October 2, 2020

Submitted electronically via: https://www.regulations.gov

Seema Verma Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule

Dear Administrator Verma:

The American Society of Echocardiography (ASE) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services’ (CMS) proposed rule (CMS-1734-P), published on August 17, 2020 in the Federal Register, regarding the proposed policy revisions to the CY 2021 Medicare Physician Fee Schedule (PFS). ASE is an organization of over 17,000 professionals committed to excellence in cardiovascular ultrasound and its application to patient care. ASE members include physicians, cardiac sonographers and other professionals dedicated to providing high-quality cardiovascular ultrasound services in both hospital and non-hospital settings.

There are several provisions in the proposed rule that adversely impact practicing echocardiographers and the Medicare beneficiaries they treat. Additional comments will be subsequently submitted in a separate letter on the Quality Payment Program provisions within the proposed rule.

In this letter, we offer comments on the following provisions:

• 2021 Proposed Conversion Factor
Telehealth and Other Services Involving Communications Technology

Requests to Add Services to the Medicare Telehealth Services List for CY 2021

Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List

Comment Solicitation on Continuation of Payment for Audio-only Visits

Comment Solicitation on Coding and Payment for Virtual Services

Comment Solicitation on Requirements of Scope of Service / In-State Licensure

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Transitional Care Management (TCM) Services

Comment Solicitation on the Definition of HCPCS code GPC1X

Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)

Valuation of Specific Codes

- Transthoracic Echocardiography (93306)

**2021 Proposed Conversion Factor**

ASE urges CMS to waive budget neutrality rules for the purpose of applying the proposed conversion factor for calendar year (CY) 2021. The proposed CY 2021 Medicare PFS conversion factor is $32.26, which represents an almost 11 percent reduction from the CY 2020 conversion factor of $36.09. The drastic 11 percent reduction in the Medicare conversion factor is necessitated by proposed additional spending of $10.2 billion, due, in part, to changes to the evaluation and management (E/M) services and related codes. Implementation of these long-overdue increases for E/M payments as well as CPT code and guideline refinements to reduce documentation burden was supported by specialty societies across the House of Medicine, including echocardiography, as we need to improve care coordination and cognitive care services for Medicare beneficiaries. We believe they should be implemented on January 1, 2021 as CMS previously finalized.

However, the proposed CY 2021 conversion factor will be lower than every annual conversion factor since 1994. What’s more, the physician fee schedule updates for years 2020 through 2025 will be zero (0) percent. Clearly, this is an egregious and unsustainable policy change for Medicare Part B providers. We request that CMS utilize its authority and flexibilities under the public health emergency (PHE) declaration to implement these changes in office visits and waive the requirement to adjust Medicare physician payments for budget neutrality. CMS must explore all regulatory avenues to waive budget neutrality rules due these changes, including working with Congress to prevent drastic cuts from occurring while physicians are still trying to recover and regain their financial footing from the effects of the COVID pandemic.

Cardiology practices are slowly re-opening and engaging patients to return for much needed care that was put on hold due to the current PHE. Practices were forced to shut down as most states enacted a temporary ban on elective surgery from March through May 2020 and also outpatient procedures such as transthoracic echocardiograms were postponed, leading to delays in much needed care. Patients had delayed management in heart failure, coronary artery disease, arrhythmias and treatment of important lifesaving chemotherapy with potential cardiotoxic effects. Now, at a time when most states have lifted restrictions and practices are safely resuming over-due care, CMS’ proposed CY 2021 conversion factor will result in devastating consequences to practices and ultimately patient care. **CMS must use any regulatory authority the agency has to prevent these looming Medicare cuts in CY 2021.**
**Telehealth and Other Services Involving Communications Technology**

We appreciate CMS’ willingness to engage in a discussion regarding telehealth and communications technology employed. During the PHE we learned it is often challenging to establish a synchronous telemedicine connection defined as "live, two-way audiovisual link between a patient and a care provider" with patients. We acknowledge that certain circumstances necessitate an in-person interaction to determine the current health status of the patient; however, for established patients, clinical decision-making and care planning is well-informed based on the existing relationship and information documented in the medical record; therefore, telephone E/M should continue to be an available and fully reimbursed option for those patients who need it. **ASE encourages CMS to make permanent the communication flexibilities put into place during the PHE, in particular, allowing coverage and reimbursement for audio-only E/M for Medicare beneficiaries.**

**Requests to Add Services to the Medicare Telehealth Services List for CY 2021**

We thank CMS for adding to the Medicare telehealth services list on an interim basis for the duration of the PHE the services listed in Table 8, including GPC1X and 99XXX, as being sufficiently similar to services currently on the Medicare telehealth services list to be added on a Category 1 basis for CY 2021.

