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September 10, 2019

Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1715-P

P.O. Box 8016

Baltimore, MD 21244-8016

RE: Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations (CMS-1715-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) 2020 Medicare Physician Fee Schedule proposed rule (CMS-1715-P) published in the *Federal Register* on August 14, 2019.

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 ACS has a vested interest in CMS' Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP), and 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 10, 2019, includes the ACS' feedback specifically regarding revisions to Medicare payment policies, but does not constitute the entirety of our comments to the CY 2020 PFS proposed rule. We will submit a separate letter addressing updates to the QPP.

PROVISIONS OF THE PROPOSED RULE FOR PFS

Determination of Practice Expense Relative Value Units

PE RVU Methodology

CMS finalized a policy in the calendar year (CY) 2018 PFS to use the most recent year of claims data to determine which Current Procedural Terminology (CPT) codes are "low volume" (i.e., those that have fewer than 100 allowed services in the Medicare claims data) for the coming year. Instead of assigning specialty mix for low volume codes based on the specialties of the practitioners reporting the services in the claims data, the Agency will use the expected specialty based on medical review and input from the American Medical Association (AMA) Specialty Society Relative Value Scale (RVS) Update Committee (RUC) and specialty societies.

For CY 2020, CMS proposes to clarify the expected specialty assignment for a series of cardiothoracic services. Prior to the creation of the expected specialty list for low volume services in CY 2018, the Agency had finalized a crosswalk to the thoracic surgery specialty for a series of cardiothoracic services that typically had fewer than 100 services reported each year. However, CMS notes that for many of the affected codes, the expected specialty list for low volume services incorrectly listed a specialty crosswalk to cardiac surgery instead of thoracic surgery. The Agency therefore proposes to update the expected specialty list to accurately reflect the previously finalized crosswalk to thoracic surgery for 91 cardiothoracic services. CMS states that the cardiac surgery and thoracic surgery specialties are similar to one another, sharing the same practice expense (PE) per hour for PE valuation, and nearly identical malpractice (MP) risk factors for MP valuation; as a result, the Agency indicates it does not anticipate this proposal having a discernible effect on the valuation of these 91 codes.

The ACS disagrees with CMS' proposal to change the expected specialty for these 91 services from cardiac surgery to thoracic surgery for several reasons: (1) when the expected specialty list for low volume codes was first developed, the affected specialty societies specifically selected cardiac surgery as the appropriate specialty for these codes; (2) 2018 Medicare utilization data indicate that, for nearly all of the 91 applicable codes, cardiac surgery was the dominant provider; and (3) the MP risk factors differ between cardiac surgery and

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thoracic surgery, which would thereby impact reimbursement rates for the affected specialties. **We believe that the RUC, with representation from all national medical specialties and subspecialties, is the most appropriate group to maintain the expected specialty list for low volume codes, and the ACS urges CMS to refer these codes to the RUC for review of expected specialty assignment prior to finalizing any changes.**

Equipment Cost per Minute: Interest Rate

In the CY 2013 PFS final rule, CMS updated the interest rates used in developing an equipment cost per minute calculation based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Agency does not propose any changes to these interest rates for CY 2020.

The ACS does not support CMS’ continued use of the 2012 SBA maximum interest rates, which are significantly lower than the 2019 rates (as shown in the table below). Relative to the Agency’s recent pricing updates for numerous supplies and equipment items, we believe that CMS should also update the interest rates used to calculate PE RVUs for such items based on current SBA data.

SBA Maximum Interest Rates: 2012 vs. 2019

Equipment Cost	Useful Life	2012 SBA Maximum Interest Rates	2019 SBA Maximum Interest Rates ¹
<\$25K	<7 Years	7.50%	9.50%
\$25K to \$50K	<7 Years	6.50%	8.50%
>\$50K	<7 Years	5.50%	7.50%
<\$25K	7+ Years	8.00%	10.00%
\$25K to \$50K	7+ Years	7.00%	9.00%
>\$50K	7+ Years	6.00%	8.00%

Changes to Direct Practice Expense Inputs for Specific Services

Equipment Recommendations for Scope Systems

¹ Tetreault, T. (2019). SBA loan rates 2019 – Current interest rates and how they work. Retrieved from <https://fitsmallbusiness.com/sba-loan-rates/>



CMS proposes to establish 23 new scope equipment codes, along with the pricing of eight such codes for which the Agency received invoices, based on recommendations from the RUC Scope Equipment Reorganization Workgroup. CMS also proposes to replace existing scope equipment items with the eight newly-priced equipment items for approximately 100 Healthcare Common Procedure Coding System (HCPCS) codes for CY 2020. The Agency seeks comments regarding the pricing of the other 15 new scope equipment items for which it did not receive invoices, and indicates that it will transition these scopes as new equipment items in future rulemaking.

The ACS appreciates CMS' acceptance of the 23 new scope equipment codes, as well as the pricing of eight of these codes, as recommended by the RUC Scope Equipment Reorganization Workgroup. We also support the Agency's scope replacement for 100 HCPCS codes as recommended by the RUC utilizing the eight scopes that CMS was able to price. The ACS encourages CMS to continue to work with the RUC workgroup and other stakeholders to obtain detailed invoices for the scopes for which it does not have price data to assist in the correct pricing and transition of these equipment items.

Technical Corrections to Direct PE Input Database and Supporting Files

CMS proposes to correct an inconsistency in the direct PE input database per input from the RUC Scope Equipment Reorganization Workgroup, which recommended deletion of the non-facility inputs for CPT codes 43231 (Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination) and 43232 (Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)) based on specialty society feedback that these services are never performed in the nonfacility setting. **The ACS agrees with the RUC workgroup's recommendation, and we urge CMS to finalize this proposal for CY 2020.**

Updates to Prices for Existing Direct PE Inputs

Market-Based Supply and Equipment Pricing Update

In CY 2019, CMS initiated a market research contract with StrategyGen to conduct a market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing, which were last systematically developed in 2004-2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. The Agency indicated that it will use data collected by StrategyGen to update pricing over a 4-year phase-in period for all supplies and equipment items reviewed using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25

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percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. For new supply and equipment codes for which CMS establishes prices during the transition years (CYs 2019-2021), the Agency will fully implement those prices with no phase-in.

In our comments on the CY 2019 PFS, the ACS highlighted several examples of significant pricing errors or problematic recommendations made by StrategyGen that we believe should have been identified and fixed by CMS during an internal validation process. Specifically, we expressed concerns with the Agency’s changes to its pricing for the evaluation and management (E/M) visit pack (SA047), which, as we described in our response to the proposed rule, is not a traditional “pack” that is wrapped and opened for single use, but instead a convenient grouping of ten individual items that are typically used during stand-alone E/M visits. As shown in Table 1, below, the correct price for this item, based upon the contents of the pack, should be \$5.468—however, despite the ACS’ feedback, CMS finalized the StrategyGen-recommended pricing of \$7.750 for SA047 for CY 2019.

TABLE 1: Pricing for Individual Supply Items Included in SA047

CMS Code	Description	Unit	QTY	CMS 2018 Price	Extended Price	NPRM Price	Extended Price	Final Price	Extended Price
SB006	Non-Sterile, sheet 40in x 60in	item	1	\$0.222	\$0.222	\$0.130	\$0.130	\$0.130	\$0.130
SB036	Paper, Exam Table	feet	7	\$0.014	\$0.098	\$0.014	\$0.098	\$0.014	\$0.098
SB037	Pillow case	item	1	\$0.307	\$0.307	\$0.470	\$0.470	\$0.470	\$0.470
SB022	Gloves, non-sterile	pair	2	\$0.084	\$0.168	\$0.300	\$0.600	\$0.300	\$0.600
SM025	Specula tips, otoscope	item	1	\$0.030	\$0.030	\$0.450	\$0.450	\$0.450	\$0.450
SK062	Patient education booklet	item	1	\$1.550	\$1.550	\$2.800	\$2.800	\$2.800	\$2.800
SB026	Gown, patient	item	1	\$0.533	\$0.533	\$3.540	\$3.540	\$0.590	\$0.590
SJ053	Swab-pad, alcohol	item	2	\$0.013	\$0.026	\$0.040	\$0.080	\$0.040	\$0.080
SB004	Cover, Thermometer	item	1	\$0.038	\$0.038	\$0.220	\$0.220	\$0.220	\$0.220
SJ061	Tongue depressor	item	1	\$0.012	\$0.012	\$0.030	\$0.030	\$0.030	\$0.030
	Total				\$2.984		\$8.418		\$5.468

In this proposed rule, CMS indicates that it was alerted by stakeholders that the price of the SA047 supply did not match the sum of the component prices of the supplies included in the pack. The Agency states that, after reviewing the prices



of the individual component supplies, it agrees there was a discrepancy in the previous pricing of SA047, and proposes to update the price of the EM visit pack to \$5.47 to reflect the prices of the pack contents. CMS would transition towards this price over the remaining years of the phase-in period (see Table 2).

TABLE 2: Proposed CY 2020 Market-Based Supply and Equipment Pricing Updates

CMS Code	Description	CMS 2019 Price	Prior CMS 2020 Price	Prior CMS 2022 Price	Updated CMS 2020 Price	Updated CMS 2020 Price
SA047	Pack, E/M visit	\$4.176	\$5.367	\$7.750	\$4.606	\$5.468

The ACS thanks CMS for acknowledging stakeholders’ input on the pricing of SA047 and correcting this error. However, we remain concerned that other bundled supply items (i.e., kits, trays, and packs) may have been similarly mispriced by StrategyGen, and request that CMS make available the contents of all supply kits, trays, and packs to facilitate both stakeholder and RUC PE Subcommittee review. Without details about the pricing for individual component supplies included by StrategyGen in bundled items, we cannot assist CMS in correcting supply codes that may have been incorrectly priced by StrategyGen.

Determination of Malpractice Relative Value Units

Section 1848(c)(2)(B)(i) of the Social Security Act requires that CMS review and adjust resource-based MP RVUs no less often than every 5 years. In the CY 2015 PFS final rule, the Agency implemented its third update of MP RVUs. In CY 2018, CMS proposed to use the most recent professional liability insurance (PLI) premium data obtained by its contractor, Acumen, to update the specialty risk factors used in calculation of the MP RVUs prior to the next mandated update; however, this proposal was ultimately not finalized for CY 2018 following extensive stakeholder feedback citing concerns about the accuracy of the premium data. CMS must conduct the next statutorily required 5-year review and update of MP RVUs in CY 2020.

In this proposed rule, the Agency solicits feedback on its proposed methodological refinements to the collection of the PLI premium data used to develop the proposed CY 2020 MP RVUs. **The ACS appreciates the additional work that CMS has undertaken to respond to our previous comments about the lack of sufficient premium data collection but remains concerned that any MP RVU updates made using the new methodology and related specialty crosswalks proposed by the Agency will unfairly reduce payments for**



providers who regularly furnish surgical services. Our specific concerns with the CMS' MP RVU update methodology, along with our recommendations to improve this methodology, are described below. **We urge CMS to address and correct these issues before finalizing any changes to MP RVUs.**

- Major versus minor surgery premiums. For the CY 2020 MP RVU update, the Agency proposes to combine minor surgery and major surgery premiums to create the surgery service risk group, which CMS asserts would yield a more representative surgical risk factor. In the CY 2015 update, only premiums for major surgery were used in developing the surgical risk factor. CMS considers surgical services with physician work RVUs greater than 5.00 as “major surgeries” for this analysis.

We believe that the Agency’s definition of “major” surgery is arbitrary and may have led to undervaluation for certain specialties and codes— such irregularities are evident in the data included in the *CY 2020 Medicare PFS Proposed Update to the GPCIs and PLI RVUs Interim Report* provided by CMS’ contractor, Actuarial Research Corporation. For example, in the *Interim Report* Table 8.B (Volume-Weighted Distribution of 2019 Physician Work RVUs by Service Risk Type by CMS Specialty), Neurosurgery’s share of total work RVUs for the “no surgery” service risk type is nearly 70 percent; Neurology is assigned that same percentage for “no surgery.” Similarly, Cardiac Surgery’s share of total work RVUs for “no surgery” is 80 percent, while Thoracic Surgery’s work RVU share is significantly lower at 18 percent for this same service risk type, despite the comparable amount of surgical care provided by cardiac and thoracic surgeons.² The Cardiac Surgery distributions of “no surgery” RVUs as a share of work are inexplicably identical to that of Cardiology.

