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September 22, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; 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; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (CMS-1734-P)

Dear Administrator Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2021 Medicare Physician Fee Schedule proposed rule (CMS-1734-P) published in the *Federal Register* on August 17, 2020.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large portion of our members' performance and reimbursement is measured and paid for under the provisions contained in this rule, the College has a vested interest in CMS' Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP).With our 100-year history in developing policy recommendations to optimize the delivery of surgical services, lower costs, improve program integrity, and make the U.S. healthcare system more effective and accessible, we believe that we can offer

insight to the Agency's proposed modifications to the PFS and QPP. Our comments below are presented in the order in which they appear in the rule.

Please note that this letter, dated September 22, 2020, includes the ACS' feedback specifically regarding revisions to Medicare payment policies, but does not constitute the entirety of our comments to the CY 2021 PFS proposed rule. We will submit a separate letter addressing updates to the QPP and other quality-related provisions.

PROVISIONS OF THE PROPOSED RULE FOR PFS

Determination of Practice Expense (PE) Relative Value Units (RVUs)

Indirect PE Per Hour (PE/HR) Data

CMS solicits comments regarding the most accurate specialty crosswalk to use for indirect PE for home prothrombin time/international normalized ratio (PT/INR) monitoring services. Specifically, the Agency seeks information on any additional costs associated with these services that are not reflected in the currently assigned PE/HR for independent diagnostic testing facilities (IDTFs), as well as which specialties would best capture these costs through the use of a crosswalk.

In 2008, the Agency established three Healthcare Common Procedure Coding System (HCPCS) Level II codes related to home INR monitoring services: one for education, one for provision of the supplies and equipment, and one for management of the patient. The applicable codes are listed in the table below.

HCPCS Code	Code Descriptor
G0248	Demonstration, prior to initiation of home INR monitoring, for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient's ability to perform testing and report results
G0249	Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes: provision of materials for use in the home and reporting of test results to physician; testing not occurring more frequently than once a week; testing materials, billing units of service include 4 tests

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G0250	Physician review, interpretation, and patient management of home INR testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include 4 tests

The ACS has numerous concerns about the labor, supplies, equipment and utilization associated with home INR monitoring services, which directly relate to the PE details—including any potential PE/HR crosswalks—for codes G0248, G0249, and G0250. Specifically, our concerns include the following:

- **Labor**—HCPCS code G0248 (*Demonstrate use of home INR monitor)* includes 75 minutes of registered nurse (RN) time for the purposes of teaching patients about the use and care of the INR monitor. However, many home monitoring services indicate that a "certified trainer" visits the patient's home to train them on how to use the PT/INR equipment.[1,2,3] **We question why the typical clinical staff type for this service is an RN when 95 percent of Medicare claims for code G0248 indicate that the service is instead furnished by the IDTF provider specialty.**

  We also question the clinical staff labor associated with HCPCS code G0249 (*Provide INR test material/equipment*), which currently includes 32 minutes of electrodiagnostic technologist time for the provision of INR test materials and equipment, and also for reporting INR test results to the physician. **We do not believe that an electrodiagnostic technologist is the appropriate clinical staff type for code G0249, as these technologists furnish cardiac event monitoring (CEM)-related services, not INR monitoring services.**

- **Supplies**—HCPCS code G0248 may be billed only once, as it refers to initial patient training for home INR testing monitor use. This service includes testing supplies for demonstration, batteries, and a patient education booklet. **We believe that a patient education booklet is likely a duplicative supply item, as the patient is expected to have already received booklet(s) related**

[1] Acelis Connected Health. (2020). *Alere home INR monitoring patient training.* Retrieved from http://www.alerecoag.com/ww/index/home-inr-monitoring/patient-training.html
[2] mdINR. (2020). *Test your blood anticoagulation level in your own home*. Retrieved from https://www.mdinr.com/PT-INR-Home-Testing-Patients
[3] Roche Diagnostics. (2020). *Self-testing: Five easy steps*. Retrieved from https://diagnostics.roche.com/us/en/coaguchek-home/CoaguChek-testing-for-me.html

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to anticoagulation at previous physician visits, and a free booklet is also supplied with INR meters.

HCPCS code G0249 may be reported just once per month. The descriptor for this code states that testing should not occur "more frequently than once a week" and that the "billing units of service include four tests." However, the supply details for G0249 indicate that six, rather than four, lancets, test strips and alcohol swabs are provided. **We question the discrepancy between the *description and billing rules* for this code, which state that four tests are performed, and the *supply details* for this code, which include supplies for six tests.**

- **Equipment**—HCPCS code G0249 includes 4,315 minutes for home INR monitor (EQ031) equipment item, which is currently priced at $1,317.50. This equipment time was assigned by CMS using a formula that amortized a $2,000 INR meter over its 4-year life.[4] **Given the assigned cost of EQ031 will be $976 for CY 2021 and $635 for CY 2022, we believe that CMS needs to decrease the minutes assigned to EQ031.**

- **Utilization**—HCPCS code G0249 had a 2019 Medicare utilization of more than 1.2 million claims. However, Medicare utilization for G0250 (*Physician INR test review, interpretation, and management)* was only 185,069—just 15 percent of G0249—in 2019. **This significant difference between the number of claims billed for the provision and review of home INR tests would indicate that physicians need to review such test data *less than twice per year*. We question whether this frequency of physician review meets Medicare medical necessity criteria for all patients receiving such services.**

- **PE/HR Rate for IDTFs**—Currently, IDTFs have the highest total PE/HR rate of all specialties at $961.34; radiation oncology has the second highest total PE/HR rate at $291.30, which is $670.04 less than that of IDTFs. Prior to CY 2010, CMS primarily used specialty data obtained from the American Medical Association (AMA) Socioeconomic Monitoring System (SMS) to develop PE/HR rates. However, the PE/HR rate for IDTFs was established in 2007 using "supplemental survey data" instead of the AMA SMS. In the CY 2008 PFS final rule, the Agency noted that, unlike most physicians' services, *remote CEM services* are furnished primarily by specialized IDTFs that, due

[4] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 42 C.F.R. § 410 (2008).

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to the nature of CEM, must operate on a 24/7 basis.[5] At that time, specialty societies and suppliers provided a rationale for additional direct PE inputs to account for items such as telephone fees for transtelephonic electrocardiographic transmission and internet access fees for the online storage and sharing of clinical information.

Given the significant changes to technology and associated decrease in costs since the IDTF PE/HR value was first developed, we believe that many of the indirect PE inputs originally recognized for IDTFs in 2007 no longer apply in 2020, nor should costs for CEM services be crosswalked to that for INR monitoring services, which do not appear to operate as a 24/7 service (i.e., the service includes just four tests per month).

As described above, we believe that codes G0248, G0249, and G0250 include inaccurate clinical staff and supply item inputs, and the PE/HR rate assigned to IDTFs in 2007 may not appropriately reflect the intensity, complexity, and providers of these specific INR services in current practice. **Instead of crosswalking IDTFs to another specialty type for the purposes of validating indirect PE assignments for home INR monitoring services, we urge CMS to consider adding new specialty assignments for cloud-based remote monitoring that include updated information about the cost of such services.**

Changes to Direct PE Inputs for Specific Services

Equipment Recommendations for Scope Systems

While CMS did not receive further recommendations from the AMA RVS Update Committee (RUC) Scope Equipment Reorganization Workgroup following the publication of the CY 2020 PFS final rule, it did receive 37 invoices associated with the pricing of the scope video system (ES031) equipment item as part of the review of the esophagogastroduodenoscopy (EGD) with biopsy and the colonoscopy code families. Based on these invoices, the Agency proposes to update the price of the ES031 scope video system equipment to $70,673.38. **We thank CMS for reviewing the invoices submitted and support the Agency's ES031 price update to correctly account for the cost of the various components included in this scope video system.**

Update on Technical Expert Panel Related to Practice Expense

[5] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 42 C.F.R. § 410 (2008).

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CMS notes that a technical expert panel (TEP) established by the RAND Corporation is currently studying potential improvements to the Agency's PE allocation methodology and underlying data. Based on the results of RAND and the TEP's ongoing research, CMS solicits comments on potentially refining the PE methodology and updating the clinical labor data used for direct PE inputs based on current salaries and compensation for the health care workforce.

The Agency began incorporating Bureau of Labor Statistics (BLS) median pay data when PE code-level details were updated in the early 2000s. The BLS data set has proven to be valid and timely, and therefore is a reliable source of information even if the wages for the same clinical staff type may vary across different specialty practices (for example, RN wages in a pediatric surgeon's office versus a pediatric neurologist's office versus a general pediatrician's office). Having an open source of data is essential to assure the accuracy of payment for PE at the code level. However, past work products and the underlying methodologies used by RAND and other CMS contractors to review PE have been opaque and inconsistent. **Therefore, we believe that the BLS remains the best and most transparent data source that is readily available for updating clinical labor information.**

CMS also seeks feedback on RAND's *Practice Expense Methodology and Data Collection Research and Analysis—Interim Phase II Report,* both as part and/or outside of the public comment process to the CY 2021 PFS proposed rule.[6] **The ACS is encouraged that CMS is engaging stakeholders on this issue, and is reviewing the novel approach for potentially updating the PE methodology described in the lengthy RAND report.** We will submit feedback on the RAND report to CMS via email per the Agency's instructions in this proposed rule.

Potentially Misvalued Services under the PFS

CY 2021 Identification and Review of Potentially Misvalued Services

Public Nominations

CMS received stakeholder requests to consider CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*) for nomination as potentially misvalued. After consideration of the

[6] Burgette, L., Cohen, C., Hero, J., et al. (2020*). Practice expense methodology and data collection research and analyses: Interim phase II report* (RR-3248-CMS). RAND Corporation. Retrieved from https://www.rand.org/pubs/research_reports/RR3248.html

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information provided, the Agency proposes to nominate code 22867 as potentially misvalued.

CPT code 22867 was reviewed twice by the RUC, and both reviews produced the same outcomes for time, visits and value. **We do not believe that the nominating stakeholders' statement that the RUC recommendation "acknowledged that CPT 22867 is more intense and complex than reference code 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment*), especially with respect to technical skill required" is accurate.** The RUC recommendation rationale makes no mention of code 63047, and the total work for code 63047 is greater than code 22867 for several reasons: 1) code 63047, which is typically an inpatient service, involves more postoperative work; 2) both codes have the same intraoperative time, however, some portion of the time for code 22867 accounts for less intense imaging services and device sizing than that of code 63047; and 3) the decompression performed for code 22867 is much less extensive when compared with the decompression for code 63047. **We do, however, agree that code 22867 is misvalued, but only because CMS did not accept the RUC's recommendation. We oppose the re-surveying of code 22867, and request that the Agency establish a work RVU of 15.00 for code 22867 based on the original RUC recommendation submitted in 2016.**

We also wish to highlight that, while the Agency only nominated one code as potentially misvalued for CY 2021, there are 22 files on its website in an addendum to the CY 2021 PFS proposed rule titled "NPRM Potentially Misvalued Code Nominations." CMS did not address the other codes in these files or describe how such codes were determined to not be potentially misvalued in this rule. The ACS reviewed several letters in the "NPRM Potentially Misvalued Code Nominations" addendum submitted by stakeholders requesting office pricing for CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*). **Based on these letters, which indicate that this procedure is safely performed 32 percent of the time in a physician office, we agree with stakeholders that code 49436 should be priced for the office setting. For this purpose, the ACS requests CMS add code 49436 to the list of potentially misvalued services for review by the RUC.**

Telehealth and Other Services Involving Communications Technology

Under its current policy, CMS adds services to the Medicare telehealth services

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list on a Category 1 basis when it determines that they are similar to services on the existing Medicare telehealth services list for the roles of, and interactions among, the beneficiary, provider at the distant site and, if necessary, the telepresenter. The Agency asserts the Category 1 criteria streamlines its review process for publicly requested services that fall into this category and expedites its ability to identify codes for the Medicare telehealth services list. For CY 2021, CMS proposes to add 9 services to the Medicare telehealth services list on a Category 1 basis.

