



September 9, 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 College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) appreciate 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). Together, our three societies represent virtually all practicing gastroenterologists who provide preventive, consultative and therapeutic care for the U.S. population.

There are several provisions in the proposed rule that adversely impact Medicare beneficiaries and the practicing gastroenterologists who treat them. Additional comments from our organizations 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
- Equipment Recommendations for Scope Systems
- Technical Expert Panel Related to Practice Expense
- 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
- 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
 - Esophagogastroduodenoscopy (EGD) with Biopsy (CPT code 43239)
 - Colonoscopy (CPT code 45385)
 - X-Ray Bile Ducts (CPT codes 74300, 74328, 74329, and 74330)

A summary of our recommendations can be found on page 11.

2021 Proposed Conversion Factor

Our societies urge 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 gastroenterology, 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 0 percent. Clearly, this is an egregious and unsustainable policy change for Medicare Part B providers. **We request 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 gain their financial footing from the effects of the pandemic.**

Gastroenterology practices are slowly re-opening and treating more patients after many states and Medicare placed a moratorium on elective endoscopy procedures earlier this year. GI practices were forced to shut down as most states enacted a temporary ban on elective surgery from March through May 2020, leading to delays in needed care. Now, at a time when most states have lifted restrictions on elective surgery and practices are safely resuming over-due care, CMS' proposed CY 2021 conversion factor will result in devastating consequences to these very GI services and patient care. For example, a recent [study](#) found that a drop in cancer diagnoses was attributed to COVID-19 and the delay in screening, including colorectal cancer screening. Another [study](#) found that screenings for breast, cervical and, colon cancer dropped by an estimated 90 percent after the declaration of the COVID-19 PHE. While the number of cancer

screenings has recently begun to rise, [a follow-up study](#) demonstrates that the expected levels of screenings are still down by a third. **CMS must use any regulatory authority the agency has to prevent these looming Medicare cuts in CY 2021.**

Equipment Recommendations for Scope Systems

We thank CMS for updating the prices of the scope video system (ES031) and Gomco (EQ235) to reflect the invoices our societies provided. We agree with CMS' proposed pricing of \$70,673.38 for ES031 and \$3,195.85 for EQ235. We support CMS' proposed transition in price increase for both pieces of equipment over the remaining two years of the pricing update, consistent with CMS' market-based supply and equipment pricing transition program. We also agree with CMS' proposal not to include an additional \$1,000 to cover the expense of miscellaneous small equipment, as the products listed on the component invoices indicated that cost of cables was already included in updated equipment pricing.

We believe it is important that CMS base its pricing for supplies and equipment on the current, real costs that physician practices and facilities incur, and we are happy to work with CMS in the future to continue to supply invoices for GI supplies and equipment.

Technical Expert Panel Related to Practice Expense

We appreciate CMS' interest in holding a Town Hall meeting to provide an open forum for discussion with stakeholders on CMS' ongoing research to potentially update the practice expense (PE) methodology and the underlying inputs. We also applaud CMS for seeking to make refinements based on current actual costs to improve payment accuracy. We urge CMS to consider practice type (e.g., small and medium physician practices, independent ASCs) as a factor in determining practice expense pricing, taking into consideration that not all entities benefit from the price discounts that large institutions are able to negotiate. We support CMS' decision not to make any proposals at this time but to continue to seek feedback from all interested parties.

As CMS seeks to improve the underlying inputs for practice expense, we urge CMS to reevaluate the formula for equipment utilization. Under current rules, CMS calculates equipment utilization at the rate at 50 percent for the majority of equipment. However, we believe CMS should allow for additional flexibility to use a lower utilization rate for equipment that is used in low-volume procedures. For example, CPT code 91200 for liver elastography includes equipment code ER101 (Fibrosan with printer) which has an "Equipment in use in office" time of 12 minutes. The procedure was performed approximately 50,000 times in the Medicare population in 2019. Using Medicare's standard 50 percent utilization rate, a practice would need to do more than 50 procedures a week to meet the utilization threshold, which is far above the number actually performed. Equipment code ER101 costs \$148,080.15, which using the 50 percent utilization calculation results in gross underpayment for the technical component of CPT code 91200. We believe CMS should investigate lowering the utilization rate for low volume codes to better reflect practice expense. We look forward to participating in the future Town Hall meeting, and we urge CMS to add equipment utilization to the discussion.