Given these distortions in work RVU assignments, the ACS questions if surgical and non-surgical RVU data were combined and applied for both specialties (Neurosurgery/Neurology and Cardiac Surgery/Cardiology), or if the non-surgical specialty data were instead crosswalked to the surgical specialties. No matter how such RVU distributions were developed, the methodology used by CMS and Actuarial Research Corporation is clearly flawed, as the surgical risk factors for neurosurgeons and cardiac surgeons are undoubtedly greater than that for neurologists and cardiologists, respectively.

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² Actuarial Research Corporation. (2019). *CY 2020 Medicare PFS proposed update to the GPCIs and MP RVUs: Interim report*. Baltimore, MD: Centers for Medicare & Medicaid Services.



To address these issues, we ask that CMS:

- Upload the detailed data for Table 8.B to its website so that all stakeholders can see how Actuarial Research Corporation developed these work RVU percentage distributions;
 - Review the data used by Actuarial Research Corporation to produce Table 8.B and assure that each specialty's attribution of work RVUs is calculated and assigned correctly;
 - Include any ZZZ add-on codes that are reported with a major procedure to the “major surgery” service risk group, even if the work RVUs for such codes are less than 5.00; and
 - Properly collect distinct premium data for both major and minor surgery if the Agency intends to continue to separate and utilize the RVUs from both categories for computations of malpractice RVUs.
- Imputation of premiums. We recognize that CMS has worked to collect more robust PLI premium information, but we remain concerned with the crosswalk imputations made by the Agency for certain specialties with insufficient data. CMS proposes to use partial and total imputation within its premium data set when CMS specialty names are not distinctly identified in the insurer filings, which sometimes use unique specialty names. In instances where insurers report data for some (but not all) specialties that explicitly corresponded to a CMS specialty, where those data were missing, the Agency would use partial imputation based on available data to establish what the premiums would likely have been had that specialty been delineated in the filing. In instances where there are no data corresponding to a CMS specialty in the filing, the Agency would use total imputation to establish premiums.

CMS states, for example, if a specialty of Sleep Medicine is listed on the insurer's rate filing, this rate will be matched to the CMS specialty Sleep Medicine. However, if the Sleep Medicine specialty is not listed on the insurer's rate filing, under this proposed methodology, the insurer's rate filing for General Practice would be matched to the CMS specialty of Sleep Medicine, as CMS believes General Practice is likely to be consistent with the rate that a Sleep Medicine provider would be charged by that insurer.

The ACS believes that incorrect crosswalks are being implemented, and we recommend that the Agency attempt to utilize any and all premium data available to determine accurate crosswalks for specialties that cannot be directly matched to one of CMS' specialty names. Per CMS' example, if Sleep Medicine premium data are available in any state(s), we ask that CMS compare those data to multiple other specialties to determine which

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have the rate filings most similar to Sleep Medicine—in this scenario, we believe that the work performed by Sleep Medicine physicians is likely more consistent with that of Neurology, and therefore would not be most similar to General Practice physicians as indicated by CMS. The Agency could verify such similarities by comparing available state data that includes premium information for all three specialties. **Most notably, we are concerned with the partial imputation crosswalks included in Table 8.C.1 of the Actuarial Research Corporation *Interim Report*, below.**

Source Specialty/Service Risk Group for Partial Imputation for Proposed PLI Premium Data³

CMS Specialty/Service Risk Group	CMS Specialty/Service Risk Group Used as a Source for Imputation
06-Cardiology (SURG)	78-Cardiac Surgery (ALL)
78-Cardiac Surgery (ALL)	06-Cardiology (SURG)
13-Neurology (SURG)	14-Neurosurgery (ALL)
14-Neurosurgery (ALL)	13-Neurology (SURG)
23-Sports Medicine (ALL)	08-Family Practice (NO SURG)
76-Peripheral Vascular Disease (ALL)	77-Vascular Surgery (ALL)
91-Surgical Oncology (ALL)	02-General Surgery (ALL)
C0-Sleep Medicine (ALL)	01-General Practice (NO SURG)

- Cardiology (SURG) and Cardiac Surgery (ALL) will not have the same MP premiums due to different levels of surgical risk between the two specialties. If a state does not have sufficient or any premium data for either of these specialties, CMS should not impute a value using a non-comparable specialty premium. **We recommend instead that CMS use available Cardiac Surgery and Cardiology premium data from the insurance rate filings provided by neighboring states or states of similar size to determine distinct premiums for the two specialties.**
- Neurology (SURG) and Neurosurgery (ALL) will not have the same MP premiums due to different levels of surgical risk between the two specialties. If a state does not have sufficient or any premium data for either of these specialties, CMS should not impute a value using a non-comparable specialty premium. **We recommend instead that CMS use available Neurology and Neurosurgery premium data from the**

³ Actuarial Research Corporation. (2019). *CY 2020 Medicare PFS proposed update to the GPCIs and MP RVUs: Interim report*. Baltimore, MD: Centers for Medicare & Medicaid Services.



insurance rate filings provided by neighboring states or states of similar size to determine distinct premiums for the two specialties.

- *Sports Medicine (ALL)* physicians are more likely to be orthopedic surgeons and perform surgical procedures, as evidenced by the fact that more than 50 percent of the specialty’s total work RVUs are attributed to “minor surgery” and “major surgery.” Therefore, it is not appropriate to crosswalk this specialty to *General Practice (NO SURG)*, the premiums of which do not include surgical risk. **We recommend instead that: (1) CMS split Sports Medicine into “SURG” and “NO SURG” service risk groups, (2) use *Orthopedic Surgery (ALL)* for imputing premium data for Sports Medicine (SURG), and (3) use *Internal Medicine (ALL)* for Sports Medicine (NO SURG).** **Alternatively, CMS could use available Sports Medicine premium data from the insurance rate filings provided by neighboring states or states of similar size to determine distinct premiums for this specialty.**
- *Peripheral Vascular Disease (ALL)* physicians are more likely to be phlebologists who focus on vein and lymphatic illnesses and perform minor, office-based surgical procedures, as evidenced by the fact that more than 50 percent of the specialty’s total work RVUs are attributed to “no surgery.” Therefore, it is not appropriate to crosswalk this specialty to *Vascular Surgery (ALL)*, for which more than 50 percent of the specialty’s total work RVUs are attributed to “minor surgery” and “major surgery.” **We recommend instead that CMS use *Family Practice (SURG)* or *Internal Medicine (ALL)* for imputing premium data or available Peripheral Vascular Disease premium data from the insurance rate filings provided by neighboring states or states of similar size to determine distinct premiums for this specialty.**
- *Surgical Oncology (ALL)* should not be crosswalked to *General Surgery (ALL)*. Although general surgeons may operate on patients with cancer, their overall practice is not specific to cancer. In contrast, most procedures performed by surgical oncologists are cancer-related, and as such, these physicians carry a different risk than that of a general surgeon; this imputation thereby creates a situation where the inherently higher malpractice risk of cancer surgery is no longer considered when calculating the MP RVUs for surgical oncologists. **We recommend instead that CMS crosswalk Surgical Oncology (ALL) to *Gynecologist/Oncologist (ALL)*, as both specialties represent surgeons who primarily treat cancer patients and would therefore have similar premiums and risks.** This can be confirmed by

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reviewing premium data for both specialties in states where these data are available.

- *Sleep Medicine (ALL)* should not be crosswalked to *General Practice (NO SURG)*. Sleep medicine physicians are typically neurologists, and would thereby likely have similar premiums as neurologists. However, as noted separately above, we disagree that Neurology premiums are equivalent to Neurosurgery premiums; **as such, we recommend that CMS refrain from crosswalking sleep medicine physicians to neurologists using partial imputation until the Neurology/Neurosurgery issue is resolved.**

The ACS urges CMS to review these proposed crosswalks and consider alternative methodologies to impute premium data.

- Premium rates for non-physician specialties. In our comments on the CY 2019 PFS proposed rule, we objected to CMS' continued crosswalking of non-physician providers (NPP) to a physician specialty (i.e., Allergy/Immunology) if premium data for such NPP specialties were not robust enough to be used in previous computations. We are pleased to see that, for the CY 2020 update, Actuarial Research Corporation has been able to collect sufficient premium data for several NPP specialties. These data confirm what the ACS has previously conveyed to CMS: NPP premiums are much less than physician premiums.

We also note that many NPP professional societies advertise various PLI companies online. Data provided by these companies could help inform CMS' review of MP RVUs. For example, the American Physical Therapy Association promotes PLI plans administered by a company called the Healthcare Providers Service Organization (HPSO). On its website, HPSO states that malpractice insurance can be "as low as \$157 per year."^{4,5} While it is likely that a premium rate of \$157 is not typical, it is also likely that the premium rate for physical therapists is not equal to that for allergy/immunology physicians.

⁴ American Physical Therapy Association. (2016). Professional liability insurance for PTs, PTAs, and students. Retrieved from <https://www.apta.org/Benefits/Insurance/ProfessionalLiability/>

⁵ Healthcare Providers Service Organization. (2019). Professional liability insurance for healthcare professionals. Retrieved from <http://www.hpso.com/individuals/professional-liability-insurance?refID=WL445j>

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Given that CMS now has premium data for several NPP specialties, the ACS recommends that CMS crosswalk NPP specialties without sufficient premium data to other NPP specialties with premium data instead of crosswalking to Allergy/Immunology. Below are our suggested crosswalks for various NPP specialties.

Proposed for CY 2020				ACS Recommended for CY 2020			
Spec. Code	Specialty Name	Risk Factor	Normalized Premium Rate	Spec. Code	Specialty Name	Risk Factor	Normalized Premium Rate
62	Psychologist	1.00	\$8,896	35	Chiropractic	0.52	\$4,603
68	Clinical Psychologist	1.00	\$8,896	35	Chiropractic	0.52	\$4,603
15	Speech Language Pathology	1.00	\$8,896	41	Optometry	0.17	\$1,539
45	Mammography Screening Center	1.00	\$8,896	41	Optometry	0.17	\$1,539
47	Independent Diagnostic Testing Facility	1.00	\$8,896	41	Optometry	0.17	\$1,539
63	Portable X-Ray Supplier	1.00	\$8,896	41	Optometry	0.17	\$1,539
64	Audiologist	1.00	\$8,896	41	Optometry	0.17	\$1,539
65	Physical Therapist	1.00	\$8,896	41	Optometry	0.17	\$1,539
67	Occupational Therapist	1.00	\$8,896	41	Optometry	0.17	\$1,539
69	Clinical Laboratory	1.00	\$8,896	41	Optometry	0.17	\$1,539
71	Registered Dietitian/ Nutrition Professional	1.00	\$8,896	41	Optometry	0.17	\$1,539
75	Slide Preparation Facilities	1.00	\$8,896	41	Optometry	0.17	\$1,539
80	Licensed Clinical Social Worker	1.00	\$8,896	41	Optometry	0.17	\$1,539

Potentially Misvalued Services under the PFS

CY 2020 Identification and Review of Potentially Misvalued Services

Public Nominations

CMS received a stakeholder request that it consider CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*) for nomination as potentially misvalued. The Agency notes that this fine needle aspiration (FNA) code was recently reviewed by the RUC. CMS did not accept the RUC-recommended work RVU of 1.20 for code 10021, stating that the intra-service time for this code decreased by 12 percent (from 17 to 15 minutes), and that total



time for this service decreased by 32 percent (from 48 to 33 minutes). The Agency asserted that the work RVU as recommended by the RUC did not reflect this decrease in time, and thereby finalized a work RVU of 1.03 based on a direct crosswalk to code 36440 (*Push transfusion, blood, 2 years or younger*).

