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October 1, 2020

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Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445–G  
200 Independence Avenue, SW  
Washington, DC 20201

Submitted electronically via [www.regulations.gov](http://www.regulations.gov)

**Subject: CMS-1734-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2021; 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**

Dear Administrator Verma:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on the payment provisions of the above-referenced notice of proposed rulemaking. Neurosurgery's comments on the quality-related aspects of the proposed rule are included in a separate letter.

## **EXECUTIVE SUMMARY**

### **Office and Outpatient Visit (Evaluation and Management) Codes**

- **Include the E/M Increases in the Global Surgery Codes.** The AANS and the CNS strongly urge the Centers for Medicare & Medicaid Services (CMS) to apply the RUC-recommended changes to the evaluation and management (E/M) component of the 10- and 90-day global surgery codes to maintain the relativity of the fee schedule and to comply with the Medicare law's prohibition on specialty payment differentials.
- **Eliminate the Proposed GCP1X Add-on Code.** Joining the chorus of stakeholders that includes the American Medical Association (AMA), American College of Surgeons (ACS), the Medicare Payment Commission (MedPAC) and others, the AANS and the CNS strongly urge CMS not to implement the GPC1X add-on code as it is unnecessary in light of the new office and outpatient E/M code structure and values. At the very least, CMS should conduct a comprehensive study on the newly revised E/M office and outpatient codes to determine whether the add-on code is necessary.

## **Conversion Factor**

- **Prevent a Steep Decrease in the 2021 Conversion Factor.** The AANS and the CNS recommend that CMS consider the following actions to prevent a steep decrease in the 2021 conversion factor to lessen the negative impact on neurosurgeons:
  - + Eliminate the GPC1X add-on code;
  - + Treat the GPC1X add-on code as a new code established by regulations and, therefore, not subject to budget neutrality (if CMS moves forward with the GPC1X add-on code);
  - + Use the authority under the public health emergency declaration to waive the budget neutrality requirements; and/or
  - + Reconsider the utilization assumptions used to determine the 2021 conversion factor

## **Practice Expense RVUs**

- **Carefully Review the Rand Analysis.** The AANS and the CNS have had concerns with previous RAND Corporation (RAND) reports on several PFS-related topics, and urge CMS to exercise extreme caution as the agency reviews the RAND analysis.
- **Collaborate with the Medical Community on any New Practice Expense Revisions.** The AANS and the CNS urge CMS to work with the RUC and specialty societies on any new practice expense (PE) data collection efforts to ensure that the data and methodology are accurate, transparent and fair.
- **Use BLS Data for Clinical Labor Costs.** CMS should continue to use the most recent Bureau of Labor Statistics (BLS) data for clinical labor costs.
- **Do Not Use Medicare Hospital Data for Physician PE.** The AANS and the CNS oppose proposals by the RAND and CMS to consider using hospital facility cost data to update practice expenses for the physician fee schedule.

## **Code-Specific Valuation**

- **CMS Should Accept RUC-Passed Values.** The AANS and the CNS recommend that CMS accept a higher percentage of RUC-passed values, which are based on valid, clinically relevant information that preserves relativity.
- **CPT Code 22867 is Misvalued.** The AANS and the CNS agree that CPT code 22867 is misvalued. The agency should use data from two previous RUC surveys and establish 15.00 work RVUs for this code.

## **Review of National Coverage Determinations**

- **CMS Should Establish a Process for Removing Outdated NCDs.** The AANS and the CNS generally support efforts by CMS to identify and remove national coverage determinations (NCDs) that are not reflective of current medical practice and agree with the agency that the local Medicare Administrative Contractors (MACs) may be better able to assess new technology as it develops across the country — provided there is improved coordination among the local carriers.

## **DETAILED COMMENTS**

### **Office and Outpatient Visit (Evaluation and Management) Codes**

For decades, physicians have struggled with burdensome documentation requirements for office and outpatient visits — otherwise known as evaluation and management (E/M) services. CMS's E/M documentation guidelines were a complex matrix of check-boxes and information that was not always the most pertinent or descriptive of the service provided and the medical decision-making necessary to determine the level of service provided to patients. The medical community was unified in its desire to reduce the burden of documenting E/M services.