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. **Our societies encourage 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 GPC1X 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 anecdotal 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 recent study, Positive Early Patient and Clinician Experience with Telemedicine in an Academic Gastroenterology Practice during the COVID-19 Pandemic¹, published in *Gastroenterology* describes a ‘real-world’ experience of patient- and clinician-rated acceptability of telephone and video outpatient visits during the initial four weeks of the emergency COVID-19 response at a large, diverse gastroenterology (GI/hepatology) practice in an academic health system. During the study period, a total of 1,718 patients had GI/hepatology visits; 104 (6%) were in person and 1614 (94%) were via telemedicine. Mean patient age was 60 (SD=16); 59% were female, 20% were Black, 64% White, and 16% Other/Unknown. In this early period, 27% of visits were conducted via video and 72% via telephone. In week 1, 7% of telemedicine visits were via video; this increased to 47% by week 4. After adjusting for study week and demographics, Black race (OR 2.6, 95% CI 1.6-4.2) and age 60+ (OR 1.9, 95% 1.4-2.7),

¹ Serper M, Nunes F, Ahmad N, Roberts D, Metz DC, Mehta SJ, Positive Early Patient and Clinician Experience with Telemedicine in an Academic Gastroenterology Practice during the COVID-19 Pandemic, *Gastroenterology* (2020), doi: <https://doi.org/10.1053/j.gastro.2020.06.034>.

were independently associated with having telephone versus video visits. There were notable racial and age differences in online portal use; 87% portal use among Whites versus 39% of Blacks; 77% among age <60 versus 48% among age 60+; P<.0001. A conclusion of the study was that practices should continue work to mitigate disparities in access to technology and low digital literacy. *The study highlights the importance of continued access to telephone E/M for patients age 60+ and Black patients who, according to the study, were less likely to be able to use video visit technology. It is important to maintain access to telephone E/M for these populations; failure to do so will further increase the racial disparities we have seen regarding both COVID-19 and colorectal cancer screening and uptake.*

The study, Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic², published in the *Journal of the American Medical Association* describes a cross-sectional 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. *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.*

A narrative review on "Telemedicine, the Current COVID-19 Pandemic, and the Future,"³ in *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. *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.*

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.

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.

² Lam K, Lu AD, Shi Y, Covinsky KE. Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic. *JAMA Intern Med*. Published online August 03, 2020. doi:10.1001/jamainternmed.2020.2671

³ Kichloo A, Albosta M, Dettloff K, et al. Telemedicine, the current COVID-19 pandemic and the future: a narrative review and perspectives moving forward in the USA. *Fam Med Community Health*. 2020;8(3):e000530. doi:10.1136/fmch-2020-000530

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"⁴ 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.**

CMS indicated concern that the practice expense of telephone visits is different from E/M visits. However, we do not believe there is a difference in practice expense between telephone and video E/M visits. Staff must still interface with patients prior to the telephone or video visit and must perform additional activities, such as preparing patients for the call or video and reviewing medication, etc. Neither video E/M visits nor telephone E/M visits require physical supplies (e.g., exam table paper), yet CMS is not proposing to reduce payment for video visits. Due to necessary patient interface prior to video and telephone E/M, we believe telephone and video visits take significantly more staff time than in-person E/M visits. Telephone E/M visits have an added advantage of avoiding issues associated with connectivity issues and internet throttling.

⁴ <https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year>

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.**

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.

TABLE 22: Proposed Prolonged Office/Outpatient E/M Visit Reporting - New Patient

CPT Code(s)	Total Time Required for Reporting*
99205	60-74 minutes
99205 x 1 and 99XXX x 1	89-103 minutes
99205 x 1 and 99XXX x 2	104-118 minutes
99205 x 1 and 99XXX x 3 or more for each additional 15 minutes.	119 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

TABLE 23: Proposed Prolonged Office/Outpatient E/M Visit Reporting – Established Patient

CPT Code(s)	Total Time Required for Reporting*
99215	40-54 minutes
99215 x 1 and 99XXX x 1	69-83 minutes
99215 x 1 and 99XXX x 2	84- 98 minutes
99215 x 1 and 99XXX x 3 or more for each additional 15 minutes.	99 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

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

Esophagogastroduodenoscopy (EGD) with Biopsy (CPT code 43239) and Colonoscopy (CPT code 45385)

Our societies thank CMS for proposing to maintain the current valuation for CPT codes 43239 and 45385, as recommended by the RUC. **We urge CMS to maintain valuations for codes 43239 and 45385 in the final rule.**

As CMS notes in this proposed rule, these codes were publicly nominated under the misvalued 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 misvalued under this review. **We urge CMS to evaluate how it considers nominations from conflicted parties as part of this public nomination process.**

Our societies chose to devote significant financial resources and member time to work with CMS and in recognition of this public nomination process. As noted in the rule, we conducted a survey for the April 2019 RUC meeting. The 2019 survey results confirmed the surveys our societies recently presented to the RUC and CMS during revaluation of CPT code 43239 for CY 2014, as well as the during the revaluation of CPT code 45385 finalized in CY 2016. In the 2014 revaluation of CPT code 43239, CMS finalized work RVUs that were *less than* the RUC's recommended work RVUs. In the 2016 revaluation of CPT code 45385, CMS finalized the RUC recommended work RVUs. It is concerning that CMS' process does not take into account the source or motive of the nomination or whether or not there have been any advances in technology or change in technique that would have resulted in a potential difference in procedure performance time since its last valuation.