The ACS supports the addition of code 10021 to the list of potentially misvalued services for review by the RUC, and wishes to reiterate that we do not agree with CMS' valuation of code 10021 as finalized in the CY 2019 PFS for the following reasons:

- ***Crosswalk code:*** Code 36440 is not a service with similar work when compared with code 10021. Code 36440 is used to report a push transfusion of blood through an already established access in a vessel and does not carry the same risk and intensity as code 10021, which involves accessing a lesion in the neck multiple times to aspirate biopsy specimens.
- ***Changes in service time:*** CMS used outdated information to track changes in time for code 10021. In 1995, the RUC surveyed code 88170 (*Fine needle aspiration with or without preparation of smears; superficial tissue (e.g., thyroid, breast, prostate)*), and the Agency incorrectly used time data obtained from this survey to calculate reductions in service time for code 10021 (*Fine needle aspiration; without imaging guidance*), which replaced code 88170 when it was deleted in 2002—there is a clear difference in the descriptors for these two codes. Further, codes 88170 and 88171 (*Fine needle aspiration with or without preparation of smears; deep tissue under radiologic guidance*) were located in the Anatomic Pathology section of the CPT code book with technical component (TC)/professional component (PC) assignments and a Medicare type of service indicator of “5” (diagnostic laboratory) when last reviewed in 1995. As indicated in the RUC database rationale, the time recorded from the 1995 survey is based on Medicare frequency weight averaged time, or time jointly agreed upon by the specialty societies that developed the work recommendation. At the time that the RUC reviewed the original specialty societies' work recommendations, the RUC allowed multiple recommendations for a single code. Code 88170 was surveyed only by radiologists and endocrinologists, who together represented less than 7 percent of the total utilization of code 88170 in 1995; 2017 survey data show that radiologists and endocrinologists now represent less than 4 percent of total utilization of code 10021. Therefore, we believe that the time data obtained from non-typical providers for a code with a significantly different descriptor in 1995 are not valid. **CMS should not have relied on changes in time from a 1995 survey of a diagnostic laboratory code with PC/TC indicators as a rationale for finalizing a work RVU that was significantly lower than the RUC's recommendation.**

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- TC/PC designations and global period: Although codes 88170 and 88171 were replaced by codes 10021 and 10022 (*Fine needle aspiration; with imaging guidance*) in 2002, and subsequently moved from the Pathology and Laboratory Section of the CPT code book to the Surgery Section, the TC/PC designation was maintained until 2003; the removal of the TC/PC designation was not discussed in the CY 2003 PFS proposed or final rules. Although the CPT Editorial Panel recognized that codes 88170 and 88171 were misplaced in the CPT code book in 2002 and created new codes 10021 and 10022, and CMS recognized that these services should not have a TC/PC designation in 2003, CMS has maintained an XXX global designation and both the Agency and the RUC referenced XXX global codes to recommend values for codes 10021 and 10022. The ACS wishes to highlight that CMS changed the multiple procedure indicator from “0” to “2” for all FNA biopsy initial lesion codes for CY 2019, which is consistent with the indicator assigned for invasive procedures. **Therefore, we believe using XXX global codes as references is incorrect and instead recommend that CMS review similar minor procedures that have a 0-day global assignment when considering the appropriate valuation for FNA biopsy codes.**

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act establishes a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) for episodes of care beginning on or after January 1, 2020. Historically, there has been a gap in Medicare coverage of OUD treatment services, and CMS anticipates current OTPs may expand access to care for Medicare beneficiaries since they will be able to receive payment from Medicare for care furnished to beneficiaries when they previously were unable to do so. The Agency proposes to create bundled payments for OUD treatment services which would include the medications approved by the Food & Drug Administration (FDA) for use in the treatment of OUD; the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing.

The United States faces a significant opioid epidemic, and the ACS applauds CMS’ proposal to establish new payment methodologies for OUD treatment services in an effort to reduce opioid-related patient harm and improve access to therapies for beneficiaries recovering from opioid addiction.

However, we note that CMS has not specified when a patient is considered to have “entered” an OTP or when the patient is considered to have “exited” the

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OTP. We ask that CMS clarify the parameters of OTPs so that patients, providers, and insurers know when the patient is currently in—or not in—the program, which determines how the care the patient receives is paid for. In addition, we ask that CMS produce a comprehensive list of specific services that are covered within OTPs, along with guidance about what services are not included under OTP payment and should be reported separately. We also question whether there will be additional payment (e.g., through an add-on code) for surgeons who engage in care coordination activities for postoperative patients entering OTPs or whether this extra work will be included in the global surgical package. **We urge CMS to address these issues before implementing its OTP payment policies.**

Physician Supervision for Physician Assistant Services

CMS proposes to update the regulation at § 410.74 that establishes physician supervision requirements for physician assistants (PAs); specifically, the Agency would revise § 410.74(a)(2) to provide that the statutory physician supervision requirement for PA services at section 1861(s)(2)(K)(i) of the Social Security Act would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services.

The ACS appreciates that these proposed revisions to physician supervision requirements for PAs, if finalized, would align state oversight capabilities with CMS' current regulations on state oversight of physician collaboration for nurse practitioner and clinical nurse specialist services. We encourage the Agency to engage with stakeholders to obtain additional feedback regarding the role of NPPs as members of the medical team to inform rulemaking that ensures an appropriate level of physician oversight occurs when NPPs furnish their professional services to Medicare beneficiaries.

Review and Verification of Medical Record Documentation

CMS proposes to establish a general principle to allow a physician, PA, or advanced practice registered nurse (APRN) who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students, or "other members of the medical team." This policy would apply across the spectrum of all Medicare-covered services paid under the PFS in all settings.

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We appreciate the Agency’s efforts to reduce documentation burden and replication of effort for clinicians, but we are concerned that this proposal does not include enough safeguards to ensure provider accountability, data integrity, and patient safety. The ACS supports this revision to *physician* medical record documentation requirements—which expand on a similar policy finalized specifically for teaching physicians in the CY 2019 PFS—for CY 2020, but asks that CMS withhold any changes to documentation requirements for *PAs and APRNs* until the Agency establishes guidelines in future rulemaking that clarify the circumstances under which an NPP would be permitted to review and verify medical records, such that NPPs may only sign off on notes made in the medical record by clinicians of the same provider type (e.g., a PA may only review and verify information included in a patient’s chart by another PA or a PA student).

Care Management Services

Principal Care Management Services

For CY 2020, CMS proposes separate coding and payment for Principal Care Management (PCM) services, which describe care management services for one serious chronic condition. Payment for PCM services would be made via two new G-codes:

- GPPP1 (*Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities*) would be reported when, during a calendar month, at least 30 minutes of physician or other qualified health care provider time is spent on comprehensive care management for a single high risk disease or complex chronic condition.
- GPPP2 (*Comprehensive care management for a single high-risk disease services, e.g., Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: one complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is*

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of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities) would be reported when, during a calendar month, at least 30 minutes of clinical staff time is spent on comprehensive management for a single high risk disease or complex chronic condition.

We believe that this proposal is best reviewed by the CPT Editorial Panel and urge CMS to delay implementation of the PCM G-codes for CY 2020.

CMS proposes these time-based PCM codes concurrently with its proposal to create add-on codes for evaluation and management (E/M) office visits for a very similar patient, and we question how GPPP1 and GPPP2 fit into the structure of the new E/M coding paradigm. In addition, there may be other codes that capture the work performed for these patients, including office visit codes, brief communication technology-based service codes, interprofessional consultation codes, remote patient monitoring codes, among others. It is critical that PCM services be appropriately described without overlap with other services, and we ask that CMS create a vignette describing the typical patient and description of service for GPPP1 and GPPP2 to justify why no existing codes (or modifications to existing codes) would cover such work. In addition, CMS has not specified what other codes can and cannot be reported with GPPP1/GPPP2, and we are concerned that the lack of clear guidance on the billing rules for these proposed G-codes would result in misreporting or abuse.

The ACS recommends that a CPT coding application for GPPP1/GPPP2 be submitted for consideration at the February 2020 CPT meeting and, if adopted, be surveyed for resource costs for the April 2020 RUC meeting. In general, we maintain that CMS should work with the CPT Editorial Panel to create CPT codes, rather than G-codes, as it is administratively burdensome for physicians to transition back and forth between CPT and G-codes, particularly because G codes do not provide important informational or exclusionary billing guidelines.

Coinsurance for Colorectal Cancer Screening Tests

CMS seeks comment on whether it should consider establishing a requirement that a physician who plans to furnish a colorectal cancer screening notify the patient in advance that a screening procedure could result in a diagnostic procedure if polyps are discovered and removed, and that coinsurance may apply.

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We appreciate the Agency’s efforts to educate physicians and beneficiaries about cost sharing obligations in order to mitigate instances of surprise billing, but do not support CMS’ proposal to shift additional burden on to physicians through a new reporting requirement. The ACS believes that the onus is on CMS—not on physicians—to inform its beneficiaries about any potential out-of-pocket expenses. However, we wish to highlight that many physicians do choose to conduct patient education regarding coinsurance, and we encourage the Agency to develop materials for distribution by physician offices that include a complete description of the Medicare preventive services benefits, including information on colorectal cancer screening, and relevant details on the applicability of cost sharing.

Valuation of Specific Codes

Tendon Sheath Procedures (CPT codes 26020, 26055, and 26160)

The RUC identified three tendon sheath procedures through a screen of services with a negative intrawork per unit time (IWPUT) and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes—this is a clear indication that the time/visit data or the work RVUs (or a combination of both) are incorrect for such codes. Consequently, revaluation of such codes should be based on a correct relative work RVU that considers both time and visits from a current survey, rather than flawed data from previous surveys.

- CPT code 26020 (*Drainage of tendon sheath, digit and/or palm, each*): CMS disagrees with the RUC-recommended work RVU of 7.79 based on the survey median for code 26020. The Agency indicates that, while it agrees that the survey data validate an increase in work RVU, it does not see a compelling reason that this service would be significantly more intense to furnish than services of similar time values. CMS therefore proposes a work RVU of 6.84, which is the survey 25th percentile.

We do not support CMS’ proposed value for code 26020. The Agency states that code 26020 should be valued similarly to code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant, [work RVU = 6.90]*), noting that both codes have the same intra-service time of 45 minutes. **However, the ACS wishes to highlight that CMS has overlooked the fact that the total time for code 26020 (262 minutes) is 20 percent greater than the total time for code 28289 (210 minutes); this difference in total time is reflective of the difference in postoperative work required for each service.** Code 26020 requires significant and careful monitoring of a patient

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that has been admitted to the hospital with a tendon sheath infection, which can escalate and result in the loss of the digit. Consultations with infectious disease specialists, inpatient bedside assessment and treatment, and review of interval notes by other providers reflect some of the necessary care that exceeds the care required for a patient undergoing the bunion repair procedure described by code 28289. Such patients are typically discharged on the same day as the procedure from an outpatient hospital department or ambulatory surgery center (ASC). The 20 percent greater amount of total time and additional inpatient care required for code 26020 clearly indicate that this code should be valued greater than code 28289.

CMS also references code 28122 (*Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus*, [work RVU = 6.76]) as a comparator for code 26020. Similar to the comparison with 28289, the total time and work for code 28122 is less than code 26020, reflective of the typical patient that is discharged the same day or after a less than 23-hour stay (i.e., inpatient care is not typical).

Further, the RUC specifically stated in its recommendation to CMS that valuing code 26020 at the survey 25th percentile would vastly underestimate the physician work required for this service, resulting in an IWPUT of 0.006 (i.e., zero). This widens the gap and skews the relativity to the RUC reference codes 26615 (IWPUT = 0.044) and 33207 (IWPUT = 0.047), along with CMS' reference codes 28289 (IWPUT = 0.044) and 28122 (IWPUT = 0.033). Even at the survey median IWPUT of 0.027 for code 26020, this value is so low that there are no comparator codes with a lower work RVU and similar IWPUT. **The ACS urges CMS to consider this additional information and accept the RUC-recommended work RVU of 7.79 for 26020.**

- CPT code 26055 (*Tendon sheath incision (e.g., for trigger finger)*): CMS disagrees with the RUC recommendation to increase the work RVU to the survey 25th percentile of 3.75 for code 26055. The Agency instead proposes to maintain the current work RVU of 3.11 based on a total time increment methodology between the codes 26020 and 26055.

We do not support CMS' proposed value for code 26055. CMS asserts that the physician time for 26055 has decreased, and as such, believes that such a reduction in time should correlate with a reduction in work RVUs. However, the current *times* for this code are based on a 2005 survey, but the current *work RVU* is based on the Harvard study—CMS should not compare the time relative to the work RVU for 26055, as these two data points are disconnected. In addition, we strongly disagree with CMS' use of the total

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time increment methodology in its valuation of this code. Codes 26055 and 26020 are distinct 90-day global period codes, not a base code and add-on service. CMS' proposed work RVU of 3.11 for code 26055 results in an IWP/UT of 0.011, a number so low that it is difficult to find another major procedure with such an intensity for comparison. An IWP/UT of 0.011 does not reflect an open surgical procedure typically performed in an ASC or other outpatient facility under moderate sedation. CMS should carefully consider the clinical information justifying the changes in physician work intensity provided by the RUC, and should examine this service de novo.