The ACS wishes to highlight that CMS' process for adding services to the Medicare telehealth list merely indicates that a given face-to-face code can be furnished and paid for using audio/video communications technology. **When making these additions, the Agency does not address the inherent differences in the provision of an in-person versus telehealth service, such as physician work, clinical staff time, and supplies and equipment—these same differences may also vary across various telehealth services and the platforms used to furnish them.** We question if CMS believes, for example, that the cost of providing a service is the same when rendered by (1) an internet-based provider group with no brick-and-mortar office presence; (2) a physician who has integrated a telehealth platform into their office's workflow and electronic systems; and (3) a physician who furnishes the service face-to-face with the patient. We are concerned that the budgetary impact on the Medicare program would be substantial if CMS proceeded to adopt a policy of paying for such different services at the same rate, despite significant variation in practice expense and other related costs.

To account for these differences, we urge CMS to create new, corresponding telehealth codes for each face-to-face code added to the Medicare telehealth list that reflect the applicable underlying service and include the appropriate inputs needed to provide the service specifically via a telehealth platform. The Agency should collaborate with the CPT Editorial Panel and the RUC to develop such codes and related guidelines for proper billing and documentation.

Comment Solicitation on Continuation of Payment for Audio-Only Visits

Through a series of interim final rules making various regulatory revisions to the Medicare program in response to the COVID-19 public health emergency (PHE), CMS established separate payment for audio-only telephone evaluation and

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management (E/M) services.[7,8] Although these services were previously considered non-covered under the PFS, CMS noted that, in the context of the PHE and especially in the case that two-way, audio/video technology is not available to furnish a telehealth service, there are circumstances where prolonged, audio-only communication between a practitioner and patient could be clinically appropriate. The applicable telephone E/M codes are listed in the table below.

CPT Code	Code Descriptor
99441	Telephone E/M service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion
99442	Telephone E/M service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion
99443	Telephone E/M service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion

For these services, CMS initially finalized on an interim basis the 2007 RUC-recommended work RVUs of 0.25 for CPT code 99441, 0.50 for CPT code 99442, and 0.75 for CPT code 99443. However, stakeholders informed the Agency that use of audio-only services was more prevalent than CMS had previously considered when establishing payment rates for such services because many beneficiaries were not utilizing video-enabled communication technology from their homes. Recognizing that there were many cases where practitioners were using audio-only interactions to manage more complex care primarily as a substitute for telehealth visits, CMS stated that the intensity of furnishing an audio-only visit to a beneficiary during the unique circumstances of the COVID-19 pandemic was not accurately captured by its initial valuation of these services.

[7] Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 F.R. 19230 (2020).
[8] Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 F.R. 27550 (2020).

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The Agency therefore finalized on an interim basis during the PHE increased work RVUs for the telephone E/M—0.48 for CPT code 99441, 0.97 for CPT code 99442, and 1.50 for CPT code 99443—based on crosswalks to established patient office/outpatient E/M CPT codes 99212, 99213 and 99214, respectively. The Agency also finalized on an interim basis to crosswalk the PE inputs from codes 99212-99214 to codes 99441-99443.

CMS does not propose to continue to pay for telephone E/M codes 99441, 99442, and 99443 under the PFS after conclusion of the PHE because, outside of the circumstances of the PHE, the Agency is not able to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology. CMS notes, however, that the need for audio-only interaction could remain as beneficiaries continue to try to avoid sources of potential infection, and in such circumstances, a lengthy phone conversation may be needed to determine if an in-person visit is necessary. The Agency solicits comments on whether it should develop coding and payment for a service similar to HCPCS code G2012 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other QHP who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*) but for a longer unit of time and with an accordingly higher value. CMS also seeks input on the appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing these services.

The ACS agrees with stakeholders' feedback to CMS that audio-only services have been broadly used during the PHE as an alternative to telehealth because of various problems associated with video-enabled communication technology experienced not only by patients, but also by physician offices. **As such, we support separate payment for telephone E/Ms as a provisional policy to remain in effect for the duration of the PHE to reduce exposure risks associated with the COVID-19 pandemic. Upon termination of the PHE, we *oppose* continued payment parity between audio-only services and office/outpatient established patient E/Ms.**

However, the ACS recognizes that eliminating coverage for audio-only services may disenfranchise beneficiaries with limited internet connectivity or access to technology with video capabilities, but we remain concerned with the many unresolved issues regarding the proper use of these codes, as well as the resource consumption and labor involved with their use. **Rather than developing a new G-code similar to G2012, we urge CMS to collaborate with the CPT Editorial**

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Panel and the RUC to update *existing* audio-only E/M codes 99441, 99442, and 99443 for future reintegration as covered services in the Medicare program. We believe that reexamination of the nomenclature and values associated with these codes via the CPT/RUC process will restore their relativity within the PFS, ensure their compliance with applicable Medicare statutes, and better reflect current practice and innovation in medicine.

In addition, we ask that CMS develop discrete and concise coding, billing, and documentation criteria substantiating the use of audio-only services in specific clinical scenarios to reduce patient safety risks and maintain program integrity. Evaluation and management that can be accomplished via audio-only interaction should not take more than approximately 30 minutes of medical discussion. Extended telephone E/Ms may imply that the patient has complex or multiple problems, or that the practitioner is experiencing significant difficulty in communicating care instructions to the patient, neither of which can be appropriately managed over a phone call without possible implications for patient safety. **We believe that audio-only E/M services should only be used to address patient problems that are simple or straightforward, and that patients requiring medical decision making at higher levels cannot and should never be evaluated via audio-only medical discussions.**

The ACS is also concerned that, if the temporarily relaxed medical necessity rules for telephone E/Ms are made permanent post-PHE, there will be potential for widespread misuse and abuse of such services under the PFS. We wish to highlight such an opportunity for abuse based on the following clinical vignette for CPT code 99443:

> A new or established patient with special needs calls to discuss onset of new and disturbing symptoms. During a 25-minute phone call, the physician reviews the history and review of systems, the description of symptoms, and current medications. She makes a recommendation to change the present medication regimen, provides reassurance, both of which are recorded in the patient's medical record, and requests follow-up in the office in one week or sooner if needed.

The intent of this telephone E/M visit was to temporarily manage a patient's complaint requiring an in-person follow-up visit, for which the physician will be able to submit two separate claims (i.e., one for the telephone visit, and another for the follow-up visit). If the same interaction occurred in person, it would be reported with one face-to-face office/outpatient E/M code, and only one claim would be submitted; abuse of these services is therefore quite possible. **We urge CMS to consider more stringent rules to limit frequency of reporting and/or**

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reporting with related in-person follow-up visits for telephone E/M codes as a mechanism to address misuse of such services.

Proposed Clarification of Existing PFS Policies for Telehealth Services

While there are no Medicare regulations that explicitly prohibit eligible distant site practitioners from billing for telehealth services provided *incident to* a physician's services, CMS states that its existing definition of direct supervision requires on-site presence of the billing clinician when the service is provided. The Agency notes that this requirement could make it difficult for a billing clinician to provide the direct supervision of services provided via telehealth *incident to* their professional services by auxiliary personnel. CMS asserts that services provided *incident to* the professional services of an eligible distant site practitioner could be reported when they meet direct supervision requirements at both the originating and distant site through the virtual presence of the billing clinician, and therefore proposes that services that may be billed incident-to can be provided via telehealth *incident to* a physicians' service and under the direct supervision of the billing clinician.

Given that telehealth coding is primarily time-based, we ask CMS to specify how time should be counted for virtual physician supervision of an incident-to service. For example, in a scenario where a distant site practitioner (1) engages in a 10 minute audio/video visit with a patient who exhibits an extensive poison ivy rash across their face and extremities, (2) spends 5 minutes initiating contact with the supervising physician, and (3) has a 10 minute virtual conversation with that physician to confirm that an oral steroid prescription is the appropriate course of treatment, we question whether the supervising physician should report 10 minutes to account for time spent with the patient, or if he/she should report 25 minutes to account for time spent with the patient in addition to time spent virtually connecting with and speaking to the distant site practitioner. **We seek clarity from the Agency if reportable time *only* includes time spent on medical discussion and therefore does not include time spent initiating the virtual connection between the supervising physician and distant site practitioner.**

CMS also proposes to clarify that, if audio/video technology is used in furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the service would not be subject to Medicare telehealth requirements and the practitioner should bill for the service as if it were furnished in person**. The ACS agrees with CMS' clarification, but we seek additional information from the Agency regarding the specific "setting" to which this policy would apply.** Specifically, we interpret such "setting" to be the setting in

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which the patient—not the practitioner—is located. Under this interpretation, for example, a physician providing an audio/video E/M service from their office to a patient in an inpatient rehabilitation facility situated within the same medical complex would report such service as an inpatient E/M rather than an office/outpatient E/M. **We ask CMS to confirm if this interpretation is correct.**

Direct Supervision by Interactive Telecommunications Technology

CMS proposes to allow direct supervision to be provided using real-time, interactive audio and video technology through the latter of the end of the calendar year in which the PHE ends or December 31, 2021. This direct supervision requirement could be met by the supervising clinician being immediately available to engage via audio/video technology (excluding audio-only) and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure.

We support direct supervision using interactive telecommunication technology as a provisional policy to remain in effect for the duration of the PHE to reduce exposure risks associated with the COVID-19 pandemic. Upon termination of the PHE, we *oppose* continued use of audio/video technology to provide direct supervision due to issues of patient safety. For instance, in complex, high-risk, surgical, interventional, endoscopic, or anesthesia procedures, a patient's health status can quickly change, and we believe it is necessary for such services to be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation. It may not be possible for a supervising physician to recognize or meet these urgent clinical needs while being present for the service, and potentially other services at the same time, only through audio/video interactive communications technology.

The Agency also seeks comment on whether there should be additional guardrails to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use if this proposal is finalized. **We do not believe CMS should proceed with this policy without first examining the need for and implementing various guardrails to ensure safety and appropriateness. For example, we urge the Agency to limit the number of clinicians a supervising physician may simultaneously engage with—as well as the number of incident-to relationships a supervising physician may be involved in at a given time—via audio/video technology.** Irrespective of the supervision component associated with the provision of an incident-to service, we believe that, in general, the Medicare payment rendered

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for such service should match the allowed reimbursement amount under the PFS for the provider type that furnished the majority of the service billed.

Comment Solicitation on PFS Payment for Specimen Collection for COVID-19 Tests

CMS finalized on an interim basis during the PHE that physicians and non-physician practitioners (NPPs) may use CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician*) to bill for services furnished *incident to* their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID-19 testing if the billing practitioner does not also furnish a higher-level E/M service to the patient on the same day. The Agency solicits feedback on whether to extend or make permanent its policy to allow physicians and NPPs to use code 99211 to bill for services furnished *incident to* their professional services new and established patients when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing.