Congress and CMS eventually initiated a review of burdensome regulatory policies, including E/M documentation requirements. Like most of medicine, the AANS and the CNS supported the efforts to modernize the E/M codes. We particularly supported changes to the documentation requirements to minimize the burdens associated with coding and reporting E/M services. When CMS and the CPT/RUC E/M Workgroup undertook this project, it was made clear that the code change proposal was intended to simplify documentation requirements and **explicitly stated that the purpose was not to redistribute payments between specialties.**

Unfortunately, this burden reduction initiative has now become a significant payment redistribution exercise, with dozens of specialties — including neurosurgery — bracing for harmful payment cuts that could jeopardize patient access to medically necessary services. It is beyond disappointing that CMS has failed to recognize the severe consequences of such steep payment cuts, which will further strain a health care system that is already stressed by the COVID-19 pandemic. Furthermore, primary care providers will have fewer choices when referring patients to specialists if health care professionals must close or limit their practices as a result of these drastic cuts.

Fortunately, there are several steps that CMS can take to prevent these cuts from going into effect, and we urge the agency to take action, as suggested below.

#### ***Include the E/M Increases in the Global Surgery Codes***

Once again, CMS has stated that it will not adjust the E/M portion of the global surgery codes to reflect the changes in values of the revised stand-alone office and outpatient E/M codes. The refusal to incorporate the work and time incremental increases for the revised office/outpatient visit codes in the E/M portion of the global surgery codes is entirely unacceptable and in contravention of the Medicare statute. This policy, coupled with other ill-conceived changes in the proposed PFS, will result in drastic cuts to neurosurgeons.

As the agency proceeds to implement the changes to the office and outpatient visit codes — which are based on the AMA CPT/RUC E/M Workgroup recommendations — **we strongly request that CMS apply the RUC-recommended adjustments to the global surgery codes starting in Calendar Year (CY) 2021.** To do otherwise will:

- **Disrupt the relativity in the fee schedule.** Applying the RUC-recommended E/M value increases to the stand-alone office and outpatient visits and select bundled codes that include E/M services (e.g., monthly end-stage renal disease, maternity care and monthly psychiatric management), but *not* also to the E/M portion of the global surgical codes, will disrupt the relativity between codes across the Medicare PFS. Congress mandated this relativity in the Omnibus Budget Reconciliation Act of 1989, which is the cornerstone of the Medicare PFS as established in 1992 and refined over the past 27 years.

- **Disregard previous precedent.** Since the inception of the fee schedule, the E/M codes have been revalued four times:
  - + In 1993, through refinement after implementation of extensive E/M coding changes;
  - + 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.

Each time payments for new and established office visits were changed, CMS appropriately incorporated these changes into the post-operative visits within the global period. There is simply no valid reason for the agency not to make these same adjustments now, and CMS should follow its own precedent by adjusting the E/M portion of the global codes accordingly.

- **Create specialty differentials.** The Medicare statute prohibits CMS from paying physicians differently for the same work. According to the law, 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.” Failing to adjust the global codes is tantamount to paying some physicians less for providing the same E/M services, in violation of the law.

In the CY 2021 PFS proposed rule, CMS asserts that the valuation methodology (i.e., building block vs. magnitude estimation) provides a rationale for why some bundled services should be increased, while the global surgery codes should not. These distinctions are flawed and fail to adhere to the statutory prohibition on paying physicians differently for the same work — which applies irrespective of the valuation methodology — and the incremental E/M-related increases should apply to all services, including the global surgery codes.

- **Inappropriately rely on section 523(a) of MACRA.** In the CY 2021 PFS proposed rule, CMS states it will not adjust the 10- and 90-day global surgical codes to reflect the increased values of the office and outpatient E/M visit codes because the agency continues to collect data on the number and level of post-operative visits included in global codes as required by the Medicare Access and CHIP Reauthorization Act (MACRA).

The MACRA data collection requirement, set forth in section 523(a), does not prohibit CMS from adjusting the global codes to reflect the new office/outpatient E/Ms code values. In fact, section 523(a) explicitly authorizes CMS to adjust global surgical code values, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project. Therefore, it is inappropriate for CMS to rely on MACRA as a reason to refrain from making necessary updates in 2021.