We appreciate that in the 2020 Medicare PFS final rule CMS removed the references to specific specialties in the code descriptor for GPC1X to allow any specialty that performs the service to report the code. However, we noticed a difference in the code descriptor that was finalized in the 2020 Medicare PFS final rule and the descriptor that appears in Table 8 of the 2021 Medicare PFS proposed rule. During a call with the AMA and other specialty societies on August 29, 2020, CMS officials were asked about the difference and confirmed that the language that was finalized in the 2020 Medicare PFS final rule is correct. **We ask CMS to clarify the specific language of the GCP1X descriptor in the 2021 Medicare PFS final rule.**

Descriptor in Table 8 of the 2021 Medicare PFS proposed rule:

GPC1X - Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)

Descriptor in the 2020 Medicare PFS final rule:

GPC1X – Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex chronic conditions (Add-on code, list separately in addition to office/outpatient evaluation and management visit new or established)

**Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List**

We thank CMS for adding a broad range of services to the Medicare telehealth services list in response to the PHE for the COVID-19 pandemic, including telephone E/M codes 99441-99443. We agree that CMS should not jeopardize beneficiary access to added services that have been clinically beneficial.
We agree with CMS that it would be disruptive to both clinical practice and beneficiary access to abruptly eliminate Medicare payment for telehealth services as soon as the PHE ends without first providing an opportunity to use information developed during the PHE to support requests for permanent changes to the Medicare telehealth services list.

We agree with CMS’ proposal to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis that would include services that were added during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria. We also agree that services added under the proposed Category 3 should remain on the Medicare telehealth services list through the calendar year in which the PHE ends.

When assessing whether there was a potential likelihood of clinical benefit for a service such that it should be added to the Medicare telehealth services list on a Category 3 basis, CMS proposes to consider the following factors:

- Whether, outside of the circumstances of the PHE, there are increased concerns for patient safety if the service is furnished as a telehealth service.
- Whether, outside of the circumstances of the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.
- Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

We disagree with the third factor in that, as it is currently worded, it explicitly excludes telephone E/M. Telephone E/M has been a vital lifeline allowing Medicare beneficiaries access to needed E/M services while allowing them to stay safe at home during the PHE. We urge CMS to consider removing the requirement for the use of two-way, audio/video telecommunications technology so that telephone E/M can continue to be provided to Medicare beneficiaries through the calendar year in which the PHE ends.

We urge CMS to use its authority to add telephone E/M codes 99441-99443 to Category 3 for coverage and payment through the year in which the PHE ends. CMS recognized in the 2021 Medicare PFS proposed rule “that the need for audio-only interaction could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor’s office.” Adding the telephone E/M codes to Category 3 would allow Medicare beneficiaries to continue to safely access needed health care. Telephone E/M services have been a lifeline for Medicare beneficiaries, many of whom do not have access to smart phones or internet for real-time video E/M visits, are not comfortable using the technology or do not have reliable internet or cell phone service.

During the COVID-19 pandemic, studies have been conducted that affirm the widespread reports from physicians that many Medicare beneficiaries have difficulty with video visits and report satisfaction with the quality of E/M services provided via telephone.
A narrative review on "Telemedicine, the Current COVID-19 Pandemic, and the Future,"\textsuperscript{1} in \textit{Family Medicine and Community Health} describes how telemedicine may also facilitate access to care, especially among rural and underserved populations, and reduce healthcare costs by decreasing emergency room visits and hospital admissions among patients with chronic illnesses. \textit{The study finds that having more frequent communication with a patient who has a chronic condition can help them avoid readmissions to the hospital and emergency department, lowering the overall cost of chronic disease management.}