The ACS does not believe that CMS should continue to allow physicians and NPPs to use code 99211 to bill for COVID-19 testing services furnished *incident to* their professional services, for both new and established patients, after the PHE ends. We are concerned that continued billing for such service post-PHE will result in higher and unnecessary cost-sharing for patients who would be charged for an office/outpatient E/M service during which *only a simple specimen collection and symptom assessment*—which do not constitute the work associated with code 99211—occurs. We also wish to highlight that, if CMS were to make this policy permanent, the Agency would need to modify its existing incident-to regulations in chapter 12 of the Medicare Claims Processing Manual, which state that initial encounters involving a new patient and new problem must include interaction with a physician or qualified healthcare professional (QHP).[9]

Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM)

RPM involves the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition. CMS finalized on an interim basis for the duration of the

[9] Centers for Medicare & Medicaid Services. (2019). Chapter 12—Physicians/nonphysician practitioners, §30.6.1.B: Selection of level of evaluation and management service. *Medicare Claims Processing Manual* (pp. 29-31).

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PHE to allow consent for the provision of RPM services to be obtained at the time services are furnished, and by individuals providing RPM services under contract with the billing physician or practitioner. The Agency seeks comment on whether this consent policy should be made permanent.

We wish to highlight that RPM-related CPT code 99453 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*) includes work for setting up and educating patients on the use of a physiologic monitoring device. The practice expense details for this code do not include actual provision of the device, indicating that "pre-service" ordering and procurement of a device is needed prior to set-up and education. **As such, we question why CMS would not require consent to be obtained during the E/M visit at which time the patient's physician determined a physiologic monitoring device was medically necessary instead of obtaining consent once the device is procured.**

In addition, CMS seeks comment on whether current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients, and asks for information that would help the Agency understand whether it would be beneficial to consider establishing coding and payment rules that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods. Specifically, CMS is interested in whether one or more codes that describe a shorter duration, for example, 8 or more days of remote monitoring within 30 days, might be useful.

The remote monitoring CPT Category I codes were developed based on new technology and included significant review of literature that met specific level-of-evidence standards. While the ACS agrees that short-term monitoring may be sometimes medically necessary and appropriate, we do not believe it is suitable for all patients. For example, we disagree with CMS' assessment that a postoperative patient should be placed on a remote monitoring service that records and stores the patient's temperature for eight days as a means of adequately assessing infection and managing medications or dosage. **We urge CMS to work through the CPT/RUC process to determine specific parameters for the general use of RPM, how long remote monitoring should occur, and which devices are available to accurately obtain data needed to adequately monitor a given condition.** CMS should not establish codes for such monitoring outside of this rigorous process, as development of such codes without input from the CPT Editorial Panel and the RUC may adversely affect patient safety.

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Transitional Care Management (TCM)

TCM services are defined by the following two codes:

- **CPT 99495** (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*);
- **CPT 99496** (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge*)

CMS notes that, when it initially established TCM billing, it also developed a list of 57 HCPCS codes that could not be billed concurrently with TCM due to concerns about duplication and overlap of time and work. In the CY 2020 PFS final rule, the Agency finalized a policy to allow concurrent billing of TCM services, when reasonable and necessary, with 16 actively priced (i.e., not bundled or non-covered) codes during the 30-day period covered by a TCM service. For CY 2021, CMS proposes to allow an additional 15 actively priced HCPCS codes to be billed concurrently with TCM. The Agency asserts that no overlap exists that would warrant preventing concurrent reporting between TCM and these 15 codes, which are listed in the table below.

Code Family	CPT Code	Code Descriptor
End-Stage Renal Disease Services (for ages less than 2 months through 20+ years)	90951	ESRD related services with 4 or more face-to-face visits per month; for patients <2 months of age
	90954	ESRD related services with 4 or more face-to-face visits per month; for patients 2-11 years
	90955	ESRD related services with 2-3 face-to-face visits per month; for patients 2-11 years
	90956	ESRD related services with 1 face-to-face visit per month; for patients 2-11 years
	90957	ESRD related services with 4 or more face-to-face visits per month; for patients 12-19 years
	90958	ESRD related services with 2-3 face-to-face visits per month; for patients 12-19 years

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End-Stage Renal Disease Services (for ages less than 2 months through 20+ years)	90959	ESRD related services with 1 face-to-face visit per month; for patients 12-19 years
	90963	ESRD related services for home dialysis per full month; for patients <2 years of age
	90964	ESRD related services for home dialysis per full month; for patients 2-11 years
	90965	ESRD related services for home dialysis per full month; for patients 12-19 years
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90967	ESRD related services for dialysis less than a full month of service; per day; for patients <2 years of age
	90968	ESRD related services for dialysis less than a full month of service; per day; for patients 2-11 years
	90969	ESRD related services for dialysis less than a full month of service; per day; for patients 12-19 years
Complex Chronic Care Management Services	G2058	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month

The ACS strongly disagrees with CMS' proposal to allow these 15 codes to be billed concurrently with TCM. Although CMS notes that the minutes counted for TCM services cannot also be counted toward other services, the code descriptors and coding guidelines in the CPT codebook do not provide details about the typical TCM times for the physician/QHP and clinical staff and also do not describe the typical work inherent in such codes. For example, the service description for end-stage renal disease (ESRD) code 90966 clearly already includes TCM work:

> "His nephrologist will manage his condition over the entire month by providing the following services: scheduled examinations for management of known and anticipated problems; episodic examinations for intercurrent changes in his general condition **including post-hospitalization;** evaluation of the integrity and functionality of his dialysis access; episodic changes in his dialysis prescription; **scheduled review of routinely collected laboratory data**; episodic administration of IV iron or other medications in the dialysis center; **episodic adjustments of home medications** including antihypertensives and phosphate binders; **establishing and modifying short- and long-term care plans in cooperation with social services, nutritional support services,**

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> **transplantation centers, and other medical specialists; and overall care coordination. The nephrologist will also likely have multiple unscheduled telephone and electronic interventions generated by the dialysis center, an ER, another physician, or by the patient or his caregiver**." [10] (emphasis added)

We do not believe that nephrologists are aware of this service description and therefore would be unaware of what work would overlap with TCM services, resulting in unintentional double billing for work of both the nephrologists and their clinical staff. We also note that nephrology reports 7 to 8 percent of the claims for subsequent inpatient hospital visits which would indicate that the intention of the TCM codes is not applicable, meaning that nephrologists are appropriately following their patients before, during and after a facility stay as medically necessary and reporting E/M services and ESRD services as appropriate. The intent and work of TCM services include overlapping work inherent to ESRD codes:

> "The intent of TCM is to prevent re-hospitalization or emergency department visits. The service requires early and frequent communication with the patient, family, other providers and agencies over the month following hospital discharge to ensure that the discharge summary and appropriate clinical information is obtained quickly and reviewed, **that the patient's medication and therapeutic regimen is reconciled and optimized and that all necessary clinical and community services are coordinated and delivered**. In addition to these non-face-to-face services, each code includes a timely face-to-face visit which typically occurs in the office but can also occur at home or other location where the patient resides. The non-face-to-face services of TCM include **communication with the patient and caregivers, communication with home health agencies**, education to support self-management and activities of daily living, **assessment of medication adherence and management, identification of community resources, facilitating access to care and services needed,** obtaining and reviewing discharge information as available, reviewing need for or follow up on pending diagnostic tests, **interaction with other qualified health care professionals, and the establishment of referrals and arranging for community resources.**" [11] (emphasis added)

[10] American Medical Association. (2019). *RUC 2020 database* [Version 3].
[11] American Medical Association. (2019). *RUC 2020 database* [Version 3].

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We also disagree that chronic care management (CCM) codes should be reportable during the same period as TCM. Two TCM codes were created to specifically address the needs of a patient at moderate and high levels of complexity after discharge from a facility for a period of 30 days. If necessary, the follow-on care management codes would be the matching chronic (moderate intensity) or complex care (high intensity) management codes that continue after the transitional care period. Chronic/complex care management is more extensive than transitional care management, and these services should be mutually exclusive. CMS' indication that these two sets of codes can be reported simultaneously with a simple cautionary statement not to duplicate time is not auditable and is open to fraud and abuse.

In addition, we wish to highlight the disconnect between physician/QHP and clinical staff times associated with TCM codes and related documentation requirements. Specifically, CPT guidance for TCM documentation states:

> "Documentation includes the timing of the initial post discharge communication with the patient or caregivers, date of the face-to-face visit, and the complexity of medical decision making."[12]

Post-discharge communication, face-to-face visit, and complex medical decision making are the ***only three services*** that must be performed and documented for TCM per CPT guidelines—however, code 99495 includes 47 minutes of physician/QHP time and 107 minutes of clinical staff time, and code 99496 includes 60 minutes of physician/QHP time and 145 minutes of clinical staff time. We question if these three services truly require the stated amount of clinical staff time for TCM post-discharge, and also whether the amount of clinical staff time for these TCM codes would be duplicative of the work associated with CCM services. We believe CPT restricted simultaneous billing of TCM and CCM codes precisely because of such potential for overlapping work.[13]

Furthermore, with many physicians now being employed by multispecialty group practices with hospital affiliations, we believe that it is likely that physicians/QHPs within the same practice are reporting both discharge management **and** TCM services, which runs contrary to the intent of the TCM codes. However, determining whether a duplication of services is occurring is often difficult because, although a multispecialty group practice may use the same

[12] American Medical Association. (2020). Transitional care management services. *CPT 2021 Professional Edition* (pp. 67).
[13] American Medical Association. (2020). Transitional care management services. *CPT 2021 Professional Edition* (pp. 67).

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electronic health record (EHR) system, each specialty department may operate under separate Tax Identification Numbers (TINs). For example, an internist in the practice's hospitalist department can share a patient's hospital stay and discharge information with another internist in the practice's family medicine department. In this scenario, the hospitalist may perform and bill for medication reconciliation as part of the patient's discharge management, and the family medicine provider may perform and bill for medication reconciliation as part of that same patient's transitional care management. Because these two departments have different TINs, it would not appear that two clinicians employed by the same practice are each billing for the same type of service for the same patient. As such, the practice would receive reimbursement for duplicative services.

The ACS opposes implementation of CMS' proposed TCM policy changes until reliable data are collected and reviewed to identify any unnecessary and wasteful duplication of services. We believe that the Agency should consider developing reporting guidelines clarifying that care coordination must occur through means other than simply sharing a patient's chart via an EHR, such that the physicians/QHPs responsible for a patient's discharge management and transitional care management specifically indicate which separate and distinct components of these services both clinicians intend to, or already have, provided. **We urge the Agency to establish a mechanism to review reporting patterns to determine how many discharge management, chronic care management, and transitional care management codes are being simultaneously reported by the same physician/QHP—or by multiple physicians/QHPs employed by the same practice—within 30 days of a patient's discharge date.**

Psychiatric Collaborative Care Model (CoCM) Services

CMS previously established HCPCS G-codes used to bill for monthly services furnished using the CoCM, which were later replaced by CPT codes 99492-99494. The Agency notes that it has received requests from stakeholders for additional coding to capture shorter increments of time spent on psychiatric collaborative care services. In response, CMS proposes to establish a new G-code to describe 30 minutes of behavioral health care manager time: GCOL1 (*Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional*). The Agency proposes to price this G-code based on one-half of the work and direct PE inputs for CPT code 99493 (*Subsequent psychiatric collaborative care management, first 60 minutes*).