Our societies agree with the April 2019 RUC recommendations that valuations for these two codes have not changed since each code was last reviewed. CMS has accepted and applied the incremental methodology for the physician work of biopsy and snare for all GI endoscopy families. **As there has been no change in the physician work of performing biopsies or snares, the established RVU increments for these procedures remain accurate. Thus, we urge CMS to finalize these recommended values and appreciate CMS for recognizing these valuations remain unchanged.**

X-Ray Bile Ducts (CPT codes 74300, 74328, 74329, and 74330)

CPT codes 74300 (*Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation*) and 74328 (*Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*) were identified on a CMS/Other screen for codes with 2017 Medicare utilization over 30,000. The code family was expanded to include CPT codes 74329 (*Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*) and 74330 (*Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*). The ACG, AGA and ASGE surveyed codes 74328, 74329 and 74330 with the American College of Radiology and we offer comments on these three CPT codes.

Our societies thank CMS for proposing to accept the RUC recommendation for CPT code 74328 at 0.47 RVUs.

CMS disagrees with the RUC-recommended 0.50 RVU for CPT code 74329 and proposes 0.47 RVU based on a crosswalk to CPT code 74328. CMS states that "the work involved in the biliary ductal and pancreatic ductal systems is similar." However, the survey participants indicated that the work associated with assessing the pancreatic ductal system (74329) is more intense than the biliary system (74328). We recognize that these differences are small, but they reflect

differing intensity between procedures that are correctly reflected by a difference in RVUs. Codes in the Medicare PFS with identical times are not assigned the same RVUs because both the RUC and CMS recognize that procedures with the same times do not have fixed intensities. We urge CMS to reject its proposal to ignore valid survey data by assigning codes 74328 and 74329 the same RVUs for the sole reason that they have the same intra-service time. **We ask CMS to respect the clinical experience and recommendations of the surveyed physicians when they indicate work differences for these codes and accept 0.50 RVUs for code 74329.**

CMS disagrees with the RUC-recommended 0.70 RVU for CPT code 74330 and proposes 0.56 RVU using a time ratio methodology applied to CPT code 74328. We fundamentally disagree with using time ratios for code valuation in lieu of survey data as we did previously when CMS proposed in the 2014 Medicare PFS final rule to follow a time ratio methodology where 1 work RVU equaled 10 minutes of intra-service time to apply to certain GI codes. Ultimately, CMS agreed with our societies and correctly rejected the 1:10 time ratio methodology. Our societies continue to believe it is inappropriate to create a methodology that establishes intensity for a specific unit of time as this is counter to the relative value methodology. We urge CMS to respect the experience of the surveyed physicians and reliability of simultaneously conducted surveys when those same physicians are indicating the increased intensity required to perform an evaluation of both the biliary and pancreatic ductal systems. **For these reasons, ask CMS to accept the RUC recommended value for 74330.**

Conclusion

We urge CMS to:

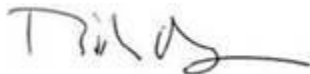
- Use its authority and flexibilities under the COVID-19 PHE declaration to waive the requirement to adjust Medicare physician payments for budget neutrality while still implementing the RVU increases to the E/M codes and to explore all avenues, including working with Congress, to prevent drastic cuts from occurring while physicians are still trying to recover and gain their financial footing from the effects of the 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.
- 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 misvalued codes from conflicted parties as part of its public nomination process.
- Finalize its proposed values for CPT codes 43239 and 45385.
- Accept the RUC recommendations for x-ray bile duct codes 74328-74330.

The ACG, AGA and ASGE appreciate the opportunity to provide comments on the CY 2021 Medicare PFS proposed rule. If we may provide any additional information, please contact Brad Conway, ACG, at 301-263-9000 or bconway@gi.org; Kathleen Teixeira, AGA, at 240-482-3222 or kteixeira@gastro.org; or Lakitia Mayo, ASGE, at 630-570-5641 or lmayo@asge.org.

Sincerely,



Mark B. Pochapin, MD, FACG
President
American College of Gastroenterology



Bishr Omary, MD, PhD, AGAF.
President
American Gastroenterological Association



Klaus Mergener, MD, PhD, MBA, FASGE
President
American Society for Gastrointestinal Endoscopy