The study, Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic\textsuperscript{2}, published in the \textit{Journal of the American Medical Association} describes a crosssectional study of community-dwelling adults (N = 4525) using 2018 data from the National Health and Aging Trends Study, which is nationally representative of Medicare beneficiaries aged 65 or older, to assess the prevalence of telemedicine unreadiness. \textit{The study estimates that 13 million older adults may have trouble accessing telemedical services; a disproportionate number of those may be among the already disadvantaged. Its conclusion was telephone visits may improve access for the estimated 6.3 million older adults who are inexperienced with technology or have visual impairment.}

\textbf{Comment Solicitation on Continuation of Payment for Audio-only Visits}

We thank CMS for recognizing early in the COVID-19 pandemic the essential nature of telephone E/M to a sizable portion of Medicare beneficiaries who lack access to the technology necessary to conduct video E/M visits, lack the required broadband or cellular phone network or do not feel comfortable using video visit technology. The March 31, 2020 COVID-19 interim final rule with comment period (IFC) in which CMS established separate payment for audio-only telephone (85 FR 19264 through 19266) allowed practitioners to treat over the telephone Medicare beneficiaries who otherwise would have had to risk their health by coming for an in-person E/M visit or who would have skipped a needed E/M entirely were it not for CMS' wise decision to cover and reimburse telephone E/M codes 99441-99443.

\textit{Again, we urge CMS to consider removing the requirement for the use of two-way, audio/video telecommunications technology so telephone E/M can continue to be provided to Medicare beneficiaries through the calendar year in which the PHE ends and use its authority to add telephone E/M codes 99441-99443 to Category 3 for coverage and payment through the year in which the PHE ends.}

We agree with CMS that in the context of the PHE and with the goal of reducing exposure risks associated with the COVID-19 pandemic, especially in cases where Medicare beneficiaries are unable or unwilling to use two-way, audio and video technology, that there are circumstances where prolonged, audio-only communication between the practitioner and the patient can be clinically appropriate.


However, the need for appropriate coverage and reimbursement of telephone E/M will not end on the date the PHE is declared over. Access to telephone E/M will continue to be necessary at least through the year in which the PHE is declared to be over.

While CPT codes 99441-99443 were valued by the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) in 2007, the value established by the RUC at that time represents a much different service than that which has been provided during the COVID-19 pandemic. It is unfair to reimburse telephone E/M at the rates established 13 years ago when the service provided was much different than today. The American College of Physicians (ACP) has proposed updated CPT guidelines and codes for telephone E/M services for consideration at the October 2020 CPT Editorial Panel meeting. Therefore, we urge CMS to continue to cover and reimburse telephone E/M codes 99441-99443 at the rate established in the March 31, 2020 COVID-19 IFC (99441, 0.48 wRVU; 99442, 0.97 wRVU; 99443, 1.50 wRVU) until these codes are updated by CPT and valued by the RUC, reviewed by CMS and published in a Medicare PFS proposed rule for public comment.

We strongly disagree with CMS’ proposal to develop coding and payment for a virtual check-in code with a longer unit of time and higher value than the current value of HCPCS code G2012. In its “Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2019” fact sheet released November 1, 2018, CMS describes virtual check-in as a “brief communication technology-based service when the patient checks in with the practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed.” Virtual check-ins of any duration are completely different from audio-only (telephone) E/M. Telephone E/M is not just a longer virtual check-in service; it is an E/M service.

In addition, there is no difference between telephone and video E/M in terms of physician time, intensity and work involved. All components are performed during both video and telephone E/M. In 2021, CPT is transitioning to basing E/M code selection on medical decision making (MDM) or time. MDM is performed for E/M provided via telephone the same as via video visits. Therefore, as the work, time and intensity of video E/M is the same for telephone E/M, we urge CMS not to reduce the current telephone reimbursement rates.

The ACP’s CPT proposal for consideration at the October 2021 CPT Editorial Panel meeting describes E/M provided via the telephone and will be valued by the RUC including physician work and practice expense. Therefore, we urge CMS not to create new HCPCS codes for virtual visits. Instead, we urge CMS to continue to cover and reimburse telephone E/M at current rates (99441, 0.48 wRVU; 99442, 0.97 wRVU; 99443, 1.50 wRVU) until these codes are valued by the RUC, reviewed by CMS and published in a Medicare PFS proposed rule for public comment.