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The ACS opposes the implementation of GCOL1 for reporting psychiatric CoCM services, and we are disappointed that CMS proposes to create such a code without first obtaining evidence that a shorter-timed code is warranted for this level of service in a recently established care model. The Agency states that the same guidelines that apply to CPT codes 99492-99494 would apply to GCOL1, but we question where such information will be published and made readily available for clinicians, coders, and payors in the absence of a HCPCS Level II codebook that outlines inclusionary and exclusionary instructions for all G-codes. CMS also indicates that the CPT time rules would apply to GCOL1, meaning that this code could be reported for 16 minutes of psychiatric CoCM services in a 30-day period.

We disagree with the assumptions made under CMS' proposal, and believe that:

1) An initial psychiatric CoCM service would never require only 16 minutes of a behavioral health care manager work in a 30-day period; and
2) 16 minutes per month is not sufficient time for the behavioral health care managers as required in CoCM.[14]

In addition, CMS established a G-code, later converted to CPT 99484, to describe general care management services for patients with behavioral health conditions, which incorporates some, but not all, of the principles associated with the CoCM. This service is reported for at least 20 minutes of clinical staff time and, in fact, includes 20 minutes of behavioral health care manager time, and as such, seems to accomplish CMS' goal for creating a reduced services code (i.e., code GCOL1 is unnecessary).

As noted above, CMS would also crosswalk the value for code GCOL1 based on 50 percent of the value for code 99493. However, the RUC survey for code 99493 was flawed. In 2017, the RUC concluded that the number of primary care physicians who responded to the survey was considered too low to be a representative sample, and that the respondents likely estimated the total time spent by all physicians/behavioral health care managers during the course of the month rather than their own individual time. The RUC agreed that the time in the survey was not reliable and recommended that the Agency's assigned times and work values for the original G-code be retained until sufficient experience was obtained to resurvey. Therefore, the proposed crosswalk for GCOL1 to a

[14] Centers for Medicare & Medicaid Services. (2019). *MLN booklet: Behavioral health integration services.* Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/BehavioralHealthIntegration.pdf

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Category I code is simply a crosswalk to a former G-code that was crosswalked by CMS.

The ACS is extremely concerned with the establishment of codes that are crosswalked multiple times to other codes that have not been validated for time and work. **We therefore urge CMS not to implement code GCOL1, and request that the Agency only crosswalk values and times to established and validated codes with sufficient evidence that the work is the same between both services.**

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic

Review of CY 2021 Policies Finalized in CY 2020 Rulemaking

Documentation via Medical Decision Making (MDM) or Time

CMS reviewed the CY 2021 E/M policies that it finalized as part of CY 2020 rulemaking including a policy to adopt new coding, prefatory language, and interpretive guidance framework provided by AMA CPT. CMS also finalized that office/outpatient E/M levels 2-5 would be selected by level of medical decision-making or by time, specifically the "**total time personally spent by the reporting practitioner**" on the day of the visit (including face-to-face and non-face-to-face time).

We strongly agree with CMS' clarification that the total time (including both face-to-face and non-face-to-face) is the total time personally spent by the reporting practitioner for office or other outpatient E/M services. We note that the CPT guidelines and code descriptors are not clear and therefore would be open to interpretation. The CPT guidelines state:

> "When time is used to select the appropriate level for E/M services codes, time is defined by the service descriptions. The E/M services for which these guidelines apply require a face-to-face encounter with the physician or ***other qualified health care professional***."[15] (emphasis added)

And also:

[15] American Medical Association. (2020). Evaluation and management services guidelines: Time. *CPT 2021 Professional Edition* (pp. 7).

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> "Total time on the date of the encounter (office or other outpatient services): For coding purposes, time for these services is the total time on the date of the encounter. It includes both the face-to-face and non-face-to-face time personally spent by the physician ***and/or other qualified health care professional(s)*** on the day of the encounter."[16]
> (emphasis added)

The definition of time has been a point of confusion from the beginning when the guidelines and the codes were finalized by the AMA. Specifically, many providers believed the CPT guidelines to mean that the total time of **both** a physician **and** a QHP could be summed for code selection. This is concerning because some practices use QHPs as clinical staff for various activities. For example, a nurse practitioner (NP) may greet and gown a patient, take vitals, review and document history, systems and medication, position the patient, coordinate home or outpatient care, and/or provide education, prior to and/or after a physician's face-to-face encounter. Each of these activities performed by the NP are already separately included in the practice expense for office/outpatient E/M codes. In addition, the CPT codebook does not include details about the specific activities that are accounted for in the practice expense inputs, and therefore a QHP will not know that time for greeting and gowning a patient and taking vitals, for example, should not be included in total time for selecting the level of the office E/M service.

As such, including NP time and physician time for code selection could represent a duplication of clinical staff services and time (i.e., "double-dipping"). We also know of no other instance where CPT guidelines include the phrase "physician and/or other qualified health care provider," making the use of this phrase an irregularity. **Therefore, we agree with CMS and believe that the most straightforward and auditable method for using time to select the level of an E/M service is to require that the time reflect the total time of the reporting practitioner.**

New Prolonged Visit Codes

CMS adopted the newly established CPT add-on code 99417 for prolonged office/outpatient E/M services:

> **99417** (*Prolonged office or other outpatient evaluation and management*

[16] American Medical Association. (2020). Evaluation and management services guidelines: Time. *CPT 2021 Professional Edition* (pp. 8).

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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 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services))

The Agency states that allowing reporting of code 99417 after the minimum time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time. CMS describes proposed reporting of 99417 in Table 22 of this proposed rule:

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 99417 x 1	89-103 minutes
99205 x 1 and 99417 x 2	104-118 minutes
99205 x 1 and 99417 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.

We strongly agree with CMS that reporting code 99417 after the minimum time of code 99205 or 99215 is met would be double counting of time. Given the value and time associated with code 99417, it is inconceivable that this code should be reported for only 1 minute above the time range of codes 99205 or 99215. **We believe that Table 22 represents correct reporting of 99417 and urge CMS to finalize this proposed reporting requirement.**

E/M Inherent Complexity Add-on Code

CMS finalized the addition of an add-on code GPC1X with the intent to provide payment for 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 condition. The Agency continues to assert that this code is needed because the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of other specialty visits. The code descriptor for this add-on code is as follows:

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> **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 condition. (Add on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*).

CMS seeks input on aspects of the code definition that are unclear, how the Agency might address these concerns, and how CMS could refine its utilization assumptions. CMS provides primary care and specialty care examples of how GPC1X can be used:

- Primary care example: GPC1X could recognize the resources inherent in holistic, patient-centered care that integrates the treatment of illness or injury, management of acute and chronic health conditions, and coordination of specialty care in a collaborative relationship with the clinical care team.

- Specialty care example: GPC1X could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals.

We restate our position that code GPC1X is not a separately identifiable service given the extensive changes to the office/outpatient E/M codes. Under the policies finalized in the CY 2020 PFS rule, this add-on code is no longer justified and therefore not warranted because CMS did not finalize a single payment rate for levels 2 through 5 visits. CMS' justification for the (then two proposed) add-on codes in the CY 2019 PFS was that the blended payment rate would have resulted in decreased payment for certain specialties that typically bill mostly level 4 and 5 visits, and also decreased payment for primary care by not accounting for the type and intensity of primary care visits. Specifically, CMS stated in the CY 2019 PFS final rule that the code was created "to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits."[17]

[17] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019, 83 F.R. 59452 [pp. 59638] (2018).

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That rationale no longer holds true under the finalized policy of retaining the multiple visit levels, as physicians may bill a higher-level E/M code for such visits based on the level of MDM or time.

The revised CPT MDM table and inclusion of physician or QHP face-to-face (FTF) and non-face-to-face (NFTF) time in the revised codes was specifically meant to reflect increased resources for patient encounters that are more complex or time-consuming. **We also note that the AMA and almost all of medical and surgical specialties agreed that GPC1X was not necessary given the ability to upcode based on MDM or time.** This is important because the AMA's CPT/RUC Workgroup on E/M specifically included an add-on code (CPT 99417) to account for more time and resources in response to the earlier CMS proposals.

With respect to the primary care example that CMS provides in this year's proposed rule, CMS still has not provided specific information about the "resources" necessary on the day of the encounter that are inherently different for a primary care physician or QHP that cannot be reported as a higher level of service using MDM or time. Higher code levels reflect greater resource use. What CMS may be describing is an extraordinary circumstance that would and should be reported with the chronic/complex care management codes for longitudinal holistic patient-centered care. If a patient does not rise to the level of needing chronic/complex care management, then the office/outpatient E/M codes should be sufficient to capture the MDM or time associated with the service. An E/M visit involving a patient with a self-limited or minor problem, minimal or no need for data to be reviewed, and/or minimal risk of morbidity does **not** require additional resources to integrate the treatment/management of the illness or injury or to coordinate specialty care in a longitudinal care model. These activities are inherent to medical decision making. This argument also applies to the specialty care example.

Another consideration is that over the past several years, CMS and the AMA CPT Editorial Panel have created numerous new "global" codes for primary care services (e.g., TCM and CCM). These codes were specifically established to report the longitudinal "between visits" work over a 30-day period. Since the inception of these codes and establishment of work RVUs, the Agency has whittled down the list of codes that may not be separately reported, and now allows almost any code to be reported in conjunction with these 30-day global codes. **We contend that these 30-day global codes represent the intent of GPC1X, which is to provide reimbursement for holistic, patient-centered, longitudinal care.**

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The RUC, the CPT Editorial Panel, and the large majority of the medical community has continued to express opposition to the GPC1X add-on code. CMS' refusal to acknowledge these comments appears to be an attempt to shift money to specific specialties. This add-on code, the descriptor, and the resources are not justified and instead duplicate the services described by 30-day global care management codes. **For these reasons, we continue to urge CMS not to implement this flawed and wasteful code.**

Proposals for CY 2021

Time Values for Levels 2-5 Office/Outpatient E/M Visit Codes

In the CY 2020 PFS proposed rule, CMS sought comment on the times associated with the office/outpatient E/M visits as recommended by the RUC. CMS acknowledged a need for clarification given that when surveying these codes for purposes of valuation, the RUC requested that survey respondents consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a timeframe of three days prior to the visit and seven days after, respectively. The resulting analysis and recommendations resulted in two conflicting sets of times: (1) the sum of the component times as surveyed; and (2) the total time as surveyed. CMS states that it believes it would be illogical for component times not to sum to the total. Table 17 from this proposed rule displays the different times. To address the perceived inconsistencies, CMS proposes to adopt the actual total times as the sum of the component times, instead of the RUC-recommended total time.