We also note that a work RVU of 3.11 for 119 minutes of physician total time is significantly undervalued compared to the CMS proposed work RVU of 3.50 for code 99205, which includes only 60-74 minutes of both physician and health care professional (QHP) face-to-face and non-face-to-face time. The work per unit time (WPUT = work RVU/total time) of 0.026 for code 26055 resulting from CMS' proposed work RVU of 3.11 clearly indicates that the value CMS is proposing is not relative. Even the survey 25th percentile work RVU of 3.75 results in a lower WPUT for code 26055 (0.032) compared with the WPUT for code 99205 (0.041). We do not believe that the work intensity for code 99205, an office visit, is 28 percent greater than the work intensity of code 26055, a major surgical procedure. **The ACS urges CMS to consider this additional information and accept the RUC-recommended work RVU of 3.75 for code 26055.**

- CPT code 26160 (Excision of lesion of tendon sheath or joint capsule (e.g., cyst, mucous cyst, or ganglion), hand or finger): CMS proposes to accept the RUC-recommended work RVU of 3.57 for code 26160. **The ACS appreciates that CMS recognizes that the RUC-recommended work RVU is the correct value for code 26160 relative to other codes in the PFS.**
- Direct PE inputs for codes 26055 and 26160: CMS proposes to refine the quantity of the impervious staff gown (SB027) supply from 2 to 1 for codes 26055 and 26160, asserting that the second impervious staff gown supply is duplicative due to the inclusion of this same supply in the surgical cleaning pack (SA043). The Agency notes that the RUC-recommended direct PE details state that a gown is worn by the surgeon and one assistant, which are reflected by one standalone gown and a second gown included in the surgical cleaning pack.

We do not support CMS' proposed PE supply change for codes 26055 and 26160. Cleaning surgical instruments does not occur in the operating room, but instead is performed in a separate room that contains the necessary chemicals, sinks and basins for removing contaminants, along with the

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supplies and equipment needed for packaging and sterilizing the cleaned instruments. This activity will never be carried out in an operating room. Protective clothing will be required for the cleaning work, which is why SA043 includes an impervious gown. In addition, we note that it is also typical that the clinical staff assisting with a procedure will continue to attend to the patient in the operating room during recovery, and that a different clinical staff person will attend to cleaning the instruments as cleaning of contaminants needs to be accomplished as soon as possible after the procedure. **The ACS urges CMS to consider this additional information and maintain the RUC-recommended quantity of two impervious staff gowns (SB027) for codes 26055 and 26160.**

Exploration of Artery (CPT codes 35701, 35X00, and 35X01)

CMS proposes to accept the RUC-recommended work RVU of 7.50 for code 35701 (*Exploration not followed by surgical repair, artery; neck (e.g., carotid, subclavian)*), work RVU of 7.12 for code 35X00 (*Exploration not followed by surgical repair, artery; upper extremity (e.g., axillary, brachial, radial, ulnar)*), and work RVU of 7.50 for code 35X01 (*Exploration not followed by surgical repair, artery; lower extremity (e.g., common femoral, deep femoral, superficial femoral, popliteal, tibial, peroneal)*). **The ACS appreciates that CMS recognizes that the RUC-recommended work RVUs are the correct values for codes 35701, 35X00, and 35X01 relative to other codes in the PFS.**

Intravascular Ultrasound (CPT codes 37252 and 37253)

CMS disagrees with the RUC-recommended work RVU of 1.80 for code 37252 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel*) and work RVU of 1.44 for code 37253 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel*), which describe intravascular ultrasound (IVUS) services. The Agency instead proposes a work RVU of 1.55 for code 37252 and a work RVU of 1.19 for code 37253. CMS states that the initial bundling of IVUS services and utilization estimates were intended to result in an overall work savings that should have been redistributed back to the Medicare conversion factor. The Agency notes that the observed utilization has greatly exceeded estimates, and CMS believes it can restore work neutrality to achieve the initial estimated savings by reducing the value of codes 37252 and 37253.

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We do not support CMS’ proposed values for codes 37252 and 37253, and disagree with the Agency’s logic for decreasing the work RVUs for these codes. CMS fails to acknowledge that the original utilization estimate was based on data available at that time, which only reflected facility claims because the codes were not priced in the office setting. More importantly, CMS ignores the fact that the work RVUs for these bundled codes are less than those for the previously separately-reported IVUS services. Therefore, on a code-by-code basis, the work RVUs for codes 37252 and 37253 represent savings from the previously unbundled IVUS services. We also wish to highlight that CMS accepted the RUC-recommended work RVUs for codes 37252 and 37253 in the CY 2016 PFS. The work of these services has not changed since that time, which is confirmed by the recent re-survey.

If these codes had not been bundled, and instead CMS had approved office pricing for the ultrasound services, the issue of “savings” would not have been a factor. As such, we do not understand CMS’ rationale that the code values should be reduced to achieve work neutrality. The Agency’s proposal to make RVU reductions when survey time and work RVU estimates did not change for 37252 and 37253 is contrary to the relativity of the PFS. It is not appropriate to simply reduce the work RVUs for any code that has an increase in utilization. **The ACS urges CMS to consider this additional information and maintain the current work RVUs for codes 37252 and 37253.**

Stab Phlebectomy of Varicose Veins (CPT codes 37765 and 37766)

CMS proposes to accept the RUC-recommended work RVUs of 4.80 for code 37765 (*Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions*) and 6.00 for code 37766 (*Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions*). We thank CMS for accepting specialty society recommendations that the global period for these codes be changed from 90-days to 10-days, which is consistent with many families of codes that typically only require a single postoperative visit within 10 days to perform a wound check and remove sutures. **The ACS appreciates that CMS recognizes that the RUC-recommended work RVUs are the correct values for 37765 and 37766 relative to other 10-day global codes in the PFS.**

Transanal Hemorrhoidal Dearterialization (CPT codes 46945, 46946, and 46X48)

CMS proposes to accept the RUC-recommended work RVU of 3.69 for code 46945 (*Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group, without imaging guidance*), work RVU of 4.50 for code 46946 (*2 or more hemorrhoid columns/groups, without imaging guidance*),

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and work RVU of 5.57 for code 46X48 (*Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy when performed*). **The ACS appreciates that CMS recognizes that the RUC-recommended work RVUs are the correct values for codes 46945, 46946, and 46X48 relative to other codes in the PFS.**

Pelvic Packing (CPT codes 490X1 and 490X2)

- CPT code 490X1 (Preperitoneal pelvic packing for hemorrhage associated with pelvic trauma, including local exploration): CMS disagrees with the RUC-recommended survey median work RVU of 8.35 for code 490X1. The Agency instead proposes a lower work RVU of 7.55, which is less than the survey 25th percentile, based on a direct work RVU crosswalk to code 52345 (*Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (e.g., balloon dilation, laser, electrocautery, and incision)*). CMS asserts that a procedure's postoperative time should not be greater than its intraoperative time, and therefore proposes to arbitrarily reduce the postoperative survey time of 60 minutes to 45 minutes. The Agency indicates that only 28 out of the 1,100 codes with a 0-day global period have a postoperative time that exceeds the intraoperative time.

We do not support CMS' proposed value for code 490X1 and disagree with the Agency's comparison of the total work for this code to that of code 52345. The typical patient for code 490X1 is a critically injured, emergent patient, and the pelvic packing procedure is usually performed as expeditiously as possible to avoid a hemorrhagic death of the patient. As such, it is clear that code 52345 is an inappropriate comparison code for 490X1, since code 52345 is an elective outpatient operation and not an emergent procedure performed on a patient that is hemodynamically unstable. Although the intraoperative time is the same for both codes, the intensity of work for code 490X1 is considerably greater. As stated in the additional rationale section of the RUC Summary of Recommendation (SOR) form for this service, code 490X1 was developed to assist in the reporting of work performed by U.S. military medical personnel at military bases overseas and on battlefields around the world. This procedure may also be performed for battle wound-type injuries, such as those sustained during the mass casualty event at the Boston marathon in 2013. This is not a common or elective procedure similar to code 52345, and should never be considered as such.

We also disagree with CMS' comparison of the postoperative time for code 490X1 to other 0-day global procedures without consideration of the

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type of work that is required for this code. There are less than 800 0-day global codes that have been reviewed by the RUC (i.e., CMS' count of 1,100 includes codes that have not been reviewed). We note that almost 240 of those 800 0-day global procedures are endoscopy services performed electively under moderate sedation in a hospital outpatient department, ASC, or office setting. The work and time to discharge a patient from an endoscopy suite is not the same as postoperatively caring for a hemodynamically-unstable patient, who is considered to be in critical condition in the operating room, the recovery room, and the intensive care unit through midnight on the day of the procedure.

Further, 125 of the 800 0-day global procedures include simple injections, biopsies, casting/strapping services, trimming nails, simple repair of wounds, and osteopathic and chiropractic services. Most of these services are performed a majority of the time in an office setting and would not include significant postservice time. Thus, it is inappropriate and incorrect to equate code 490X1 to these types of 0-day global codes for purposes of reviewing postoperative time. For the remaining 0-day global services, only the tracheostomy codes represent procedures with comparable intensity to code 490X1; however, once a tracheostomy is performed, the patient will not require significant postoperative care related to the procedure, as the airway has been established and ventilation is assured.

To support the postoperative time proposed by the RUC for code 490X1, the affected specialty societies and the RUC both agreed that the typical patient will still be unstable and their hemodynamic status will be monitored very closely for more than the 10 minutes included in the postoperative package for monitoring patient recovery; during this time, significant coordination with other treating physicians, surgeons, and ICU staff will be necessary. Time for this activity is not included in the postoperative package, and the RUC agreed that a total of 60 minutes of postoperative time in the operating room, recovery unit, and intensive care unit on the day of this procedure is justified. In addition, upon further analysis of the raw survey data, we note that over 65 percent of all survey respondents indicated 50 minutes or more postoperative time, and of the 28 respondents with recent (12 month) experience, 60 percent indicated 60 minutes or more. We do not believe, and there is no evidence to the contrary, that these experienced clinicians overestimated the time they spend postoperatively on the day of a pelvic packing procedure.

The ACS does not find it appropriate that survey times from experienced clinicians should be changed or disregarded because the times do not fit CMS' observed pattern of low intensity, outpatient procedures. The intensity of the intraoperative work for code 490X1 is comparable to other

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urgent and emergent lifesaving procedures. There are very few procedures where time is of essence, and a split second makes a difference between life and death, and as such, the fact that these procedures do not take hours should not dictate or correlate with how much postoperative time is required. We believe that the rationale submitted by the RUC and the additional details above justify the survey median work RVU of 8.35 for code 490X1 and pre, intra, and post times of 50, 45, and 60 respectively. **The ACS urges CMS to consider this additional information and accept the RUC recommendations for work and time for code 490X1.**

- CPT code 490X2 (Re-exploration of pelvic wound with removal of preperitoneal pelvic packing including repacking, when performed): CMS disagrees with the RUC-recommended survey median work RVU of 6.73 for code 490X2. The Agency instead proposes a lower work RVU of 5.70 based on the survey 25th percentile value. CMS supports this valuation with a reference to code 39401 (*Mediastinoscopy; includes biopsy(ies) of mediastinal mass (e.g., lymphoma), when performed*), which has a work RVU of 5.44, intraservice time of 45 minutes, a total time of 142 minutes.

We do not support CMS' proposed value for code 490X2 and disagree with the Agency's comparison of the total work for this code to that of code 39401. Code 39401 describes a diagnostic biopsy procedure that is typically performed as an outpatient procedure on a stable patient. In contrast, the typical patient undergoing the procedure described by code 490X2 will likely still be critically ill and unstable, having survived significant pelvic trauma within the 24 to 48 hours prior to the procedure. The intensity of removing the pelvic packing pads one by one and ensuring the patient remains hemodynamically stable is much greater than taking mediastinal biopsy(ies). As pointed out at the RUC meeting during the discussion of code 490X2, removal of the pads may start new bleeding from the multiple vessels in the pelvis, which must be addressed at the time of pad removal. The key reference code chosen by the survey respondents— code 37193 (*Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed*) is much more comparable to the work of code 490X2 than the comparator chosen by CMS.

The table below outlines several recently reviewed 0-day global codes with similar intraoperative time and intensity as code 490X2. These codes support the RUC-recommended work RVU of 6.73 for this code.

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CPT	Long Descriptor	RVW	IWPUT	Total Time	Intra Time
36903	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment	6.39	0.109	96	50
58561	Hysteroscopy, surgical; with removal of leiomyomata	6.60	0.114	121	45
490X2	Re-exploration of pelvic wound with removal of preperitoneal pelvic packing including repacking, when performed	6.73	0.111	143	45
31276	Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed	6.75	0.127	98	45
52352	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)	6.75	0.118	118	45
43275	Endoscopic retrograde cholangiopancreatography (ERCP); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)	6.86	0.113	108	50
52344	Cystourethroscopy with ureteroscopy; with treatment of ureteral stricture (eg, balloon dilation, laser, electrocautery, and incision)	7.05	0.120	125	45
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	7.10	0.136	91	45
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	7.10	0.136	91	45

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CPT	Long Descriptor	RVW	IWPUT	Total Time	Intra Time
93460	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	7.10	0.113	118	50
52345	Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (eg, balloon dilation, laser, electrocautery, and incision)	7.55	0.128	135	45

We believe that the rationale submitted by the RUC and the additional details above justify the survey median work RVU of 6.73 for code 490X2. **The ACS urges CMS to consider this additional information and accept the RUC recommendations for work and time for code 490X2.**

Open Wound Debridement (CPT codes 97597 and 97598)

- CPT code 97597 (Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less): CMS disagrees with the RUC-recommended survey median work RVU of 0.88 for code 97597. The Agency instead proposes a lower work RVU of 0.77 based on a crosswalk to code 27369 (*Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography*), which has a work RVU of 0.77, intraservice time of 15 minutes, and total time of 28 minutes.

