supports this proposal. We also recommend that CMS clarify in final rulemaking that facility-based outpatient therapy providers, who have been identified as eligible to furnish and bill these CBTS the PHE, also are recognized as eligible to furnish and bill these codes on a permanent basis.

Medicare Diabetes Prevention Program

The Medicare Diabetes Prevention Program expanded model (MDPP) is a clinical intervention of intensive group-based training sessions around healthy diet, weight control, and physical activity. During the COVID-19 PHE, CMS is temporarily allowing the delivery of MDPP sessions virtually. CMS is not proposing to allow this permanently. The ATA strongly recommends that CMS allow MDPP sessions to be delivered virtually in order to increase access to an important service proven to reduce risk of developing diabetes. CMS should also allow CDC-recognized diabetes prevention program suppliers to provide virtual services for beneficiaries during the pandemic and beyond.



Remote Patient Monitoring

In this proposed rule, CMS seeks to clarify and answer questions about remote physiologic monitoring, or remote patient monitoring, or RPM, codes for which it has created payment in recent years. The ATA appreciates CMS addressing stakeholder questions, but some of the clarifications provided in this rule are inconsistent with stakeholders' previous understanding of the codes and would greatly disrupt current clinical practice and operations. The ATA provides comments here to improve clarity around RPM codes.

CMS also further solidifies the agency's view that RPM is appropriate for both chronic *and* acute conditions. The ATA strongly supports payment for RPM as a digital health service for both chronic and acute conditions, in addition to pre- and post-op monitoring, and appreciates the opportunity to continue a dialogue with CMS to refine these new codes to ensure they adequately reflect operations for the variety of use cases for which RPM is clinically beneficial.

Codes used to describe RPM services

In this rule, CMS clarifies a vision for the process of RPM. As CMS explains it, first, the RPM service is initiated and the patient is trained to use the device (billed with code 99453) and the patient is monitored for the first 30 days, including programming the device to do so (99454). After the first 30-day collection period, the clinician spends 40 minutes reviewing the data collected each 30-day period (99091). Last, the clinician or clinical staff develops a treatment plan informed by the data and spends at least 20 minutes talking to the patient about it (99457 and 99458). The process CMS newly describes in this rule is not aligned with best practices currently used when providing RPM services. This also creates confusion as 99091 is not supposed to be billed concurrently with 99457 or 99458.

The review of the data and the development of a treatment plan informed by the data are not two clinically distinct services – and should likely occur within the same month. The codes 99457 and 99458 should be sufficient to cover both the review of the data and the development and continual monitoring of a treatment plan each calendar month. This is further supported by the fact that the review of data and treatment planning will often occur at the same time, but that 99091 and 99457/99458 are not supposed to be billed concurrently.

Thus, the time associated with 99457 (20 minutes) should describe the time it takes to perform all of those activities, including any necessary communication with the patient. In this rule, CMS proposes that at least a 20-minute synchronous video conversation would need to occur to bill 99457. This is not consistent with clinical need nor is it consistent with the way the code is valued. Instead, the code should reflect the time it takes for the clinician or clinical staff to review the data and adjust the care plan, including discussing that with the patient. In the rule, CMS asserts that the conversation with the patient should occur via synchronous video technology. There is clinical utility in care planning occurring over other synchronous platforms,



such as secure live SMS texting. If a synchronous video visit with the patient is warranted, the clinician should bill a telehealth visit code, not 99457.

Using 99091 for the review of data would further be problematic as it cannot be done “incident to the general supervision”, which severely limits its utility. The ATA strongly supports team-based care, including for remote monitoring, and recognizes the value of non-physician providers (such as nurses) for providing such care.

Finally, the ATA recommends that the time period for both 99453/4 and 99457/8 should be consistent. Currently, the former is 30 days and the latter is a calendar month. These should align to fit clinical practice. CMS should clarify that co-pays are waived for RPM for any condition throughout this PHE and that CMS will urge Congress to permanently waive the co-pay requirement for RPM services.

To summarize, the ATA recommends clarifying that 99457 and 99458 can be billed for the time spent during the calendar month both reviewing the data and communicating with the patient about the data, short of an actual patient visit.

Data collection over a 30-day period (16 day requirement)

CMS outlines that according to the CPT guidebook for the codes initiating RPM (99453 and 99454), the order for RPM should include monitoring for at least 16 days in a 30-day period. During the COVID-19 PHE CMS decreased that requirement to 2 days in order to increase access to services. In this rule, CMS states that post-PHE, the requirement will revert to 16 days of data collection over a 30-day period. However, CMS requests comments on clinical scenarios that would warrant a different number of days monitored.

The ATA describes below a number of different clinical scenarios for which 16 days of monitoring data is not the appropriate amount. Rather than keep an arbitrary day requirement for billing RPM services or have multiple codes with multiple different day requirements, the ATA recommends that the requirement be consistent with the actual physician or clinical staff order for that patient. This ensures that the days of data collection over a 30-day period is clinically appropriate.

Some clinical scenarios where RPM is beneficial, but 16 days of monitoring is not the appropriate number in a 30-day period:

- As CMS recognizes, 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 biometric monitoring to prevent 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 appropriate 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.