TABLE 17: RUC-Recommended Pre-, Intra-, Post-Service Times, RUC Recommended Total Times for CPT Codes 99202-99215 and Actual Total Time

HCPCS	Pre-Service Time	Intra-Service Time	Immediate Post-Service Time	Actual Total Time	RUC-Recommended Total Time
99202	2	15	3	**20**	22
99203	5	25	5	**35**	40
99204	10	40	10	**60**	60
99205	14	59	15	**88**	85
99211	--	5	2	**7**	7
99212	2	11	3	**16**	18
99213	5	20	5	**30**	30
99214	7	30	10	**47**	49
99215	10	45	15	**70**	70

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We agree with CMS that the time data submitted by the RUC is conflicting. We also agree that the RUC survey of the E/M codes that included collection of time before and after the day of the encounter is inconsistent with the reporting of these codes for time only on the day of the encounter. We have previously argued that this survey methodology resulted in an overestimation of time and work. **That said, we strongly agree with the Agency that the total time in the CMS work time database should reflect the sum of the pre-, intra-, and post-times collected using the RUC survey. We support use of the actual total time that CMS presents in Table 17.** This methodology is consistent with the total times for all other codes in the PFS.

Revaluing Services that are Analogous to Office/Outpatient E/M Visits

CMS noted in the CY 2020 PFS rule that it believes that there are services other than global surgical codes for which the values are closely tied to the values of the office/outpatient E/M visit codes because, according to the Agency, many services have E/M visits explicitly built into their definition or valuation. CMS reviewed some of these services, and we provide feedback on such review below.

As an overarching comment, all global codes with inherent E/M visits in the global period should be incrementally adjusted when the values and times for E/M services change. This policy should be applied to all global codes, regardless of whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both. Specifically, the review of a global code using magnitude estimation includes an understanding that a certain number and level of E/M visits is inherent. Therefore, the incremental increases maintain relativity between global procedures and discrete E/M services, and also recognize that the compelling evidence for an increase in work to perform an E/M service is the same for codes based on a global period.

End-Stage Renal Disease (ESRD) Monthly Capitation Payment Services

CMS proposes to increase the work, physician time, and PE inputs in the form of clinical staff time for ESRD codes based on the marginal difference between the 2020 and 2021 office/outpatient E/M visit work, physician time, and PE inputs built into such codes. The proposed adjustment can be found in Tables 19 and 20 of this rule. The Agency's rationale is that the monthly bundled payments for ESRD services were constructed using a building block methodology, and the number of office/outpatient E/M visits were component parts of those bundles. CMS also states that the specified number of visits in the code descriptor must be furnished in order to bill for the service.

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The CPT Editorial Panel created the following CPT codes for monthly ESRD-related services:

- **CPT 90951–90962** for monthly ESRD-related services with a specified number of visits;
- **CPT 90963–90966** for monthly ESRD-related services for home dialysis patients; and
- **CPT 90967–90970** for home dialysis patients with less than a full month of services (billed per encounter)

We wish to highlight that not all of the ESRD-related service codes 90951-90962 were based on a building block methodology of discrete E/M services. For example, the value and time for code 90951 is based on a crosswalk using magnitude estimation to code 99295 (*Initial inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or less*)—which was deleted in 2009— because insufficient survey data were obtained. This value was supported by a suggested range of visits (i.e., magnitude estimation), not by the result of a survey determination of number of visits, nor the use of the building block methodology. Similarly, code 90954 (listed on tables 19 and 20) was crosswalked using magnitude estimation to code 99293 (*Initial inpatient neonatal critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age*)—which was deleted in 2009—based on specialty information that a pediatric nephrologist typically attends each dialysis session, and therefore code 99293 would properly reflect the extensive and intensive physician work and further reflect the relativity between codes 90951 and 90954.

For the rest of the ESRD codes, the numbers and levels of visits were not determined as a result of surveys that led to use of the building block methodology; rather, they were negotiated using magnitude estimation in comparison to the above two codes. This is evidenced by the fact that the codes do not include visits in the time/visit data in the CMS database, and instead the values are based on total time. **We support a fair and consistent policy for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies.**

Transitional Care Management (TCM) Services

CMS proposes to increase the work RVUs associated with the TCM codes commensurate with the new valuations for the level 4 (CPT 99214) and the level 5 (CPT 99215) office/outpatient E/M visits for established patients. CMS'

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rationale is that both TCM codes include a required face-to-face E/M visit (either a level 4 or 5 office/outpatient E/M).

TCM services are described by the following two codes:

> **CPT 99495** (*Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*)
>
> **CPT 99496** (*Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge*)

Both codes 99495 and 99496 were valued based on the survey median value using magnitude estimation. Building block methodology was not used for the RUC recommendation for these global codes. Specifically, the RUC compared the survey median work RVU and time for code 99495 to codes 99214, 99215, 99310, and 99204, and agreed that the survey median value—using magnitude estimation—appropriately accounted for the physician work. Similarly, the RUC used magnitude estimation to value code 99496 by comparing the survey median work RVU and time to codes 99215, 99205, 99306, and 90962. **We support a fair and consistent policy for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies.**

Global Services

General

CMS notes that while the RUC recommended values for 10- and 90-day global codes that incorporated the increased values of the office and outpatient E/Ms, it did not make changes to the valuation of the 10- and 90-day global surgical packages to reflect changes made to values for the office/outpatient E/M visit codes while the Agency continues to collect and analyze data on the number and level of office/outpatient E/M visits that are actually being performed as part of these services. **We reiterate that it is inappropriate for CMS to not apply the RUC-recommended changes to global codes starting in CY 2021**. To do otherwise will:

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- ***Disrupt the relativity in the fee schedule***: Applying the RUC-recommended E/M value increases to stand-alone E/Ms, select global codes, and select bundled services—but not to the E/Ms that are included in the global surgical package—will result in the disruption of the existing relativity between codes across the Medicare PFS. Changing the values for some bundled services that include E/M services, but not for others, disrupts this relativity, which was mandated by Congress, established in 1992, and refined over the past 27 years. Indeed, since the inception of the fee schedule, E/M codes have been revalued three times: in 1997 (after the first five-year review), in 2007 (after the third five-year review), and in 2011 (after CMS eliminated consult codes and moved work RVUs into the office visit codes). When the payments for new and established office visits were increased in these instances, CMS also increased the bundled payments for these post-operative visits in the global period. **The Agency should apply a fair and consistent policy for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies.**

- ***Create specialty differentials***: Per Medicare statute, CMS is prohibited from paying physicians differently for the same work, and the "Secretary may not vary the . . . number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."[18] Failing to adjust the global codes is tantamount to paying some doctors less for providing the same E/M services, and thereby in violation of the law. In the CY 2021 PFS proposed rule, CMS points to the method of valuation (i.e., building block versus magnitude estimation) for a rationale as to why some bundled services should be increased in value to reflect the revised office/outpatient E/M values, while global codes should not. However, this statutory prohibition on paying physicians differently for the same work applies regardless of code valuation method. Therefore, the incremental increases should apply to the global codes.

- ***Inappropriately rely on section 523(a) of MACRA***: In the CY 2021 PFS proposed rule, CMS refers to its decision in the CY 2020 PFS final rule to not make changes to the valuation of the 10- and 90-day global surgical packages to reflect the increased values for the office/outpatient E/M visit codes while the Agency continues to collect data on the number and level of post-operative visits included in global codes as required by MACRA. The MACRA data collection requirement, set forth in section 523(a), does not prohibit CMS from applying the RUC-recommended incremental increases to the

[18] The Public Health and Welfare: Payment for Physicians' Services, 42 U.S.C. §1395w-4(c)(6).

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office/outpatient E/Ms codes to global codes. In fact, section 523(a) specifically authorizes CMS to adjust surgical services, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project. In addition, it is inappropriate for CMS to rely on the implementation of MACRA, which became effective in 2015, as a reason to refrain from making necessary updates in 2021. This inaction punishes a subset of physicians who, like all healthcare practitioners, are experiencing the pressures of a global pandemic as well as steadily rising costs of labor and supplies necessary to maintain a viable and safe practice.

- ***Ignore recommendations endorsed by nearly all medical specialties***: The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) in 2019 to recommend that the full incremental increase of work and physician time for office visits be incorporated into the global periods for each CPT code with a global period of 10-day, 90-day, and MMM (maternity). The RUC also recommended that the practice expense inputs should be modified for the office visits within the global periods. In the CY 2021 PFS proposed rule, CMS is using the RUC recommendation as part of the rationale for proposing to increase the values of the maternity services codes and select other bundled services, but then ignores the RUC's advice by not applying the same logic to the global bundled codes.

As we noted earlier under the "Revaluing Services Analogous to Office and Outpatient E/Ms" section of this comment letter, even the primary care global care management code values were based on magnitude estimation. Again, we strongly urge CMS to apply the RUC-recommended changes to the E/M component of the global codes in order to maintain the relativity of the fee schedule. **We support a fair and consistent policy for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies.**

Maternity Care Services

CMS proposes to increase the maternity packages by accepting the RUC recommendations incorporating the revaluation of the office and outpatient E/M codes. CMS provided the following rationale:

- The codes were valued using a building-block methodology as opposed to the magnitude estimation method that is commonly used to value the 10- and 90-day global services and therefore that each visit packaged into the global was explicitly accounted for;

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- CMS believes that the packaged visits are actually furnished because of evidence-based standards and guidelines;
- CMS agreed with the RUC approach for translating the increases in the E/Ms to the maternity care services codes, that is, by adding in the marginal differences in work, physician time, and practice expense in the form of clinical staff time between the current and 2021 E/M values; and
- The change would be in line with the Agency's broader focus on improving maternal health and birth outcomes by supporting risk identification and ensuring appropriate interventions and referrals.

Proper maternity care is important for healthy babies and a healthy society. **We support fair and relative payment for maternity care codes and for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies.**

Assessment and Care Planning for Patients with Cognitive Impairment

CMS proposes to increase the value of CPT code 99483 (*Assessment and care planning for patients with cognitive impairment*), which replaced HCPCS code G0505 in 2018. CMS' rationale for such increase is to maintain payment accuracy, and the Agency states that the valuation of this service reflects the complexity involved in assessment and care planning for patients with cognitive impairment by including resource costs that are greater than the highest-valued office/outpatient E/M visit. However, after the implementation of the new office/outpatient E/M services beginning on January 1, 2021, the work RVU for CPT 99205 would be higher than CPT 99483, which would create a rank order anomaly between these codes.

We do not agree with the Agency's rationale that code 99483 should be increased so that it remains valued higher than code 99205. The method of valuation for 99483 did not include a requirement that it be valued above 99205. By way of background, the work RVU and time for code 99483 is based on survey data and magnitude estimation. The RUC accepted the survey median work and time in comparison to key reference code 99327 (*Domiciliary or rest home visit for the evaluation and management of a new patient*), which had a slightly higher total work RVU and time. As support, the RUC also compared 99483 to 99205 and 99235. The RUC did not use any code as a crosswalk for valuation of 99483, and 99205 is not inherent to this service.

The code descriptor for 99483 states that the MDM is moderate or high complexity, which is the same level of MDM as codes 99204, 99214, 99205, and 99215. Depending on who is performing this service (i.e., a physician or a QHP),

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the patient can be either new or established. Given that a majority of practitioners reporting this service are primary care physicians or QHPs, code 99483 is most often billed for established patients. This code also includes a significant amount of clinical staff time at the level of an RN with physician or QHP time for supervision of activities required to report this service. Lastly, this is a timed code that indicates that 50 minutes are typically spent face-to-face with the patient and/or family or caregiver. Again, no part of the valuation of code 99483 requires that it be valued greater than code 99205, and depending on MDM, the work associated with this service could actually be similar to code 99214.