Furthermore, the AANS and the CNS believe that the agency has fulfilled its MACRA requirement to collect data on the global surgical codes. As we, the RUC, the ACS and other stakeholders have pointed out, the RAND studies of the global surgical codes are highly flawed. Rather than relying on this flawed and incomplete work to propose any future changes to the global surgery codes, CMS should instead utilize the RUC process to review code values periodically. This process was recently used, for example, to revalue the cataract code and can be effectively employed on a code-by-code basis, as contemplated by section 523(a).

- **Ignore recommendations endorsed by nearly all medical specialties.** In 2019, the RUC, which represents the entire medical profession, voted overwhelmingly (27-1) to recommend that the full, incremental increase of work and physician time for office visits be incorporated

into the global codes for each CPT code with a global period of 10-day, 90-day and MMM (maternity). The RUC also recommended modifying the practice expense inputs for the office visits within the global periods. In the CY 2021 PFS proposed rule, CMS uses the RUC recommendations as a rationale for increasing the values of the maternity services codes and other select bundled services. However, at the same time, the agency rejects the RUC recommendations related to the global surgery codes. Cherry-picking the RUC recommendations is arbitrary and capricious in violation of the Administrative Procedures Act.

**Again, we strongly urge CMS to apply the RUC-recommended changes to the E/M component of the global surgery codes to maintain the fee schedule's relativity and comply with the Medicare law's prohibition on specialty payment differentials.** Furthermore, we believe the agency has fulfilled its requirement to collect data on global surgery services and, therefore, should drop further efforts to systematically devalue or eliminate the global surgical codes.

### ***Eliminate the Proposed GPC1X Add-on Code***

To reduce the burdens associated with E/M documentation, in 2018, CMS proposed restructuring the coding system for office and outpatient visits by collapsing the E/M codes from five to two levels. Because certain specialties would experience payment cuts under this scheme, CMS proposed add-on codes to provide an additional payment — specifically for primary care and certain specialty visits — to minimize payment cuts associated with these code changes.

Ultimately, CMS did not move forward with the single payment proposal and will instead retain the multiple levels of E/M codes. Nevertheless, the agency is still planning to adopt a new add-on code — GPC1X for visits that serve as a focal point for all medical or for ongoing care related to a patient's single, serious or complex chronic condition — even though the agency's justification for including an add-on code in the new E/M approach no longer exists. Now, instead of correcting a system that would have resulted in unfair payment reductions, the agency is creating a new coding scheme that inappropriately discriminates among physician specialties — over-inflating payments to individual specialties and causing steep cuts to others. Again, cuts of the magnitude will further strain a health care system that is already stressed by the COVID-19 pandemic.

**Joining the chorus of stakeholders that includes the AMA, ACS, MedPAC<sup>1</sup> and others, the AANS and the CNS strongly urge CMS not to implement the GPC1X add-on code.** More than \$3.3 billion will be redistributed between specialties if this code is implemented, and it is a significant contributor to the steep reduction in the conversion factor. Since there is no longer a need for the add-on code — which is a holdover from the previous single bundled payment proposal that was replaced by the CPT/RUC E/M Workgroup structure — CMS should drop plans to implement it.

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<sup>1</sup> In its Sept. 13, 2019, comment letter to CMS, MedPAC stated the following: "We do not support CMS's proposal to combine the two new add-on codes for primary care visits (GPC1X) and specialized medical care visits (GCG0X) that use additional resources into a single add-on code (GPC1X) that describes the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition." MedPAC raised numerous questions about the proposed add-on code, noting, "Even though CMS proposes to revise the standard codes for E&M office/outpatient visits, the agency states that this new add-on code is needed to account for the additional resource costs inherent in furnishing some kinds of E&M visits. However, CMS does not specify these additional resources or the types of visits that require additional resources. CMS's proposed definition for this code appears to cover a very wide range of visits. Does CMS intend for this code to be billed along with all or the majority of E&M office/outpatient visits? How will clinicians document the necessity of billing this code? Assuming that CMS increases the work RVUs for the standard codes for E&M office/outpatient visits, what is the rationale for creating this add-on code?"