As care environments become increasingly virtual, it will be necessary for the RPM reimbursement structure to be nimble enough to reflect the full range of clinical needs that can be served by technology.

Multiple devices for multiple conditions

In the rule, CMS newly clarifies that 99453 is to be billed once per patient per episode of care and 99454 is not to be billed more than once per patient during a 30-day period even when multiple devices are supplied to a patient. This could be severely limiting for patients with multiple chronic conditions that may require different devices for monitoring different physiological functions or conditions warranting multiple devices for optimal monitoring, such as for acute conditions that benefit from multiple biometric readings to track and measure recovery. For example:

- A patient with Type 2 diabetes may need a glucometer and a weight scale;
- A patient with chronic obstructive pulmonary disease (COPD) may need an inhaler sensor, and a pulse oximeter;
- A patient with chronic kidney disease may need a blood pressure cuff and a weight scale; and
- A patient undergoing cardiac rehab may need a blood pressure cuff, an EKG, and a pulse oximeter.

The ATA recommends that CMS clarify that the codes can only be billed once per device, but that additional codes can be billed for monitoring for additional clinically appropriate devices by the same provider or by other providers. It would be particularly infeasible for multiple providers to know what other providers are billing and to determine which provider gets to bill the clinically necessary device in a month when a patient needs multiple devices.

FDA definition of device

CMS clarifies in this rule that the device associated with RPM must be a device that meets the FDA's definition of a medical device, but that the device does not necessarily have to be registered or cleared by the FDA in order to qualify for use with RPM (e.g., if the RPM device is exempt from such registration or clearance). The FDA's definition of medical device is not limited only to hardware; it does include



software as Software as a Medical Device apps fall within the definition of medical device. The ATA supports this standard as it allows software and other technology to be eligible for RPM. The ATA encourages CMS to further clarify that devices whose FDA product code has been formally placed under enforcement discretion should also satisfy the requirements to be a device associated with RPM services.

We also encourage CMS to further explore the clinical utility of reimbursement for monitoring patients remotely through the regular collection and evaluation of Patient-Generated Health Data (PGHD), inclusive of patient-reported information. One way to do this would be to create a new virtual check-in code that supports the collection and evaluation of PGHD.

Beneficiary consent by auxiliary personnel or clinical staff

During the COVID-19 PHE, CMS has allowed beneficiary consent to be obtained not just by the billing clinician, but by auxiliary staff. In this rule, CMS proposes to make this change permanent. The ATA supports the permanent ability of auxiliary personnel or clinical staff to obtain beneficiary consent.

Treating new patients

During the COVID-19 PHE, CMS has allowed RPM services to be delivered to both established patients and new patients. CMS proposes to revert to only allowing RPM to be delivered to established patients after the PHE. The ATA agrees that a provider-patient relationship is necessary to deliver RPM services. However, all states allow a provider-patient relationship to be established virtually. Therefore, it should be appropriate for a clinician to establish a relationship with the patient in a prior new E/M visit, that could be done virtually. To date, CMS has not published guidance on physicians using telehealth (i.e., real-time interactive audio-video technology) to conduct a new patient E/M service via telehealth in connection with enrolling a beneficiary in an RPM program. However, we do know that, for Medicare telehealth services, CMS allows the use of real-time interactive audio-video technology to satisfy the face-to-face element of an E/M service. The ATA recommends that CMS clarify that it is necessary to establish a provider-patient relationship (as defined by state law), but that the relationship can be established with a new virtual E/M visit associated with the initiation of RPM services. CMS should make clear that no prior in-person examination is required, consistent with state law.

Temporary COVID flexibilities

The ATA recommends that the COVID-related flexibilities for RPM should remain in place until the end of the calendar year *following* the year in which the PHE ends. This should be done in order to give added certainty to patients and providers.

Telehealth in Federally Qualified Health Centers and Rural Health Clinics

Federally qualified health centers (FQHCs) and rural health clinics (RHCs) are not listed in statute as telehealth providers for Medicare telehealth services under section 1834(m). During the pandemic, Congress directed CMS to create a temporary



payment system for FQHCs and RHCs to act as distant sites for providing telehealth services. The ATA supports permanently including FQHCs and RHCS as distant sites for telehealth services and ensuring they are adequately reimbursed for those services. The ATA is working with Congress to add FQHCs and RHCs to statute and to ensure a fair permanent payment system, which is not currently reflected by the temporary payment created for the pandemic.

Additionally, FQHCs and RHCs should be reimbursed for providing RPM services. The all-inclusive rate for FQHCs and RHCs, when initially defined by CMS, did not foresee the increased use of RPM and how it would become a method of clinician-patient interaction separate and distinct from the traditional face-to-face visit. The ATA recommends CMS review the FQHC and RHC billing practices to allow RPM as separate and distinct patient interactions and establish the same billing codes for RPM services, regardless of the traditional bricks-and-mortar care delivery location.

Lastly, the ATA similarly supports the ability of home health agencies to provide and be adequately reimbursed for telehealth services and RPM services.

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, Director, Public Policy at kzebley@americantelemed.org.

Kind regards,

A handwritten signature in black ink, appearing to read "Ann Mond Johnson", followed by a period.

Ann Mond Johnson
CEO
American Telemedicine Association