The increases to the office/outpatient E/M codes were based on an increase in work and an increase in total face-to-face and non-face-to-face time. The CY 2021 intra-service time for code 99205 will be 59 minutes, which exceeds the typical time for code 99483. As such, it is possible that 99483 is in fact appropriately valued relative to 99205 (i.e., the value of 99483 should be lower than 99205) given that there was no corresponding increase in work for 99483. In addition, 99483 could also be compared to 99215 or 99214. Comparison to these codes would not support CMS' rationale for refining code 99483 to exceed the value of 99205. **We do not agree with arbitrarily increasing the work RVUs and times for code 99483 based on information that is both inconsistent with the code descriptor and inconsistent with the original valuation using magnitude estimation. Correct and relative valuation for this service should be referred to the RUC for review.**

Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness Visits (AWV)

CMS proposes to increase the values of G0438, G0439, and G0402. CMS provides the rationale that these codes were valued based on direct crosswalks to the office/outpatient E/M visits of 99204 and 99214, respectively. The descriptors of these codes are as follows:

- **G0438** (*Annual wellness visit; includes a personalized prevention plan of service (pps), initial visit*)
- **G0439** (*Annual wellness visit; includes a personalized prevention plan of service (pps), subsequent visit*)
- **G0402** (*Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment*)

We have significant concerns with the rationale for adjusting these codes based on increases to 99204 and 99214. Although CMS states that codes G0438,

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G0439, and G0402 were based on direct crosswalks to 99204 and 99214, CMS assignment of a crosswalk for these codes has never been validated. First, the annual wellness visit dominant diagnosis code is Z00 (general exam without complaint, suspected or reported diagnosis), which describes a visit that is not meant to address any patient problems, conditions, illnesses or injuries. Second, codes G0438, G0439, and G0402 were identified by the RUC as potentially misvalued in 2016. The primary providers of these services did not express interest in surveying or reviewing these codes because they did not "believe" the codes were overvalued, and because CMS did not identify these codes as misvalued via the Agency's process for identifying misvalued codes. Therefore, the services represented by G0438, G0439, and G0402 have never been vetted through the RUC process to determine if they rise to the level of codes 99204 and 99214, and as such, the CMS-assigned crosswalk has never been validated.

Even if the RUC did survey G0438, G0439, and G0402 and had an opportunity to validate codes 99204 and 99214 as crosswalks, it is unlikely that these crosswalks would have ultimately been recommended by the RUC. The current code descriptor for 99204 states that 45 minutes of face-to-face service was typical, even though the face-to-face time in the CMS database was 30 minutes. The new CY 2021 intra-time for code 99204 is 40 minutes. Given that the typical face-to-face time for G0438 is 30 minutes, this does not reach the time for 99204. In fact, a webpage on the American College of Physician's (ACP) website indicates that additional E/M codes may be reported on the same date as an annual wellness visit (AWV), suggesting that the annual wellness visit does not rise to the level of 99204 or 99214:

> "Medicare will pay a physician for an AWV service ***and*** a medically necessary service, e.g., a mid-level established office visit, Current Procedural Terminology (CPT) code 99213, furnished during a single beneficiary encounter. It is important that the elements of the AWV not be replicated in the medically necessary service. Physicians must append modifier -25 (significant, separately identifiable service) to the medically necessary E/M service, e.g. 99213-25, to be paid for both services. For example, for the patient who comes in for his Annual Wellness Visit and complains of tendonitis would be billed as follows: CPT ICD9, G0438 V70.0, 99212-25 726.90 (tendonitis)." [19] (emphasis added)

[19] American College of Physicians. (2020). *How to bill Medicare's annual wellness visit.* Retrieved from https://www.acponline.org/practice-resources/business-resources/payment/medicare-payment-and-regulations-resources/how-to-bill-medicares-annual-wellness-visit-awv

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We also wish to highlight that the AWV is reported nearly 50 percent of the time with an additional office E/M code.[20] For example, in 2018, code G0438 was reported 23.8 percent of the time with code 99214 and 15.0 percent of the time with code 99213. Similarly, in 2018, code G0439 was reported 26.4 percent of the time with code 99214 and 16.9 percent of the time with code 99213. At a minimum, this indicates a significant duplication of clinical staff time for two E/M services reported by the same provider on the same date.

Another example that the annual wellness visit is not extensive or intense enough to be crosswalked to 99024 and 99214 can be seen on an American Academy of Family Physicians (AAFP) AWV resource webpage, where the AAFP describes the visit as a "focused" physical exam, but not a comprehensive "head-to-toe" physical.[21] This example corresponds to a level 2 office visit under current CPT E/M code descriptors and is clearly not more than level 3 MDM under the revised CY 2021 office/outpatient E/M codes.

Welcome to Medicare Visit*	Annual Wellness Visit (AWV)
Medicare pays 100%. Covered only once in a lifetime; must be provided within the first 12 months of patient's enrollment in Medicare.	Medicare pays 100%. Initial AWV covered 12 months after enrollment in Medicare or 12 months after the Welcome to Medicare visit. Subsequent AWVs may be provided annually.
A **focused physical exam,** review of the patient's health, and development of a plan to keep the patient healthy. **Not a comprehensive, "head- to-toe" physical.**	A **focused physical exam**, review of the patient's health, and development of a plan to keep the patient healthy. **Not a comprehensive, "head-to- toe" physical.**

*Also known as Initial Preventive Physical Examination, or IPPE.

The same AAFP webpage goes on to provide guidance about scheduling, conducting, and billing an annual wellness visit, which further confirms that the IPPE and AWV services include focused exams rather than comprehensive exams.

[20] American Medical Association. (2019). *RUC 2020 database* [Version 3].
[21] Cuenca, A. (2012). Making Medicare wellness visits work in practice. *American Academy of Family Physicians Journal of Family Practice Management, 19*(5). Retrieved from https://www.aafp.org/fpm/2012/0900/fpm20120900p11.pdf

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The Welcome to Medicare visit and annual wellness visit are to review the patient's wellness and develop a plan to keep the patient healthy. They include a focused physical exam – not a comprehensive, "head-to-toe" physical exam.

If the patient has one or two additional medical problems, the physician may choose to treat these at the same time as the wellness visit. This additional service will be billed separately and, therefore, is subject to the Medicare deductible/coinsurance/co-pay.

If the patient has multiple medical conditions that need treatment, we recommend scheduling a regular office visit and explaining that the wellness visit can be scheduled when he or she is feeling better.

If the patient requests a comprehensive physical exam in addition to a wellness visit, two separate appointments may be needed. Schedule the wellness visit and recommend that the patient schedule the comprehensive physical exam (which is not covered by Medicare) after the wellness visit if it still seems necessary.

SAMPLE SCRIPT 1

Patient: "I've heard Medicare is covering physicals." Or "I want to schedule a complete physical exam."

Scheduler: "Are you calling to schedule the new annual wellness visit benefit that is covered by Medicare or are you wanting the Welcome to Medicare visit, which is available to anyone in their first year of Medicare coverage?"

Note: If the patient wants the Welcome to Medicare visit, jump to Script 2.

Patient: "I would like to schedule the annual wellness visit."

Scheduler: "The annual wellness visit is an overview of your health and focuses on developing a plan to keep you healthy. Just so you know, it does not include or replace a complete, 'head-to-toe' physical exam."

Patient: "I understand. I would like to schedule the annual wellness visit. I only have a few minor concerns."
Scheduler: "I'll be happy to schedule your annual wellness visit. Please understand if the doctor addresses your additional medical concerns, that service will be subject to your Medicare deductible or coinsurance."

Note: Schedule the annual wellness visit appointment and recommend the patient read his or her Medicare information about what to expect during the annual wellness visit.

Lastly, we note that "screening" services (e.g., G0101, G0102, G0436, G0444) are to be reported in addition to the annual wellness visit per AAFP instructions. The entire encounter essentially is an example of "component" coding, with the

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actual portion related to the annual wellness visit comprising only a very small component of the visit overall.

Given that the primary providers of an AWV describe the service as a focused exam to be reported with other services, and that the AWV codes have never been reviewed by the RUC, the ACS does not believe that the actual AWV service represents work described by a level 4 office/outpatient E/M code. **As such, we disagree with CMS' proposal to adjust the value and times for these codes in concert with changes to level 4 E/M codes for CY 2021. We urge CMS to consider decreasing the values assigned to these codes.**

Emergency Department Visits

CMS proposes to increase the following emergency department (ED) E/M visit levels as follows:

- Increase CPT 99283 from 1.42 wRVUs to 1.60 wRVUs
- Increase CPT 99284 from 2.60 wRVUs to 2.74 wRVUs
- Increase CPT 99285 from 3.80 wRVUs to 4.00 wRVUs

CMS' rationale is that these increases are necessary to support the historical relationship between the office and outpatient and ED E/M visit code sets, such that ED visit levels 1-3 have had the *same* value as office and outpatient E/M new patient visit levels 1-3, and ED visit levels 4-5 have been valued *higher* than office and outpatient E/M new patient visit levels 4-5. CMS' rationale is also based on the intent of the most recent valuation of these codes, which was conducted because stakeholders expressed concerns that the work RVUs for ED E/M services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus EDs, where these services are furnished.

The ED visit codes no longer share the same guidelines and reporting instructions as the revised office/outpatient E/M codes, which represent a new and different coding paradigm for CY 2021. The AMA CPT/RUC Workgroup on E/M, which drafted the new office/outpatient E/M codes and guidelines, is positioned to move forward to other families of E/M codes, possibly including ED visit codes. In contrast to the discrete office/outpatient E/M visits, ED work often includes many other services similar to the component coding for the Medicare annual wellness visit discussed above. **For these reasons, we urge CMS to allow the stakeholders who report ED visit codes to work through the CPT and RUC process to determine a correct coding paradigm for their work, as ED visit**

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codes and office/outpatient visit codes are no longer similar services with similar reporting guidelines.

Therapy Evaluations

CMS proposes to increase the work RVUs for a number of therapy evaluation services. CMS states that, for these codes, a significant portion of overall work is associated with assessment and management, similar to the work included in the office/outpatient E/M visits. CMS provides the current and proposed work RVUs for the therapy services in Table 21 in this rule.

CMS provides the following rationale for such increases:

- The proposal is based on a broad-based estimate of the overall change in the work associated with assessment and management to mirror the overall increase in the work of the office/outpatient E/M visits;
- Even though there is no direct relationship to the office and outpatient E/M services, CMS states that it adjusted the values based on a volume-weighted average of the increases to the office/outpatient E/M visit work RVUs from CY 2020 to CY 2021; and
- It is important to the relativity of the PFS to revalue these services to reflect the overall increase in value associated with spending time assessing and managing patients, as reflected in the changes to work values for the office/outpatient E/M visits, particularly in recognition of the value of the clinicians' time which is spent treating a growing number of patients with greater needs and multiple medical conditions.