CMS notes that the RUC recommended an intraservice time increase from 14 minutes to 15 minutes (+7 percent) and a total time increase from 24 minutes to 29 minutes (+21 percent), along with a work RVU increase from 0.51 to 0.88 (+73 percent). The Agency states that, although they do not imply that the changes in time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, it believes that modest changes in time should be appropriately reflected with a commensurate change in the work RVUs since the two components of work are time and intensity. In the case of code 97597, CMS asserts that it is more accurate to propose a lower RVU to account for these modest increases in the surveyed work time.

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We do not support CMS’ proposed value for code 97597 and disagree with the Agency’s rationale about changes in surveyed time. In its discussion of the proposed value and time changes, CMS ignores the extensive history of the valuation for code 97597 that was provided in the RUC SOR form, along with the related discussion about coding changes at the RUC meeting itself. The current value for code 97597 was proven to be based on a flawed methodology in the previous survey process, along with flawed utilization estimates and work neutrality calculations resulting from extensive CPT coding changes for the wound care codeset. The RUC accepted compelling evidence that there was a change in the typical patient as some of the lower level work for code 97597 was removed to be reported with other new wound care codes, and that there was also a change in the typical provider from physical therapist to physician, confirming the change in work.

Further, CMS’ argument regarding changes in time is contradictory to how the Agency reviewed other codes in this same proposed rule for similar services. For example, CMS proposes to increase the work RVU from 0.48 to 0.75 (+98 percent) for code 99212, which requires straightforward medical decision-making related to a patient with a self-limited or minor problem (i.e., an office visit for an established patient with a self-limited problem that is treated with an over-the-counter medication), even though the intra-time increased only by 1 minute (10 minutes to 11 minutes) and the total time increased by 2 minutes (16 minutes to 18 minutes). In addition, CMS’ proposed work RVU of 0.75 for code 99212 compared with its proposed work RVU of 0.77 for code 97597 represents only a 3 percent difference, even though the total time for 97597 is 61 percent greater. A similar comparison can also be made using code 99213 (proposed work RVU = 1.30, total time = 30 minutes) which requires a low level of medical decision-making similar to code 97597 (proposed work RVU = 0.77, total time = 29 minutes).

When the RUC determined that the work RVU recommendation for code 97597 would be the survey 25th percentile value of 0.88, it considered the relationship of code 97597 to key reference service codes 11042 and 99213 (valued at 0.97 with 23 minutes of total time, with proposed increases to 1.30 work RVUs and 30 minutes of total time). If considering work per unit time, the value that CMS proposes for code 97597 significantly undervalues the physician work compared to codes 99212 and 99213, which are shown in the table below.

CPT	CMS Proposed Work RVU	Total Time	Work Per Unit Time
97597	0.77	29	0.027
99212	0.75	18	0.042
99213	1.30	30	0.043

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Even at the RUC-recommended work RVU of 0.88 for code 97597, its work per unit time (0.030) is still significantly lower than codes 99212 and 99213 for similar physician services.

We also disagree with the Agency's comparison of the total work for code 97597 to that of code 27369. We note that the work RVU of 0.77 for 27369 was derived by the Agency using a reverse building block from the RUC-recommended work RVU of 0.96. CMS disregarded the compelling evidence that code 27369 was replacing Harvard-based code 27370, which was not well-defined and was being misreported by Family Practice (24 percent), Physical Medicine and Rehabilitation (19 percent), and General Practice (8 percent). In addition, code 27370 was reviewed by orthopaedic surgeons during the Harvard study. The RUC agreed that there was compelling evidence that the time and work RVU for (to-be-deleted) code 27370 were flawed, and that the review of new code 27369 should be conducted as a unique, distinct, new service. CMS' application of a reverse building block methodology to times for deleted code 27370 in order to calculate a value for code 27369 was faulty, and we do not agree that code 27369 should be used as a valid crosswalk for valuing code 97597.

In addition to strong comparisons to the proposed time and work RVUs for office visit codes, the RUC-recommended value of 0.88 is supported by other similar 0-day global integumentary services, including codes 11305 (*Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less*) [work RVU = 0.80 and 14 minutes intra-service time] and 11301 (*Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm*) [work RVU = 0.90 and 15 minutes intra-service time]. Further, the IWPUT (0.039) for code 97597 with a work RVU of 0.88 is similar to other debridement codes (e.g., 11000, 11042). **The ACS urges CMS to consider this additional information and accept the RUC-recommended work RVU of 0.88 for code 97597.**

- **CPT code 97598 (Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof):** CMS proposes to accept the RUC-recommended work RVU of 0.50 for code 97598. **The ACS appreciates that CMS recognizes that the RUC-recommended work RVU is the correct value for code 97598 relative to other codes in the PFS.**

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Negative Pressure Wound Therapy (CPT codes 97607 and 97608)

In 2013 and 2014, the ACS participated in the CPT application and subsequent RUC review of codes 97607 and 97608, which describe negative pressure wound therapy with the use of a disposable system. Based upon the revised coding scheme for negative pressure wound therapy, CMS deleted the G codes that were previously used to report codes 97607 and 97608. However, due to obstacles faced by the Agency in developing accurate payment rates for these services within the PE RVU methodology, including the indirect PE allocation for the typical practitioners who furnish these services and the diversity of the products used in furnishing these services, both codes were contractor priced beginning in CY 2015.

In response to stakeholder feedback, CMS evaluated these codes and determined there was adequate volume to change their payment status to “active.” The Agency proposes to assign an active status to codes 97607 and 97608, along with the RUC-recommended work RVUs of 0.41 for code 97607 and 0.46 for code 97608 and RUC-recommended PE inputs with minor adjustments. **The ACS agrees with the proposed work RVUs and PE details for both codes and appreciates CMS changing the payment status to active.**

Proposed Policies for CY 2021 for Office/Outpatient E/M Visits

Office/Outpatient E/M Visit Coding and Documentation

Accepting CPT Coding, Prefatory Language, and Interpretive Guidance

CMS proposes to adopt the new code descriptors, prefatory language, and interpretive guidance framework that have been issued by the AMA/CPT for office/outpatient E/M visits (CPT codes 99202-99215) for CY 2021. The Agency believes this proposal would accomplish greater burden reduction than the policies finalized in the CY 2019 final rule for CY 2021 and would be more intuitive and consistent with the current practice of medicine. As we stated in previous comment letters, we did not support the collapse of work RVUs into one single blended payment rate as finalized for CY 2021 in the CY 2019 MPFS final rule. The single payment rate would have been calculated from current office/outpatient E/M values that are resourced-based, but the blended payment rate itself would not have been a resourced-based value. **As such, we support CMS’ proposal to retain the 5 office/outpatient E/M levels (4 levels for new patients), and to not move forward with the finalized policy that would have created a blended payment rate for office/outpatient E/M levels 2 through 4.**

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The new CPT office/outpatient E/M framework will:

- Delete code 99201;
- Revise the remainder of codes 99202-99215 by removing history and examination as key components for selecting the level of E/M service, but adding the requirement that a “medically appropriate” history and/or examination must be performed in order to report codes 99202-99215;
- Make the basis for code selection **either** the level of medical decision-making (MDM) performed **or** the total time spent performing the service on the day of the encounter;
- Change the definition of the time element associated with codes 99202-99215 **from** *typical* face-to-face time **to** *total* time spent on the day of the encounter by the physician and/or other QHP;
- Change the amount of time associated with each code; and
- Revise the MDM elements associated with codes 99202-99215.

It is important to remember that the impetus for the current CPT coding and reporting changes by both CMS and AMA/CPT was to decrease documentation burden and thereby reduce work. For CY 2019, CMS has in fact lightened the burden of documentation in electronic health records (EHRs) in a number of ways, including:

- Allowing patient notes written by a medical student to be used for billing purposes after the attending signs off;
- Simplifying documentation of history and exam for established patients by requiring only medically necessary documentation;
- Requiring review and verification rather than re-entry of a chief complaint or other historical information entered into the record by ancillary staff or even by the patient; and
- Eliminating medical necessity documentation for home visits.

For 2021, the CPT guidelines and coding changes further reduce documentation burden. All of these changes, when implemented, will clearly reduce the burden of documentation, time, and ultimately, work for the provider. **We agree with updating E/M codes to reflect current practice, but we also agree with CMS that there are valid concerns with how time will be used to select a level of code and how the codes were reviewed and valued by the RUC.**

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Time

CMS proposes to adopt the new time ranges indicated in the CPT code descriptors as revised by the CPT Editorial Panel. CMS states that the total time **personally spent by the reporting practitioner** on the day of the visit should be used.

However, CPT coding and guidance state that for coding purposes, time for these services includes both face-to-face (FTF) and non-face-to-face (NFTF) time spent by the **physician and/or QHP(s)** on the day of the encounter. We agree with CMS that the total time reported should reflect the total reporting practitioner time and not the total time of the physician and/or any number of QHPs. **CMS should clarify whether time spent by those other than the reporting practitioner should count toward the total time for selecting the appropriate code level. CMS should also clarify whether NFTF time should count toward the total time for selecting the appropriate code level.**

CMS expresses confusion and asks for comment related to the disconnect between the day of encounter time in the CPT code descriptors/guidance and the time collected by RUC survey. The new CPT guidance indicates that beginning in 2021, when total time on the date of encounter is used to select the appropriate level of office visit service code, both the FTF and NFTF time personally spent by the physician or QHP are summed to select the appropriate code. For the survey, however, the respondents were instructed to incorporate typical time within 3 calendar days prior to the office visit, the day of the encounter, and within 7 calendar days after the day of the visit when responding to the time estimates. **We are concerned that this disconnect contributed to the survey being unintentionally flawed.** In addition, there were no clarifying instructions in the survey about whether to report time estimates by typical time or by MDM. As such, we will not know whether a survey response's very low or very high time estimate is based on MDM, time, or due to a misunderstanding of the revised coding structure. This confusion may have resulted in mixed reporting estimates.

We are convinced that the survey respondents did not understand the new coding guidelines and code descriptors, which comprised over 10 pages in the survey instrument. We base this observation on the fact that, for some respondents, the day of encounter time exceeds the time range in the code descriptor, indicating that more education is needed. With additional education on the new codes, however, we believe that physicians and coders will recognize when to use higher level codes. For example, if the physician and/or QHP total time on the day of an encounter is 30 minutes, even for a minor self-limited problem for an established patient, then code 99214 may be reported instead of 99212 or 99213.

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A survey of the revised codes was premature because **there was no education about the new coding paradigm and how it differed from the coding practice that has been in place for over 25 years.** Physicians and QHPs could not be expected to understand the significant differences and nuances of the new coding structure when responding to the survey for codes that have been in place longer than many of their careers. The ACS reviewed the combined survey statistics from all 51 societies and noted that the survey 25th percentile work RVU for the established patient visit codes is remarkably similar to the current 2019 work RVUs, further contributing to our concerns that the survey respondents did not fully understand the new coding guidelines.

The ACS is on record as disagreeing with the process used by the RUC for collecting time data and then using those data to develop work RVU recommendations. Although the ACS participated in the RUC survey process, we did not agree with the recommendations that were presented to the RUC. Such recommendations were supported by only 50-60 percent of the participants, not all of the survey participants.

For these reasons, we urge CMS to delay implementation of any work RVU changes and instead maintain the current work RVUs for the codes, and then request a survey after at least one year of reporting. We reiterate that the impetus for the current CPT coding and reporting changes by both CMS and AMA/CPT was to decrease documentation burden and thereby reduce work. We do not understand how changes to coding and reporting that are intended to reduce work and reduce burden also resulted in significant increases in work RVUs and time. **Further, we recommend that a new modifier be established to indicate when time alone is used to report a level of office/outpatient E/M code.** This will allow analysis of claims data to determine whether time or MDM are the driving factors of office/outpatient E/M services to help inform bundled payment models.