At the very least, **CMS should conduct a comprehensive study of the newly revised E/M office and outpatient visit codes to determine whether the add-on code is necessary in light of the structure and values assigned to these revised E/M codes (CPT codes 99202-99215 and prolonged services codes).**

### **Conversion Factor**

CMS has estimated that the Medicare conversion factor will decrease from \$36.0896 to \$32.2605 — a 10.6 percent reduction! 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. While we understand the constraints on the agency to maintain budget neutrality, the extraordinary cut to the conversion will result in an overall 7% pay cut neurosurgery, and even larger cuts for critical services such as treatments for stroke. At a time when neurosurgeons are struggling with the financial impact of the COVID-19 pandemic — including pay cuts from the suspension of elective surgery, salary reductions, furloughs and layoffs — now is not the time for additional cuts to the health care system.

**To prevent such a steep decrease in the 2021 conversion factor, the AANS and the CNS recommend the following:**

- **Eliminate the GPC1X add-on code;**
- **Treat the GPC1X add-on code as a new code established by regulations and, therefore, not subject to budget neutrality (if CMS moves forward with the GPC1X add-on code);**
- **Use the authority under the public health emergency declaration to waive the budget neutrality requirements; and/or**
- **Reconsider the utilization assumptions used to determine the 2021 conversion factor.**

### **Practice Expense RVUs**

As CMS undertakes to review PE RVUs, we recommend that the agency provide numerous opportunities for stakeholder engagement — including conducting town hall meetings and input via written comments. We look forward to reviewing proposals from CMS developed in collaboration with the RUC and others. In the meantime, we offer the following comments on aspects of the practice expense issue.

#### ***Carefully Review the Rand Analysis***

CMS indicates that it is reviewing two reports regarding practice expenses prepared by RAND. The first is a study by the RAND technical expert panel (TEP) to consider potential improvements to the agency's PE allocation methodology and underlying data. CMS is also reviewing the RAND report, "Practice Expense Methodology and Data Collection Research and Analysis — Interim Phase II Report." CMS clearly states that it is not proposing changes to PE data collection or PE methodology in the proposed rule and will not make adjustments in practice expenses without further input from stakeholders. However, because the AANS and the CNS have had concerns with previous RAND reports on several PFS-related topics, **we urge CMS to exercise extreme caution as the agency reviews the RAND analysis.**

#### ***Use the Bureau of Labor Statistics Data for Clinical Labor Costs***

CMS has called for comment on the best source of data for PE clinical labor costs. We note that CMS has used the BLS median pay data to reflect staff wages for more than a decade. Although not perfect, the BLS data are transparent and publically available. Any proposed alternatives should be thoroughly vetted to ensure that the transparency, reliability and accuracy are demonstrably better. In

the meantime, **the AANS and the CNS urge CMS to continue to use the most recent BLS data to determine clinical labor costs.**

### ***Ensure Accurate Practice Expense Survey Data Collection***

Since 2010, CMS has used the AMA Physician Practice Information (PPI) survey to update specialty-specific practice expense per hour data to develop PE RVUs. After a decade, the agency and the AMA are considering options for an updated data collection project. In March 2020, the AMA conducted a PE pilot study to prepare for a new PE data collection project. The AMA has promised to convene a meeting in 2021 to bring stakeholders together to review the data and begin planning for a new survey. **The AANS and the CNS urge CMS to work with the RUC and specialty societies on any new PE data collection effort to ensure that the data and methodology are accurate, transparent and fair.** The agency should consider lessons learned from the 2020 AMA pilot survey and the previous AMA 2007/2008 PPI survey.

### ***Do Not Use Medicare Hospital OPPS Data for Physician PE Costs***

**We oppose proposals by RAND and CMS to consider the use of hospital facility cost data to update practice expenses for the physician fee schedule.** Although translating hospital data to physician practices may seem simple, it is wrong to assume that these two practice environments share the same cost structures. Hospitals have vastly greater purchasing power and leverage than individual or large group practices. Furthermore, as the RUC has pointed out, the approach violates current law (Section 4505 of the Balanced Budget Act of 1997). RAND readily admits that using Medicare Hospital Outpatient Prospective Payment System (OPPS) data is challenging because of the:

- Difference in the underlying costs and services mix between office and outpatient settings;
- Use of different procedure codes for similar services; and
- Grouping of services determines the payment rates.

Although RAND has proposed some “workarounds” to overcome some of the difficulties, we still do not agree that using hospital data is appropriate. The RUC has indicated that if the RAND analysis and methodology using hospital data were implemented, 60% of all services would increase or decrease by 50% or more in the PE component, causing significant disruption across the PFS. Instead, **the AANS and the CNS join the RUC in urging CMS to work with the AMA, the RUC and the specialties to refocus its efforts on developing a new PE data collection project that allows all stakeholders to provide feedback.** The agency should provide sufficient time to discuss and plan for all aspects of the study and consider all potential consequences.