First, these codes, which are not crosswalked to E/Ms, include many flaws in their original valuation. For example, the CPT Editorial Panel established three physical therapy codes—97161, 97162, and 97163—to describe different levels of work for the physical therapy assessment of patients, which are listed in Table 21. These codes were reviewed by the RUC Health Care Professionals Advisory Committee (HCPAC), and work RVU recommendations were made for three different levels of service: 0.75, 1.18, and 1.50 work RVUs, respectively. The Agency, however, chose to ignore the RUC's recommendations and blend the work RVU for all three codes into one value as if they were one service by applying the same work RVU (1.20) and times across all three codes. As a result of this decision, CMS overpaid for two of the services and underpaid for the third, therefore making an overall overpayment for 97161, 97162, and 97163. **In 2019, CMS paid for an additional 631 million work RVUs for these three codes over what would have been paid if CMS had accepted the RUC recommendations**. CMS' current proposal of a work RVU of 1.54 for all three

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codes will continue the overpayment for these services compared to the original RUC recommendations.

Second, continuing with the physical therapy code example, codes 97161, 97162, and 97163 do not include management. Part of CMS' rationale for increasing the work RVUs for these services is that a significant portion of overall work is associated with assessment and management, similar to the work included in the office/outpatient E/M visits. But this rationale does not apply for these evaluation codes that do not include management.

If the Agency believes that adjustments to work RVUs for these codes is required "in recognition of the value of the clinicians' time that is spent treating a growing number of patients with greater needs and multiple medical conditions," then an adjustment to all the codes in the entire fee schedule with face-to-face services (including surgical codes) is warranted because all providers are seeing the same type of older/sicker patients who have greater needs and multiple medical conditions. **We urge CMS not to implement the proposed increase to these therapy codes. To do so will amplify a previous miscalculation and misvaluation by CMS for codes that, in the Agency's own words, "do not specifically include, were not valued to include, and were not necessarily valued relative to, office/outpatient E/M visits."**[22]

Behavioral Healthcare Services

The psychotherapy code set is divided into two categories:

- **Psychotherapy furnished as stand-alone codes:** 90832, 90834 and 90837
- **Psychotherapy add-on codes delivered in conjunction with an E/M:** 90833, 90836 and 90838

CMS proposes to increase the values associated with the codes describing psychotherapy that can be furnished as a stand-alone service (codes 90832, 90834 and 90837). CMS' rationale is that because the psychotherapy codes that are furnished in conjunction with an E/M are necessarily billed with an E/M, the overall value for psychotherapy furnished in conjunction with office/outpatient E/M visits will naturally increase. However, in order to maintain relativity, CMS states that it must adjust the stand-alone psychotherapy visits proportionally.

[22] Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 F.R. 50074 [pp. 50133-50134] (2020).

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This proposal is based on a flawed methodology, which CMS readily admits by recognizing that this is not a methodology typically used to value services. We do not understand the logic that requires increasing the values for codes that are specifically *not* reported with an E/M service because of changes to the values of E/M services.

The stand-alone codes, which were established for NPPs to report psychotherapy services, were not valued based on a comparison to the psychotherapy codes delivered in conjunction with an E/M (codes 90833, 90836 and 90838). These are two distinct codes sets: one for NPPs and one for physicians/ QHPs representing different levels of similar work. In fact, the values for the stand-alone codes (90832, 90834, 90837) were based on the median survey response using magnitude estimation. At no time did the RUC ever consider that the total value for physician/QHP codes *plus* an E/M should be equivalent or relative to the codes reported by NPPs (e.g., psychologists and clinical social workers). **CMS' methodology is clearly flawed, and we urge the Agency not to implement these changes.**

Ophthalmological Services

CMS received a request to revalue the follow ophthalmologic codes in accordance with the updates to the office and outpatient E/Ms:

- **CPT 92002** (*Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient*)
- **CPT 92004** (*Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, 1 or more visits*)
- **CPT 92012** (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient*)
- **CPT 92014** (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits*)

CMS does not propose to revalue these services. CMS provides the following several points as its rationale:

- Even though these codes are traditionally valued "relative to office/outpatient E/M visits," CMS cited that the codes have not been revalued at the RUC since 2007;

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- CMS expresses skepticism about the number of visits included in the package;
- CMS states that the new office and outpatient E/M values have a time concept tied to them that are inapplicable to these ophthalmological services and that the relationship between the two separate code sets and for relying on both of them is unclear; and
- CMS cited that the four codes are reported, depending on the code, 4 to 14 percent of the time with Modifier ~25 (*significant, separately identifiable E/M service by the same physician on the same day of the procedure or service*). While there are similar Modifier ~25 trends with ED visits and office and outpatient E/Ms, CMS states it believes that visit/evaluation codes furnished the same day as a minor procedure are not closely analogous to stand-alone office/outpatient E/M visits, and therefore should not be revalued commensurate with the increase to stand-alone office/outpatient E/M visits for 2021.

Based on the code value increases for analogous, bundled, crosswalked, and other codes discussed above, we do not see a sound rationale for CMS refusing to apply the increases to these ophthalmology codes as well. Part of the Agency's rationale is that even though these codes are traditionally valued "relative to office/outpatient E/M visits," the codes have not been revalued at the RUC since 2007. However, CMS is proposing to increase the values for the Annual Wellness Visits, which are codes that have **never** been reviewed by the RUC. CMS also expresses skepticism about the number of visits included in the global package; however, all four of these ophthalmology codes are valued based on a single visit on the date of encounter, and the level of that visit is directly compared to levels of office E/M codes.

In addition, CMS states that the new office and outpatient E/M values have a time concept tied to them that are inapplicable to these ophthalmological services, and that "the relationship between the two separate code sets and the reason for relying on both of them is unclear." However, CMS does not acknowledge that office/outpatient E/M codes may be reported based on MDM (and not time), and this set of ophthalmological E/M services have clear definitions in the CPT codebook describing and differentiating MDM, which was the basis for comparison to office/outpatient E/M codes.

CMS also states that the four codes are reported 4 to 14 percent of the time with Modifier ~25 indicating a procedure has also been performed. However, as we noted above in the section on the AWV codes, primary care societies (e.g., AAFP and ACP) advocate use of Modifier ~25 with office E/M codes in addition to both the annual wellness visit code and the screening codes. It is inconsistent for the

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Agency to deny increases to this set of codes based on data for codes that other codes are billed with (even if only 4 percent), and yet not apply this same rule to the AWV code set. **We urge CMS to establish clear, valid, and consistent policies and not apply rules differently based on whether the specialty is primary care or a surgical specialty.**

Proposed CY 2021 Conversion Factor

CMS estimates the CY 2021 PFS conversion factor to be 32.2605, which reflects the budget neutrality adjustment of -10.61 percent and the 0 percent statutory update factor We are strongly opposed to CMS reducing the Medicare conversion factor from $36.0896 to $32.2605. This decrease lowers the 2021 conversion factor below the 1994 conversion factor of $32.9050, which would be approximately $58.02 today in current dollars.[23,24] This extraordinary cut to the conversion factor is triggered not only by an unprecedented increase to office/outpatient E/M codes, but almost equally by a single new CMS assigned add-on code (GPC1X) that the AMA and almost all medical specialties agree is invalid. The cut is also exacerbated by proposed increases to select global codes. The additional spending to support these increases, along with the increases to stand-alone office/outpatient E/M visits, totals $10.2 billion.

The reduction of the conversion factor, paired with the failure to incorporate the revised office/outpatient E/M values in the global codes, will result in drastic cuts to many physician specialties. These cuts come at a time when specialists are struggling with the financial impact of the COVID-19 pandemic in many ways, including pay cuts from the suspension of elective surgery, salary reductions, furloughs, and layoffs. **We urge CMS to thoughtfully implement any action that Congress might take to enact legislation to waive Medicare's budget neutrality requirements for these E/M adjustments.**

Proposed Valuation of Specific Codes for CY 2021

Modified Radical Mastectomy (CPT code 19307)

[23]American Medical Association. (2020). *History of Medicare Conversion Factors*. Retrieved from https://www.ama-assn.org/system/files/2020-01/cf-history.pdf
[24]U.S. Bureau of Labor Statistics. *Consumer Price Index Inflation Calculator*. Retrieved from https://www.bls.gov/data/inflation_calculator.htm
*Using the U.S. Bureau of Labor Statistics inflation calculator, the conversion factor in 1994, $32.9050, is worth approximately $58.02 today. This means that the proposed CY 2021 reduction of the conversion factor to $32.2605 is an even steeper cut when adjusted for inflation and is by far the lowest conversion factor since its inception in 1992.

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CMS proposes to accept the RUC-recommended work RVU of 17.99 and direct PE inputs for code 19307 (*Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle*). **We thank CMS for accepting the RUC recommendations for this code.**

Toe Amputation (CPT codes 28820 and 28825)

- CPT code 28820 (*Amputation, toe; metatarsophalangeal joint*): CMS disagrees with the RUC-recommended work RVU of 4.10 for code 28820 and instead proposes to crosswalk the value to code 33958 *(Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)*, which has a work RVU of 3.51. The Agency bases this decision on a comparison of RUC-recommended total time to the current CMS database total time, and states it believes that a further reduction in work RVUs is warranted given the significant reduction in RUC-recommended physician time.

  The ACS is concerned that CMS may have overlooked the extensive background and compelling evidence indicating that the current work RVU for code 28820 is invalid. A flawed methodology of the previous valuation based on inaccurate Medicare data was used by the Agency to falsely claim code 28820 was typically an outpatient service, and information was provided to the RUC and CMS noting a change in patient population. Neglecting to consider a change in the typical patient for code 28820—but using a similar rationale to increase other codes related to primary care services—is an example of CMS' failure to consistently apply the same standards to all codes in the PFS.

  We disagree with the crosswalk to 33958 that CMS chose based on total time. The work of this procedure is described simply as advancing or withdrawing the cannula(e) until ECMO flows are adequate. The procedure is also designated as a 0-day global code that erroneously includes an inpatient hospital visit. CMS has been clear in its rulemaking that 0-day global codes include pre-, intra-, and post-time, and the inclusion of a hospital visit in code 33958 runs contrary to the Agency's definition of 0-day global. Furthermore, code 33958 has low Medicare utilization. As such, code 33958 is not an appropriate comparator code.

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If CMS chooses to compare work using total time, we believe the key reference code 11044 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq. cm or less*) is a better comparator. Code 11044 is typically reported for debridement of a lower extremity ulcer with minimal local anesthesia. Debridement is tedious work, but not intensive or complex. In comparison, code 28820 requires more complex decisions regarding skin and soft tissue incisions and bone resection to be able to fashion flaps for closure after resection. Additionally, attention to vessels and blood flow to adjacent toe(s) add both complexity and intensity to this procedure and warrants a higher intensity. Both codes require almost identical total time: total time for code 11044 is 116 minutes and total time for code 28820 is 113 minutes. **Code 11044 time and work details support a value of 4.10 for 28820.** Relative to "cognitive" work time, the total time of 113 minutes on the day of this toe amputation procedure is comparable to reporting 1 x 99215 and 3 x 99417 for a work RVU of 4.63, which further supports a work RVU value of 4.10 for code 28820. **We strongly urge CMS to accept the RUC-recommended value of 4.10 for code 28820.**

- CPT code 28825 (*Amputation, toe; interphalangeal joint*): CMS disagrees with the RUC-recommended work RVU of 4.00 for code 28825 and instead proposes to assign a value that is 0.10 work RVUs less than the CMS-assigned value for code 28820 in recognition of the incremental difference between these two toe amputation services. CMS bases this decision on a comparison of RUC-recommended total time to the current CMS database total time. The Agency states that it believes that a further reduction in work RVUs is warranted given the significant reduction in RUC-recommended physician time.