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Comment Solicitation on Requirements of Scope of Service / In-State Licensure

We acknowledge and thank CMS for addressing the challenges of delivering quality care to beneficiaries during the COVID-19 pandemic. Clinicians have been able to respond quickly to provide necessary services to patients who have not been permitted or able to travel to in-person appointments because of the flexibilities implemented regarding in-state licensure for telehealth services. Beneficiaries have been able to access echocardiographers to provide consultations and care to patients across longer distances, opening their practices to patients across state lines who may have limited access to care. For example; patients with congenital heart disease and infants and children with cardiac disease may not have a specialist locally who are able to properly interpret and make diagnoses based on an echocardiogram. This flexibility has been critical in addressing the ongoing need for care.

This is a flexibility – allowing physicians who are appropriately licensed in a state, to provide care to beneficiaries no matter the residence or physical location of said beneficiary – is an area in which ASE would like to collaborate with CMS. While this would enable scaling of best practice, we believe a proper implementation could be achieved through accreditation for laboratories performing echocardiography services and resulting in highly qualified/credentialed physician at the accredited facility interpreting the service.

This process sets in place guardrails to ensure all echocardiography services performed meet specific regulations and standards. The Intersocietal Accreditation Commission – Echocardiography (formerly ICAEL) ensures that the laboratory’s quality assurance policies and procedures are in place on both sides of the service and that physicians and sonographers are adequately trained and maintain continuing education.

Ensuring a high level of quality in echocardiography is a primary goal of the ASE. Our society wants to safeguard that those performing echocardiography services provide high-quality care with images actionable for patient management. Accreditation will also assist in decreasing variations in the ways different staff members and departments care for patients. Further, it would put a process in place for services performed across state-lines to ensure laboratory performing the service and the physician delivering the interpretation provide beneficiaries with consistent, quality care throughout the diagnostic and therapeutic continuum. We encourage CMS to use its authority to implement a mandatory accreditation policy that will permit accredited laboratories to share echocardiography images with accredited laboratories across state lines. This will allow appropriate, high-quality care for beneficiaries, no matter physical location.

Transitional Care Management (TCM) Services

In CY 2020, CMS finalized a policy to allow concurrent billing of TCM services with certain services, when reasonable and necessary. For CY2021, CMS proposes to expand that policy and permit additional (not bundled or non-covered) HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM. Our members are encouraged by these additions, in particular Chronic Care Management (CCM) code G2058 as it is crucial that once a patient leaves the facility setting, the specialist and primary care provider both continue to care for the patient and support them as they return home.
The ability to bill CCM and TCM within the same month prevents a disconnect between TCM and CCM care staff and encourages a coordinated hand-off between teams for more connected, focused care. Our societies applaud CMS’ decision to expand the list of additional services permitted to be billed concurrently with TCM. We urge CMS to finalize the policy to permit the new CCM code (G2058) to be billed with TCM (99495-99496) in the same month when reasonable and necessary.

**Comment Solicitation on the Definition of HCPCS code GPC1X**

In the CY 2020 PFS final rule, CMS finalized the HCPCS add-on code GPC1X which describes the “visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex condition.” We thank CMS for listening to our feedback and not restricting billing for GPC1X based on specialty.

In the 2021 Medicare PFS proposed rule, CMS is soliciting public comments regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how they might address those concerns, and how they might refine their utilization assumptions for the code. We urge CMS to provide more transparency about its assumptions regarding frequency of submission and financial impact on specialties. Clear rules must be established for GPC1X or it will be underused by physicians who, fearing audit risks, will be reluctant to use it. Lack of clear rules also raises the risk that providers will be found guilty of fraud when audited. We urge the Agency to publish clear reporting instructions and documentation guidelines to prevent misuse and additional audits.

**Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)**

CMS reviewed its final policy for 2021 regarding the reporting of prolonged office/outpatient E/M visits finalized in the CY 2020 PFS final rule. To report these visits beginning in 2021, CMS finalized CPT code 99XXX (Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services).