Code 99XXX (Prolonged office visit)

CMS also states that code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*) should only be reported when time is used for code selection and when the time for a level 5 office/outpatient visit is exceeded by 15 or more minutes. CMS demonstrates how the prolonged office/outpatient E/M visit time would be reported in Table 26 of this proposed rule:

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TABLE 26: Total Proposed Practitioner Times for Office/Outpatient E/M Visits When Time Is Used to Select Visit Level

Established Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)	CPT Code
40–54 minutes	99215
55-69 minutes	99215x1 and 99XXXx1
70-84 minutes	99215x1 and 99XXXx2
85 or more minutes	99215x1 and 99XXXx3 or more for each additional 15 minutes
New Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)	CPT Code
60-74 minutes	99205
75-89 minutes	99205x1 and 99XXXx1
90-104 minutes	99205x1 and 99XXXx2
105 or more minutes	99205x1 and 99XXXx3 or more for each additional 15 minutes

The use of 99XXX as described in this table does not align with the CPT guidelines and CMS’ description in the text of this proposed rule. Per CPT, code 99XXX is used when the maximum time for a level 5 visit (54 minutes for established patient and 74 minutes for a new patient) is exceeded by an additional 15 minutes, not when the maximum time for a level 5 visit is exceeded by between 1 and 15 minutes, as the chart currently shows. **CMS should consider the table below as correct reporting.**

Established Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)*	CPT Code
40-54 minutes	99215
70-84 minutes	99215x1 and 99XXXx1
85-99 minutes	99215x1 and 99XXXx2
100 or more minutes	99215x1 and 99XXXx3 or more for each additional 15 minutes
New Patient Office/Outpatient E/M Visit (Total Practitioner Time, When Time is Used to Select Code Level)*	CPT Code
60-74 minutes	99205
90-104 minutes	99205x1 and 99XXXx1
105-119 minutes	99205x1 and 99XXXx2
120 or more minutes	99205x1 and 99XXXx3 or more for each additional 15 minutes

**It is unclear whether this refers to reporting practitioner time alone, or time spent by other QHPs, as discussed above.*



CMS also proposes to adopt its interpretation of the revised CPT prefatory language and reporting instructions that codes 99358-99359 (prolonged NPTF E/M work related to a FTF visit) would no longer be reportable in association or “conjunction” with office/outpatient E/Ms. Specifically, CMS indicates that when time alone is used to select a level of office/outpatient E/M service, any additional time spent by the **reporting practitioner** on a prior or subsequent date of service could not count toward the required time for reporting codes 99202-99215 or 99XXX nor be reportable using codes 99358-99359. CMS bases this interpretation on the way that the RUC surveyed the office/outpatient E/M codes to include 3 days prior, day of, and 7 days after the encounter. CMS also notes that codes 99358-99359 describe time spent beyond the “usual” time, which is not defined in CPT guidance. CMS is seeking comment but also believes codes 99358-99359 may need to be redefined, resurveyed, and revalued.

We agree with CMS' discussion that the interrelationship of codes 99202-99215 and 99XXX with codes 99358-99359 adds to the confusing nature of the new coding paradigm for reporting office/outpatient E/M services. This further supports our belief that the survey respondents for codes 99202-99215 did not understand the new coding paradigm and that CMS should delay changes to valuation and time for codes 99202-99215 until after these codes and other interrelated codes such as 99358-99359 are in use for one year. This will provide the CPT Editorial Panel time to revise the codes and/or guidance to more clearly describe correct reporting. This will also provide time for education of practitioners and to allow time to gain experience with reporting so as to result in more confident survey data.

Split/Shared E/M Service

The CPT guidelines are inconsistent with the Medicare guidelines for split/shared E/M services. Per CMS guidelines, “split/shared” office visit E/M services only apply to established patients:

“In the office/clinic setting when the physician performs the E/M service the service must be reported using the physician’s UPIN/PIN. When an E/M service is a shared/split encounter between a physician and a non-physician practitioner (NP, PA, CNS or CNM), the service is considered to have been performed “incident to” if the requirements for “incident to” are met and the patient is an established patient. If “incident to” requirements are not met for the shared/split E/M service, the service must be billed

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under the NPP’s UPIN/PIN, and payment will be made at the appropriate physician fee schedule payment [emphasis added].”⁶

The new CPT introductory guidelines for the new patient office visit codes 99202-99205, on the other hand, specifically describe “incident to” work and time of both the physician and QHP for selecting a level of code. This appears to conflict with the Medicare Claims Processing Manual. **We ask that CMS clarify whether, in accepting the CPT guidelines for new patient office visit codes, the incident-to rules will no longer apply.**

Office/Outpatient E/M Visit Revaluation

The Agency proposes to adopt the RUC-recommended work RVUs for all of the office/outpatient E/M codes (99202-99215) and for the new prolonged services add-on code (99XXX). CMS notes the Medicare Payment Advisory Commission’s (MedPAC) concerns that office/outpatient services are undervalued in the PFS, and asserts that the office/outpatient E/M code set has become passively devalued given that values for outpatient E/Ms have remained unchanged, while the coding and valuation for other types of services under the PFS have been updated to reflect changes in medical practice. The Agency states that the information the agency reviewed on the RUC valuation was based on an extensive survey the RUC conducted of over 50 specialty societies demonstrating that office/outpatient E/M visit levels are generally more complex for most clinicians.

As we indicated in our previous comment letters to the RUC, and discussed above, we strongly support maintaining the current work RVUs and times for the office visit E/M codes until education, and further CPT and CMS coding clarification are provided. Determining the correct and fair values for these codes is immensely important, given that they represent the foundation of value for many other CPT codes. Although CMS states concerns that office/outpatient services are undervalued, to the extent that the work complexity of an E/M encounter may have changed, the E/M coding system has clearly provided adequate flexibility for physicians to report accurately—and insurers to reimburse appropriately—for the increased work complexity. This coding flexibility to report increased intensity is exemplified by the shift of reporting higher level codes shown in the tables below.

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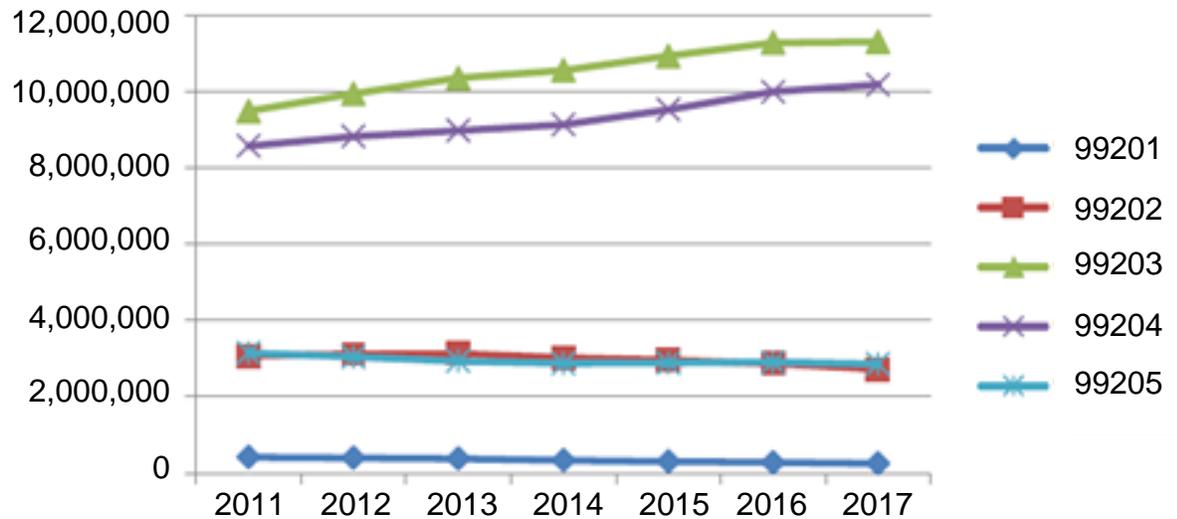
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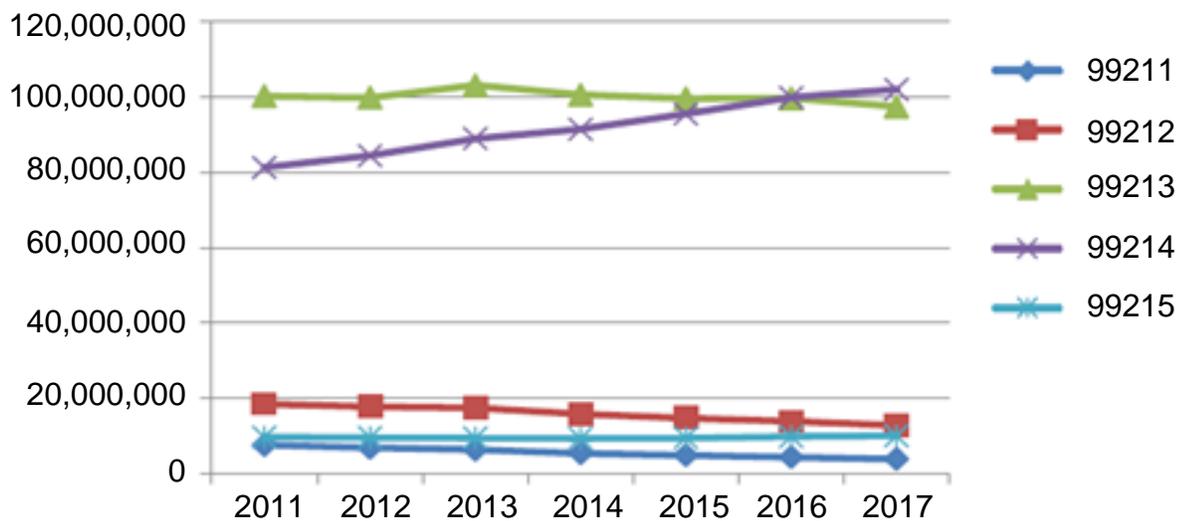
⁶ Centers for Medicare & Medicaid Services. (2019). Medicare Claims Processing Manual Chapter 12 Section 30.6.1 - Selection of Level of Evaluation and Management Service. Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>



Office Visit, New Patient, Medicare Claims



Office Visit, Established Patient, Medicare Claims



Also, as we mentioned above, although the RUC survey was conducted by 51 specialty societies, the recommendations presented to the RUC for consideration were decided by a simple majority. Unanimous agreement among the 51 specialty societies was not achieved in arriving at the specialty recommended values. The ACS did not support the values presented to the RUC.

In addition, we believe that the data on which some of the recommendations were based, specifically the survey times, were flawed. As discussed above, we are not



confident that the survey respondents understood the new coding guidelines and code descriptors when completing the survey. We base this concern on the fact that for some survey respondents, the day of encounter time exceeds the time range in the code descriptor. The survey instructions were also confusing because the code descriptors refer to time on the “day of encounter” for code level selection, yet the survey indicates that time should incorporate the time spent 3 days prior to the encounter as well as time spent 7 days after the encounter. And most importantly, we believe the survey was premature because there was no education about the new coding paradigm and how it differs from the coding practice that has been in place for over 25 years.

In summary, we urge CMS to maintain the current E/M values for the office visit E/M codes. We suggest that the RUC conduct a survey after physicians and coders have had at least one year of experience with the new codes in order for the RUC to collect more accurate data from providers who have actually used the new coding paradigm. This delay will also provide valuable information on a shift in reporting that will likely take place and that CMS should take into consideration before implementing new code values.

Simplification, Consolidation and Revaluation of HCPCS Codes GCG0X and GPC1X

CMS indicates that despite proposing to adopt the RUC-recommended values for the revised office/outpatient E/M codes, the Agency believes that the code set still does not appropriately reflect differences in resource costs between certain types of office/outpatient visits. In the CY 2019 PFS, CMS finalized the creation of HCPCS codes GCG0X, which describes the inherent complexity associated with certain types of specialist visits, and GPC1X, which describes the additional resources associated with primary care visits. These new codes were created to address stated shortcomings in the E/M code set related to primary care and certain types of specialty care visits. In the CY 2020 proposed rule, CMS proposes to delete code GCG0X and revise the code descriptor for GPC1X to describe 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. CMS proposes to value HCPCS code GPC1X at 100 percent of the work and time values for CPT code 90785, which describes additional work associated with certain psychotherapy or psychiatric services. CMS believes that code 90785 represents the most appropriate crosswalk for the revised HCPCS code GPC1X.

We do not agree that HCPCS code GPC1X should be compared to and crosswalked to CPT code 90785, which was established to report extraordinary services related to psychotherapy or psychiatric services. The initial estimated

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Medicare utilization for code 90785 was approximately 70,000; however, a review of the Medicare claims data and provider utilization and payment data indicate that code 90785 was reported almost 420,000 times in 2017 and that 40 percent of the claims were reported by only 88 clinicians. In fact, one clinician reported the code 9,406 times in for only 91 beneficiaries. An ill-defined code such as GPC1X clearly has the ability to be misreported and abused.