  The ACS is concerned that CMS may have overlooked the extensive background and compelling evidence indicating that the current work RVU for code 28825 is invalid. During a previous review, CMS used a reverse building block approach to reduce the value for code 28825, resulting in an intraoperative work intensity (IWPUT) of 0.010 and work per unit time (WPUT) of 0.026. These time and intensity assignments are significantly less than a majority of procedures and services in the PFS (including cognitive services) and do not represent relativity. In addition, information was provided to the RUC and CMS noting a change in patient population for this code. Neglecting to consider a change in the patient for code 28820—but using a similar rationale to increase other codes related to primary care services—is an example of CMS' failure to consistently apply the same standards to all codes in the PFS.

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We believe that relativity should be maintained between codes 28825 and 28820. Review of the RUC survey information shows a slight 5-minute difference in the same-day postoperative period. Although we believe the postoperative work is the same, and the incremental time difference is a survey anomaly, we do agree that the intensity and complexity of 28825 compared to code 28820 might be slightly less. **As such, we support the RUC recommendation of a 0.10 difference in work RVUs for these two codes.**

When comparing work using total time, the same arguments provided above for code 28820 apply to code 28825. We believe the key reference code 11044 *(Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq. cm or less)* is a good comparator. Code 11044 is typically reported for debridement of a lower extremity ulcer with minimal local anesthesia. Debridement is tedious work, but not intensive or complex. In comparison, 28825 requires more complex decisions regarding skin and soft tissue incisions and bone resection to be able to fashion flaps for closure after resection. In addition, attention to vessels and blood flow to adjacent toe(s) add both complexity and intensity to this procedure and warrants a higher intensity. Both codes require almost identical total time: total time for code 11044 is 116 minutes and total time for code 28825 is 108 minutes. **Code 11044 time and work details support a value of 4.00 for code 28825.** Relative "cognitive" work time, the total time of 108 minutes on the day of this toe amputation procedure is comparable to reporting 1 x 99215 and 3 x 99417 for a work RVU of 4.63, which further supports a work RVU of 4.00 for code 28825. **We strongly urge CMS to accept the RUC-recommended value of 4.00 for code 28825.**

- Direct Practice Expense Inputs

Facility Pre-Service Clinical Labor Time

CMS proposes to refine facility pre-service clinical labor times to conform to the 000-day global period standards for both codes 28820 and 28825. As select major surgical global procedures with a 90-day global are reassigned to a 0-day global in recognition of multimodal postoperative work, it is important to remember that these are still the same major surgical procedures with respect to the preoperative clinical staff work. Codes 28820 and 28825 are typically performed in a facility setting (94 to 98 percent of the time) under general anesthesia on patients with significant comorbidities.

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The change to a 0-day global was requested to account for variable postoperative care, and in no way alters the major procedure pre-service clinical staff work that is typical for such procedures. The ACS recommended, and the RUC agreed, that the 90-day global major surgery pre-service standard for the facility setting remained appropriate. The typical patient requiring a toe amputation in the facility setting will have multiple comorbidities, such as diabetes and peripheral vascular disease. Clinical staff will have various phone calls with the office of the primary care provider and other physician specialists to obtain medical history and with the patient/family to pre-plan for post-discharge at-home assistance and ambulation equipment. Preoperative clearance for anesthesia and scheduling space and necessary equipment in the operating room will be necessary. Clinical staff will also provide education about the procedure and answer patient/family questions. The risks, benefits, and complications will be reviewed. This work is not just "extensive use of clinical staff" related to procedures that have always had an assignment of a 0-day or 10-day global (e.g., endoscopy or laceration repair).

We believe it is disingenuous of CMS to impose a standard for these codes without regard to the clinically significant information that has been provided. The Agency's reassignment of global periods for select codes does not negate the fact that a major procedure is *still* a major procedure, and that the pre-time facility clinical staff time for a major procedure is independent of the global assignment. In fact, CMS has allowed other 0-day, 10-day, and XXX global codes to include 60 minutes for facility pre-service clinical staff time. As certain codes are moved to a 0-day global assignment based on multimodal postoperative work, we urge CMS to consider the evidence provided to support the preoperative clinical staff requirements. **We urge CMS to accept the RUC-recommended preoperative clinical staff time of 60 minutes for codes 28820 and 28825.**

Non-Facility Intra-Service Clinical Labor Time (CA011)

CMS proposes reduce the non-facility clinical labor time for "Providing education/obtaining consent" (CA011) from the RUC-recommended time of 5 minutes to a standard time of 2 minutes. CMS accepted extensive use of clinical staff in the non-facility setting for both codes, which did not include the 7 minutes that applies to this extensive use input. The relevant specialty societies explained, and the RUC agreed, that the standard non-facility 0-day global extensive use of clinical staff for this activity is 7 minutes—however, this activity will typically be provided in office on the day of service, instead

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of in the pre-service period. In the summary of recommendation that was provided to the RUC and forwarded to CMS, the ACS stated:

> Previously, 10 minutes was assigned to the pre-service period for this activity (CA004). The standard time for non-facility 0-day office extensive used of clinical staff is 7 minutes, but we are reducing the clinical staff time to 5 minutes as typical for education and responding to patient questions on day of service, instead of in the pre-service period. This is a major surgical procedure—a body part is being removed. Although it is uncommon to perform this in an office setting, it is still a major procedure and should be treated as such. This activity includes the clinical staff re-describing the procedure with a focus mainly on what the patient will undergo/see/hear pre-procedure as well as during the procedure. There will be many tasks being performed that the patient would not normally see in a facility under anesthesia. The patient will be educated to understand how local anesthesia and a block works – that they will still feel pressure during the procedure but should not feel sharp pain as they watch a toe being removed. The education will also include a discussion on what to expect after the procedure, confirming the patient will have the assistance needed post-procedure at home. As with any consent discussion, the details of the procedure will be discussed, the risks, benefits, complications will be discussed, and all questions answered by both the clinical staff and physician before the actual signature is obtained. Numerous other codes include non-facility clinical staff time for CA011 that is greater than 2 minutes. These were approved on a case-by-case basis.

The clinical staff work related to education for this major procedure is not standard and not insignificant, and we urge CMS to accept the RUC-recommended 5 minutes of patient education and consent for codes 28820 and 28825.

Non-Facility Intra-Service Clinical Labor Time (CA013)

CMS proposes to refine the non-facility clinical labor time for "Preparing room, equipment and supplies" (CA013) from the RUC-recommended time of 5 minutes to a standard time of 2 minutes.

We disagree that 2 minutes is sufficient for the clinical staff to not only set up the room in standard fashion for an E/M service, but to also set up the supplies, including the medium instrument pack, and confirm that the necessary cautery and suction machines are running correctly. These

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supplies and multiple pieces of equipment are not typical for most office procedures. It is important to note that the 2-minute standard was developed based on preparing a room for an E/M service, not a major procedure. It is also important to note that CMS proposed accepting the RUC-recommended time of 4 minutes for CA013 for office/outpatient E/M codes for CY 2021. Clearly, if an office E/M service room set up takes 4 minutes, a major procedure with multiple pieces of equipment and many supplies will require more set up time. **We urge CMS to accept the RUC-recommended CA013 time of 5 minutes for codes 28820 and 28825.**

Non-Facility Equipment Time

CMS proposes to refine the equipment time to conform to the proposed changes in the clinical labor time. **We urge CMS to accept the information provided above regarding clinical staff time and accept the RUC-recommended equipment times for codes 28820 and 28825.**

Esophagogastroduodenoscopy (EGD) with Biopsy (CPT code 43239)

CMS proposes to maintain the RUC-recommended work RVU of 2.39 and direct PE inputs for code 43239 (*Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple*). **We thank CMS for accepting the RUC recommendations for this code.**

Colonoscopy (CPT code 45385)

CMS proposes to maintain the RUC-recommended work RVU of 4.57 and direct PE inputs for code 45385 (*Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique*). **We thank CMS for accepting the RUC recommendations for this code.**

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

We are disappointed that the Agency does not propose to accept the RUC recommendation to maintain the value for code 74300 (*Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation*) based on a survey that confirmed the total time was accurate. Instead, CMS takes advantage of the fact that this code was under review and chose to reduce the value via a crosswalk to key reference code 74021 (*Radiologic examination, abdomen; 3 or more views*), which has less total time. This is another example of CMS' failure to consistently apply the same standards to all codes in the PFS. While there is no evidence that the work or total time for

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code 74300 has changed, CMS feels compelled to significantly reduce the value for this code and uses an office-based imaging code with less time to reduce the work value of an intraoperative imaging code whose time did not change. **The value for code 74300 should not be reduced.**

Immunization Administration (CPT codes 90460, 90461, 90471, 90472, 90473, and 90474 and HCPCS codes G0008, G0009, and G0010)

We disagree with the rationale that CMS has provided to adjust the PE RVUs for this set of codes to equal those for code 36000 (*Introduction of needle or intracatheter, vein*) based on the RUC's assertions regarding the importance of appropriate resource-based valuations for vaccine administration services. First, code 36000 is a bundled service that is not recognized for payment by CMS, nor has it ever been reviewed by the RUC. Second, code 36000 includes a multispecialty visit pack, which would be a duplication of resources for the vaccination codes, and also includes an angiocatheter that would never be used for vaccine administration.

It is important to note that, in the RBRVS system, the Agency has established a multistep equation for developing PE RVUs—step 5 of this equation assigns a scaling adjustment to direct expenses, and step 23 assigns a scaling adjustment to indirect expenses. In this proposed rule, these factors were 0.6145 and 0.3893, respectively, and were applied across the board to all codes. These factors are meant to maintain the "pool" for PE RVUs from year to year, including years during which CMS adds new covered services/benefits. Arbitrarily assigning a specific PE RVU to this set of vaccination codes is another example of CMS' failure to consistently apply the same standards to all codes in the PFS, and as such, takes payment for resources away from one group of providers and assigns it to another group of providers.

We do not agree that the PE RVUs for this set of immunization administration codes should be hard-entered at a specific value that is crosswalked to a service that does not include similar resources—this defeats the purpose of a resource-based relative value scale. In addition, we urge the Agency to recognize Pharmacists as a Medicare specialty, as these providers independently provide immunization services in the community setting, reaching many patients who do not have access to a physician for such services.

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OTHER PROVISIONS OF THE PROPOSED RULE

Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 mandates ECPS under Medicare Part D in accordance with an electronic prescription drug program beginning January 1, 2021. In recognition of the time and resources practices must invest to comply with Drug Enforcement Agency (DEA) guidance for ECPS, as well as additional challenges presented by the current COVID-19 PHE, CMS proposes to delay the EPCS requirement until January 1, 2022. The Agency solicits comments on this proposed change to the ECPS implementation date, and also seeks feedback regarding the impact on such requirement on overall interoperability and medical record systems.

We appreciate CMS' acknowledgement of the many hardships faced by prescribers and facilities related to the integration of ECPS into their workflows, and we support delayed implementation of this requirement. We will submit detailed comments regarding ECPS use and compliance in response to CMS' *Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information* (CMS-3394-NC).

The ACS appreciates the opportunity to provide feedback on the PFS and looks forward to continuing dialogue with CMS on these important issues. If you have questions about our comments, contact Vinita Mujumdar, Regulatory Affairs Manager, at vmujumdar@facs.org.

Sincerely,

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