In the 2021 Medicare PFS proposed rule, CMS stated it believes that allowing reporting of CPT code 99XXX after the minimum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes would result in double counting time. As a specific example, the time range for CPT code 99215 is 40-54 minutes. If the reporting practitioner spent 55 minutes of time, 14 of those minutes are included in the services described by CPT code 99215. Therefore, CMS believes only 1 minute should be counted towards the additional 15 minutes needed to report CPT code 99XXX and prolonged services should not be reportable as we finalized last year. CMS proposes that when the time of the reporting physician or non-physician practitioner is used to select office/outpatient E/M visit level, CPT code 99XXX could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service.
Tables 22 and 23 from the proposed rule indicated that CMS will not allow providers to report 99XXX until they have exceeded a level 5 office/outpatient E/M visit by the entire 15 minutes. This seems to contradict CPT’s guidance for time-based codes which considers a unit of time to be attained when the midpoint is passed (e.g., a code requiring 15 minutes can be reported when 8 minutes or more have passed). If one applies CPT rules, providers should be able to report 99XXX after 82 minutes have passed for 99205 and 62 minutes for 99215. If CMS finalized its proposal not to allow providers to report 99XXX until the level 5 visits are exceeded by a full 15 minutes, providers will have to follow different rules for Medicare than for commercial payors, which follow CPT rules. Therefore, we urge CMS to align its rules for reporting 99XXX with AMA’s rules for CPT to prevent confusion for providers.

Valuation of Specific Codes

Transthoracic Echocardiography (CPT code 93306)

Our societies thank CMS for proposing to accept the RUC recommendations for valuation of CPT code 93306. We also would like to address the practice expense input for ultrasound gel. There was a discrepancy in that the PE spreadsheet correctly included 25 ml, while PE SOR incorrectly stated 50 ml. The PE spreadsheet is accurate and therefore we request 25 ml of ultrasound gel be included.

As CMS notes in this proposed rule, these codes were publicly nominated under the mis-valued code initiative in the CY 2019 final rule. These codes were nominated by a national commercial insurer. This commercial insurer directly negotiates reimbursement rates with our members and other specialties on codes pertaining to this request for review. The Medicare PFS has significant influence in these negotiations. Thus, it is a clear conflict for an insurer to use a public nomination process to garner leverage in day-to-day private negotiations. Our societies expressed our profound disappointment that CMS chose to finalize these codes as potentially mis-valued under this review. We urge CMS to evaluate how it considers nominations from conflicted parties as part of this public nomination process.

Our society, along with other specialties who also found their codes nominated, chose to devote significant financial resources and member time to work to address this issue. As noted in the rule, we
conducted a survey for the April 2019 RUC meeting. The 2019 survey results from all surveying specialties largely confirmed the accuracy of the valuation established. It is concerning that CMS’ process does not take into account the source or motive of the nomination. In this instance Anthem, as a payer in both commercial and Medicare Advantage markets, seemed to have multiple conflicts of interest. **We urge CMS to finalize these recommended values and appreciate CMS for recognizing these valuations.**

**Conclusion** We urge CMS to:

- Use its authority and flexibilities under the COVID-19 PHE declaration to waive the requirement to adjust Medicare physician payments for budget neutrality while still implementing the RVU increases to the E/M codes and to explore all avenues, including working with Congress, to prevent drastic cuts from occurring while physicians are still trying to recover and regain their financial footing from the effects of the COVID pandemic.
- Remove the requirement for the use of two-way, audio/video telecommunications technology so that telephone E/M can continue to be provided to Medicare beneficiaries through the calendar year in which the PHE ends and use its authority to add telephone E/M codes 99441/99443 to Category 3 for coverage and payment through the year in which the PHE ends.
- Implement an accreditation program for echocardiography services to ensure high quality patient care and promote quality echocardiographic diagnostic evaluations.
- Continue to cover and reimburse telephone E/M at current rates (99441, 0.48 wRVU; 99442, 0.97 wRVU; 99443, 1.50 wRVU) until these codes are valued by the RUC, reviewed by CMS and published in a Medicare PFS proposed rule for public comment instead of creating new HCPCS codes for virtual visits.
- Finalize its policy to permit the new CCM code (G2058) to be billed with TCM (99495-99496) in the same month when reasonable and necessary.
- Publish clear reporting instructions and documentation guidelines for GPC1X to prevent misuse and additional audits.
- Evaluate how CMS considers nominations for potentially mis-valued codes from conflicted parties as part of its public nomination process.
- Finalize its proposed values for CPT code 93306.

The ASE appreciates the opportunity to provide comments on the CY 2021 Medicare PFS proposed rule. If we may provide any additional information, please contact Irene Butler at (919) 297-7162 or ibutler@asecho.org.

Sincerely,

Judy Hung, MD, FASE
President
American Society of Echocardiography