We disagree with the establishment of code GPC1X. This new add-on code is not necessary, given CMS' proposal to adopt the new CPT framework for E/M code level selection, which allows for selecting a higher level service when more complexity (or more time) is required. In the CY 2019 MPFS proposed rule, CMS stated the need for GPC1X and GCG0X is justified in order to account for additional costs and resources not reflected in the proposed single payment rate for levels 2 through 5 visits.

With respect to GPC1X, CMS states:

“We believe the proposed value for the single payment rate for the E/M levels 2 through 5 new and established patient visit codes does not reflect these additional resources inherent to primary care visits, as evidenced by the fact that primary care visits are generally reported using level 4 E/M code. Therefore, to more accurately account for the type and intensity of E/M work performed in primary care-focused visits, we are proposing to create a HCPCS add-on G-code that may be billed with the generic E/M code set to adjust payment *to account for additional costs beyond the typical resources accounted for in the single payment rate for the levels 2 through 5 visits* [emphasis added].”⁷

And with respect to GCG0X, CMS states:

“We are also proposing to create a HCPCS G-code to be reported with an E/M service to describe the additional resource costs for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches we believe are generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding. Due to these factors, *the proposed single payment rate for E/M levels 2*

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⁷ 83 FR 35704



*through 5 visit codes would not necessarily reflect the resource costs of those types of visits [emphasis added].*⁸

Under the CY 2020 proposal, however, **this add-on code is no longer justified and therefore not warranted because CMS is no longer proposing a single payment rate for levels 2 through 5 visits.** CMS' justification for the 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. **That rationale no longer holds true under the new proposal of retaining the various levels, because physicians may bill a higher level E/M code for such visits, based on the level of MDM or time.** We note that the revised CPT MDM table and inclusion of both physician and QHP FTF and NFTF time in the revised codes was meant to reflect increased resources as patient encounters were more complex or time consuming. If CMS still believes that extraordinary office/outpatient E/M work cannot be accurately reported with the new coding structure, then we suggest that CMS consider establishing a modifier similar to modifier 22 (*Increased procedure services*) and require documentation to support the substantial additional work.

Also, it is unclear which specialties CMS anticipates will utilize this code. Although the text of the proposed rule states that CMS intends for HCPCS code GPC1X to be used 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, when asked at a MPFS briefing hosted by the AMA on August 13, the CMS representatives responded that the Agency anticipates that *all* office/outpatient E/M visit levels billed by *all* physicians would be submitted with this add-on code. This is contrary to CMS' stated reasons for proposing code GPC1X, so we request clarification. Further, the code descriptor does not provide context for the reporting time frame of the revised office/outpatient E/M codes (i.e., day of encounter or 11-day global) and/or restrictions for reporting with other services (e.g., chronic care management, complex care management). **We urge CMS to delay implementation of code GPC1X until the many other coding changes have been updated and clarified. If, after that time, such a code is warranted, the add-on code should be brought through the CPT process to update guidelines, instructions, and exclusions for reporting prior to implementation.**

We also request clarification on how CMS expects the use of the revised HCPCS code GPC1X to be distinct from the use of the newly proposed PCM code. CMS

⁸ 83 FR 35704

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is proposing separate coding and payment for PCM services, which describe care management services for one single chronic condition. CMS states that, especially for specialties that use office/outpatient E/Ms to report a majority of their services, there can be significant resources involved in care management for a single high risk disease or complex condition that is not well accounted for in existing coding. **We question why CMS believes that both GPC1X and the PCM codes are needed to account for care management of a single high risk or complex condition, and we ask for clarification as to why reporting a higher E/M level would not account for these additional resources involved. Stated another way, we request that CMS describe what additional resources are not accounted for by reporting a higher E/M level.**

Implementation Timeframe

CMS proposes that these policy changes for office/outpatient E/M visits would be effective for services furnished starting January 1, 2021. We appreciate CMS taking steps to finalize a new major policy over a year from when it will take effect to allow time for provider education and further feedback; however, as stated above with respect to the adoption of the new E/M values and times, **we suggest instead that CMS delay work RVU and time changes, and request that the RUC conduct a survey after at least one year of experience so that more accurate data can be collected from experienced providers who understand the new coding paradigm and have reported the codes.**

Global Surgical Packages

CMS does not propose to use the RUC-recommended values for E/M visits to adjust the office/outpatient E/M visits that are bundled into global code payment. CMS does not provide a clear rationale in the proposed rule for holding back from taking this step, but when asked at the MPFS briefing hosted by the AMA on August 13, CMS representatives stated that the Agency was mandated by MACRA Section 523 to use data that have been collected to revise the values of global codes. As part of MACRA, Congress requires CMS to develop a process to gather information to value surgical services from a representative sample of physicians and required that the data collection begin no later than July 1, 2017. MACRA also required that, beginning in CY 2019, CMS must use the information collected as appropriate, in addition to other available data for improving the accuracy of valuation of surgical services under the PFS. CMS also directs stakeholders to review three reports produced by its contractor, RAND Corporation, and to consider alternative ways to address the values for these services.

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Lack of Inclusion of RUC-Recommended E/M Values in Global Code Payment

As we stated in our comment letter to CMS, dated August 15, 2019, co-signed by 53 organizations, we are strongly opposed to CMS failing to incorporate into the global codes the adjusted values for the revised office/outpatient E/M codes. By failing to adopt all of the RUC-recommended work and time values for the revised office visit E/M codes for CY 2021, including the recommended adjustments to the 10- and 90-day global codes, CMS improperly proposes to implement these values in an arbitrary and piecemeal fashion. **If CMS plans to move forward with the proposal to adopt the RUC-recommended values and times for office/outpatient E/M codes, it is inappropriate to not also apply the incremental RUC-recommended changes to global codes.** If CMS finalizes the proposal to adjust the office/outpatient E/M code values, the agency must apply these updated values to the global codes. It is imperative that CMS take this crucial action because to do otherwise will:

- Disrupt the relativity in the fee schedule: Applying the RUC-recommended E/M values to stand-alone E/Ms, but not to the E/Ms that are included in the global surgical package since the inception of the fee schedule, will result in disrupting the relativity between codes across the Medicare physician fee schedule. Changing the values for some 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 office visit codes were increased in these instances, CMS also increased the bundled payments and time for office visits in the global codes. This was in recognition of the fact that the Harvard study set relativity of all procedures and services when the first PFS was implemented.
- Create specialty differentials: Per the 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.”⁹ 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. Again, the Harvard study set relativity of all procedures and services when the first PFS was implemented. The E/M codes

⁹ 42 U.S. Code §1395w-4(c)(6)

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were studied and valued and the global codes were developed using the same E/M visit intensity.

- Run afoul of section 523(a) of MACRA: CMS points to the ongoing global code data collection effort as a reason for not applying the RUC-recommended changes to office/outpatient E/M codes to global codes. In addition, the Agency states that it is required to update global code values based on objective data on all of the resources used to furnish the services included in the global package. These arguments conflate two separate issues. The issue that CMS raises regarding MACRA legislation is not related to maintaining relativity across the fee schedule based on current data in the CMS work/time file. In fact, Section 523(a) specifically authorizes CMS to make adjustments to surgical services, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project.
- Ignore recommendations endorsed by nearly all medical specialties: The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) to recommend that the full 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-days, 90-days and MMM (maternity). The RUC also recommended that the practice expense inputs should be modified for the office visits within the global periods.

Again, if CMS moves forward with accepting the RUC-recommended values and time for office/outpatient E/M codes, we strongly urge CMS not to finalize a policy that fails to apply these same RUC-recommended changes to both stand-alone office visit E/M codes and the office visit E/M component of the global codes.

RAND Reports

CMS contracted with RAND to collect and analyze data as part of the MACRA mandate. RAND describes its findings in three reports, which we comment on in below.

RAND Report #1: Claims-Based Reporting of Post-Operative Visits for Procedures with 10- or 90-Day Global Periods

Beginning July 1, 2017, CMS required practitioners in groups of 10 or more, practicing in nine specified states, to report code 99024 for each postoperative visit after select procedures with 10- and 90-day global periods in order to collect data on the number of postoperative visits that were provided associated with

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those global services. This RAND report analyzes Medicare claims data (and reported 99024 codes) for procedures furnished between July 1, 2017 and June 30, 2018. The key findings include:

- Postoperative visits reported:
 - When examining single, non-overlapping procedures linked to postoperative visits, RAND found that 3.7 percent of 10-day global periods had one or more postoperative visits reported.
 - When examining single, non-overlapping procedures linked to postoperative visits, RAND found that 70.9 percent of 90-day global periods had one or more postoperative visits reported.
- Reported visits compared with expected:
 - The ratio of observed to expected postoperative visits provided with 10-day global periods was 0.04.
 - The ratio of observed to expected postoperative visits provided with 90-day procedures was 0.39.
- To address concerns of underreporting, RAND performed a sensitivity analysis of practitioners who appeared to be actively engaged in reporting postoperative care (“robust reporters”), and found moderately higher rates of postoperative visits that were still lower than expected.

While we have a number of questions about the RAND analysis, we are most concerned about the CMS data collection process. There is no way to confirm that the data reported through this program accurately represent the patterns of postoperative visits and care provided after 10- and 90-day global procedures. Therefore, absent a way to verify the validity of the data, it is not possible to verify the validity of the report’s conclusions. The data collection process was flawed for multiple reasons, including:

- Lack of adequate notice/education: CMS did very little outreach to physicians on the requirement to report 99024 code data. Many specialty societies worked diligently to inform their members of the new reporting requirement, but we strongly believe that a large percentage of physicians who were required to report simply could not be adequately informed. We are aware of only a few of our members receiving a single and somewhat ambiguous letter from CMS on this issue and the need to report after the reporting period had already begun.
- Definition of “practice”: CMS required physicians in practices of 10 or more to report postoperative visit data; however, a “practice” was defined not as practitioners sharing the same tax ID number (TIN) as CMS defines groups in

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all other cases of CMS reporting, but rather, as those who share “business or financial operations, clinical facilities, records, or personnel.”¹⁰ This broad definition of “practice” was difficult to explain to physicians and created considerable confusion about who was required to report.

- Need for near perfect reporting: In order to draw valid conclusions on the number of postoperative visits provided, near perfect reporting would be required. Statistical analyses exist to account for small amounts of under- or over-reporting, but attempting to obtain accurate results presumes that almost all expected reporters are reporting almost perfectly most of the time. Without a way to confirm this assumption, it would not be valid to assume that the collected data are accurate. Not only is this confirmation lacking, but we have received feedback from surgeon leaders in some of the 9 states that attempts to submit data were met with difficulties due to claims scrubber programs that may have resulted in failure to report.
- Confirmation of reported 99024 claims: Despite repeated requests from stakeholders, CMS did not establish a process by which practitioners could confirm that CMS received submitted claims for reported 99024 codes. The need for confirmation is critical given the numerous hurdles for reporting. These include required updates to practice management software and updates to code scrubbing protocols in the claims clearinghouses to allow transmission of claims for 99024 to CMS, but not to other commercial payers or to self-pay patients. Without some form of feedback, it is impossible for physicians to know whether or not the 99024 codes that they attempted to report were actually transmitted and received. Therefore it is very possible that the collected data are not accurate.

We also have a number of concerns with RAND’s analysis:

- Definition of “practice”: As described above, CMS defined a “practice” as those who share “business or financial operations, clinical facilities, records, or personnel.” RAND, however, defined practice by TIN.¹¹ We appreciate that RAND recognized the confusion surrounding this definition, and we agree that use of the TIN is a better proxy for group size compared to the CMS definition. However, we received many questions that highlighted the deep confusion and lack of understanding of the CMS definition of “practice” for purposes of reporting. Even if RAND now uses the TIN as a measure instead for analysis, the confusing definition of “practice,” at the time when

¹⁰ 82 FR 33950

¹¹ 82 FR 33950

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physicians were determining whether they should report could have deterred some who were part of a TIN of 10 or more clinicians from actually reporting, thereby contributing to underreporting. So our concerns remain regarding whether all the required reporters were adequately informed that they were in fact required reporters, even if retrospectively the group size is evaluated based on the TIN.