### **Code-Specific Valuation**

#### ***CMS Should Accept RUC-Passed Values***

While CMS accepted approximately 75 percent of the RUC’s work relative value recommendations submitted for 2021, we believe that the percentage should be higher. We share concerns expressed in the RUC’s comment letter to CMS about the agency’s use of flawed methodologies — including time ratios and incremental adjustments — to determine code values. In many scenarios, CMS selects an arbitrary combination of inputs to apply, including:

- Total physician time;
- Intra-service physician time;
- “CMS/Other” physician times;
- Harvard study physician times;

- Existing work RVUs;
- RUC-recommended work RVUs;
- Work RVUs from CMS-selected crosswalks; and/or
- Work RVUs from a base code.

This selection process appears arbitrary and allows the CMS to select values from the vast array of possible mathematical calculations, rather than establishing values based on valid, clinically relevant information that preserves relativity. **The AANS and the CNS recommend that CMS improve this process by accepting the RUC process and recommendations**, rather than using a mishmash of other less valid options.

### ***CPT Code 22867 is Misvalued***

CMS had received requests to consider as potentially misvalued, CPT code 22867 (Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level). **The AANS and the CNS agree that the code is misvalued. However, we urge the agency to review the history of the RUC recommendation for the code, rather than requiring the time, expense and effort involved in a new survey.**

CMS has the necessary survey data from the specialties who perform this service — which has been surveyed and reviewed twice by the RUC with the same outcome. Moreover, the RUC Relativity Assessment Workgroup (RAW) recently reviewed CPT code 22867 under the “new technology” screen and confirmed the technology itself has not changed since the last survey. We disagree with the statement made by the nominating stakeholders 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], [e.g., spinal or lateral recess stenosis]), single vertebral segment), especially with respect to technical skill required.”

This code was reviewed twice by the RUC with the same outcome for time, visits and value. 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. **We oppose the re-surveying of code 22867 and request that CMS establish a work RVU of 15.00 for code 22867, based on the original RUC recommendation submitted in 2016.**

### **Review of National Coverage Determinations**

CMS has established a process for removing outdated NCDs (i.e., those 10 years or older), allowing local MACs to determine coverage previously governed by an NCD. In general, **we support CMS's efforts to identify and remove NCDs that are not reflective of current medical practice and agree with the agency that the local MACs may be better able to assess new technology as it develops across the country — provided there is improved coordination among the local carriers.** Unfortunately, we have some concerns about how the MAC multi-jurisdictional Carrier Advisory Committees (CACs) have been used in the last few years. For example, in the recent review of percutaneous vertebral augmentation for compression fractures, the MACs conducted a multi-jurisdictional CAC meeting. Subsequently, however, the MACs each issued separate but identical local coverage determinations (LCDs) that ignored many of the stakeholders' comments from the CAC meeting. The LCDs all had different comment periods, requiring interested specialty societies to submit separate but virtually identical comments to each MAC and make seven individual formal requests for reconsideration. While we are hopeful the MACs will ultimately issue reasonable LCDs



for this particular procedure, it points out the need for better coordination and oversight of the LCD process.

## **CONCLUSION**

The AANS and the CNS appreciate the opportunity to provide feedback on these specific payment provisions in the CY 2021 Medicare PFS proposed rule. We are particularly concerned about CMS's failure to incorporate the increased E/M office visit work into the 10- and 90-day global surgical code values. We also strongly believe that the GPC1X add-on code is unnecessary and should be scrapped. Taken together, these two actions would significantly mitigate the steep cuts scheduled for surgeons whose practices continue to be on precarious footing given the COVID-19 pandemic. Now is not the time for any cuts to the health care system, so we urge CMS to take all necessary steps to prevent any Medicare payment reductions.

Thank you for considering our comments. In the meantime, if you have any questions or need additional information, please feel free to contact us. We are eager to work with the agency to provide the best care possible for our patients. We appreciate the expertise, hard work and dedication of CMS leaders and staff, especially during the COVID-19 public health emergency.

Sincerely,



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