- “Clean” procedures: Because patients may undergo multiple procedures on the same day or over a short period of time, the analysis was limited to “clean” procedures, defined as billed procedures with 1 billed unit of service, that do not overlap with the 10 or 90-day global period for any of the patient’s other procedures. This method was used as a method to link a given procedure and postoperative visit unambiguously. An *Annals of Surgery* article states that “...Among the 293 procedure codes, 60.83% of procedures with 10-day global periods and 59.99% of procedures with 90-day global periods were clean.”¹² It is not clear, but we assume this means that approximately 40 percent of possible records were not included in the analyses. This is a significant limitation and represents a possible bias toward less complicated operations.
- Sensitivity analysis: The report acknowledges that the results showing fewer postoperative visits than expected could be due to underreporting. As such, the methodology includes a sensitivity analysis whereby the results were compared to a subset of physicians defined as “robust reporters.” These physicians were found to have performed 10 or more procedures with 90-day global periods and reported at least 1 claim for a postoperative visit for at least half of the procedures performed beginning July 1, 2017.¹³ The article does not explain why a “robust reporter” is defined as only reporting 1 postoperative visit for half of the procedures performed, which is a tiny fraction of the expected number under the current valuation of global codes. For the robust reporters, if the data are not capturing 100 percent of the claims (either because the code is not being reported for all procedures as expected or because submitted codes were not being received/processed by CMS) then that means even for robust reporters up to half of the postoperative visits were not being captured (i.e., the results of this study would be underestimating the proportion of postoperative visits by half). Also, this definition of “robust reporters” would include many reporters that joined late, believed they only

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¹² Kranz, A. M., Mulcahy, A., Ruder, T., Lovejoy, S., Mehrota, A. (2018). Patterns of postoperative visits among Medicare fee-for-service beneficiaries. *Annals of Surgery*, 1-9.

¹³ Kranz, A. M., Mulcahy, A., Ruder, T., Lovejoy, S., Mehrota, A. (2018). Patterns of postoperative visits among Medicare fee-for-service beneficiaries. *Annals of Surgery*, 1-9.



needed to report once for each code, or for some reason stopped reporting. There is no way to be certain these partial reporters were not excluded from being grouped as “robust reporters”. The analysis also compared data from “high volume reporters,” defined as those who billed 10 or more procedures with 90-day global periods. But the article does not explain whether high volume reporters reported any 99024 codes at all or whether there was any connection between providing more 90-day services and more accurately reporting the associated 99024 codes. Therefore, we are not confident that the sensitivity analysis accounts for the concerns about skewed data caused by underreporting.

- **Underreporting:** We are alarmed by the conclusion in the *Annals of Surgery* article that, “...underreporting is unlikely to fully explain the low proportion of expected postoperative visits provided. In subanalysis limited to surgeons who were actively reporting their postoperative visits, the patterns were largely similar, suggesting that a large share of expected postoperative visits are not delivered.”¹⁴ This statement presumes that data reported by those physicians defined as “actively reporting” are reflective of the actual number of postoperative visits provided. But these physicians count as “robust reporters” if they were found to have performed 10 or more procedures with 90-day global periods and reported at least 1 claim for a postoperative visit for at least half of the procedures, which is much less than the expected number of postoperative visits. Similarly, it does not provide any substantiation that these physicians were reporting 99024 for all the postoperative visits that they provided, nor does it provide substantiation that claims submitted by the physician were received.
- **Inclusion of non-reporters:** In a briefing with RAND organized by the AMA on August 13, the authors of the report indicated that when calculating the ratio of observed to expected postoperative visits for both 10- and 90-day global procedures, physicians who could have reported, but did not report, were considered to have reported no visits. To conclude that those who did not report were affirmatively reporting that they did not provide any visits related to the global procedures is inappropriate since there is no way to know with certainty whether no visits were provided or whether some other reason (lack of knowledge of reporting requirements, problems with practice management systems, issues with clearinghouses, etc.) prevented the providers from reporting instead. This is especially concerning given that only 46 percent of providers expected to participate submitted tracking code 99024 for the 1-year

¹⁴ Kranz, A. M., Mulcahy, A., Ruder, T., Lovejoy, S., Mehrota, A. (2018). Patterns of postoperative visits among Medicare fee-for-service beneficiaries. *Annals of Surgery*, 1-9.

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period on which the report was based (i.e., more than 50 percent of providers expected to report were erroneously assumed to never perform a postoperative visit). In addition, only 17 percent of physicians were classified as “robust reporters,” meaning that the majority of those who reported did not even submit 1 claim for a postoperative visit for at least half of the procedures performed in the measurement period.

- 10-day global period: There are many instances in which postoperative visits that are related to a 10-day global service are performed outside of the 10-day period (for example, on day 14). In the August 13 briefing with RAND, attendees asked whether RAND investigated and/or were able to confirm whether postoperative visits for codes with a 10-day global period that were performed outside the 10-day global period were tracked in some way. These postoperative visits could have been either not reported with a discrete E/M or reported with 99024 instead. For example, there are many instances where minor surgery is performed on tension-sensitive areas and sutures may be retained for more than 10 days. RAND could not confirm if this was a pattern that was missed in their analysis. We believe that many providers have recognized that if a postoperative visit were required related to a 10-day global procedure, for example to remove sutures, that they could not separately report that service even if the visit were outside of the 10-day window.

Given the high degree of ambiguity related to the CMS data collection process and the concerns about the methodology that RAND used to analyze the data, the authors' conclusions about the results are not valid and it is not appropriate to make a recommendation to reassess payment for surgical procedures based on these flawed data.

RAND Report #2: Survey-Based Reporting of Post-Operative Visits for Select Procedures with 10- or 90-Day Global Periods

Per MACRA, Congress directed CMS to collect data on the number and level of postoperative visits during the global period. The required reporting of CPT code 99024, as described above, was in response to the mandate to collect data on the number of visits. In order to collect data on the level of visits, RAND developed a survey to collect data on the types of care provided in postoperative visits for three procedures: cataract surgery, hip arthroplasty, and complex wound repair. The key findings related to time and work, where CMS compared reported physician time and work to physician time and work implied by the E/M visits considered by CMS when valuing the procedures as listed in the Physician Time File.

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RAND found that:

- Reported physician time and work were generally similar, but slightly less, than Physician Time File levels for cataract surgery and hip replacement.
- Reported physician time and work were higher than expected from the Physician Time File for complex wound repair.

We question why RAND does not consider staff time as contributing to the level of the visit, and instead considers this time purely as part of PE in the RUC process. In cases where QHPs bill “incident-to” physician services or even separately report Medicare services, both the work of the physician and the QHPs combined time is used to select the level of the visit. **If CMS uses this information to inform further discussion, the QHP time should be taken into consideration as well when assessing the time for these and other global codes.**

RAND Report #3: Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-day Global Periods

In this report, RAND uses the claims-based data on the number of postoperative visits to adjust valuation for procedures with 10- and 90-day global periods. To provide estimates to frame the discussion of revising payment for global services, RAND revalued procedures by adjusting work RVUs, physician time, and direct PE based on the difference between the number of postoperative visits observed via claims-based reporting and the expected number of postoperative visits used during revaluation (also known as the “reverse building block” approach). Their key findings include:

- Depending on which observed visit metric was used as an input in revaluation, the updated work RVUs were between 38 percent and 40 percent lower for procedures with 10-day global periods.
- Depending on which observed visit metric was used as an input in revaluation, the updated work RVUs were between 18 percent and 30 percent lower for procedures with 90-day global periods.
- The estimated change in Medicare payment for specialties (including an updated conversion factor), resulted in a range of updates from 3.0 percent to -18.4 percent. General surgery would receive an -11.8 percent payment cut.

The RAND report begins with the blanket assumption that procedures with 10-day and 90-day periods are overvalued, specifically, are valued as having too

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many RVUs. This assumption is based on the prior RAND studies. RAND uses the findings from the first report to apply the 4 percent observed vs. expected ratio from 111 10-day global services, for which reporting was required, and the 39 percent observed vs. expected ratio from 185 90-day global services, for which reporting was required, to all surgical global services (over 4,200 codes) using the reverse building block methodology. **For the reasons we described in our comments on the first report, above, it is not appropriate to use these flawed results to make recommendations on updated values for global services, let alone use the results themselves to calculate those recommendations.**

The first RAND report concludes with limitations of the analysis:

“...we sought to address concerns about underreporting of post-operative visits by conducting subanalyses limited to practitioners who were actively reporting their post-operative visits. However, we recognize that reporting of post-operative visits for these practitioners also may not be complete. Moreover, we observed differences in the characteristics of procedures performed by these robust reporters, and, as a result, their patterns of care may not be generalizable to the broader population of practitioners required to report post-operative visits.”¹⁵

As stated in the first study, it is not appropriate to generalize the results of the first study to all practitioners required to report. **It is therefore far less appropriate to generalize the results of the first study to all specialties and all global services.**

RAND made several assumptions as part of this approach, one of which is that RAND assumes that bundled postoperative visits that were not observed did not occur. For the reasons we discussed above, **this is an incorrect assumption because there is no way to know with certainty that the visits that were not reported truly did not occur.**

RAND also used the median observed visits as a primary approach for analysis because medians are used elsewhere in the valuation process. The report does not describe where else in the valuation process the median observed visits are used for analysis. The RUC often uses the median values when utilizing survey results for making recommendations to CMS. But this approach is to correct for potential

¹⁵ Kranz, A., Ruder, T., Mehrota, A. and Mulcahy, A. (2019). *Claims-based reporting of post-operative visits for procedures with 10- or 90-day global periods: Final report*. Santa Monica, CA: RAND Corporation.

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overreporting of time and work in survey responses. In contrast, overreporting is highly unlikely and would be quite difficult if not impossible when complying with the required reporting of code 99024 because physicians would have to intentionally report additional codes, and EHRs and practice management systems would likely prevent any instances of overreporting.

It is not appropriate to use flawed, incomplete, and inaccurate results to make recommendations on updated values for global services. Even if RAND’s analysis and methodology were sound, the conclusions cannot be relied upon if there is no certainty that the underlying data are valid.

Comment Solicitation on Revaluing the Office/Outpatient E/M Visit within TCM, Cognitive Impairment, Assessment/Care Planning and Similar Services

CMS seeks comment on whether to adjust the RVUs (in future rulemaking) for services for which the values are closely tied to the values of the office/outpatient E/M visit codes, such as transitional care management services (99495, 99496), cognitive impairment assessment and care planning (99483), the Initial Preventive Physical Exam (G0438), and the Annual Wellness Visit (G0439). CMS notes that while some of these services do not involve an E/M visit, the Agency valued them using a direct crosswalk to the RVUs assigned to an office/outpatient E/M visit(s), and for this reason they are closely tied to values for office/outpatient E/M visits.

The CPT codes that CMS references were surveyed by the RUC and the current work RVUs are based on magnitude estimation, not a crosswalk to any E/M code. **If a stakeholder believes any of these codes are potentially misvalued, they should go through the CMS process of nominating codes, followed by the RUC process for review.** In addition, the CPT codes that CMS references include typical FTF time of the reporting provider. This definition is distinctly different from the new coding paradigm for office visit E/M codes.

The G-codes that CMS references have never been surveyed to prove that the CMS-assigned time and work RVUs are valid. These codes have specific requirements and specific excluded work that can be separately reported, including office visit E/M codes. **If a stakeholder believes that any of these codes are potentially misvalued, they should go through the CMS process of nominating codes and then through the RUC process for review.**

OTHER PROVISIONS OF THE PROPOSED REGULATIONS

Deferring to State Scope of Practice Requirements

Ambulatory Surgical Centers

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In order to participate in Medicare, ASCs must meet certain Conditions for Coverage (CfCs), including two patient assessment requirements for patients having surgery in an ASC: (1) anesthetic risk and pre-surgery evaluation, and (2) pre-discharge evaluation. CMS proposes to revise its ASC CfCs to permit an anesthesiologist, in addition to a physician, to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure. For those ASCs that utilize non-physician anesthesiologists, also known as certified registered nurse anesthetists (CRNAs), this revision would allow them to perform the anesthetic risk and evaluation on the patient they are anesthetizing for the procedure to be performed by the physician.

The ACS joins the American Society of Anesthesiologists (ASA) in its opposition to CMS' proposal to allow CRNAs to independently perform preoperative assessment of anesthetic risk and presurgical evaluation in the ambulatory surgical setting, which we believe would remove current and necessary level of oversight that has ensured enhanced patient safety and procedural efficiency in ASCs. We ask CMS to consider the following issues:

- CRNAs do not have the education or training to provide this evaluation: Nurse anesthetists are valued members of the anesthesia care team, but their training does not include the knowledge and skills necessary to expand their role in the manner CMS proposes. The extensive training provided to physicians is essential to ensure that the pre-surgical patient assessment takes into account underlying comorbidities and to confirm that the ambulatory setting has the resources needed to manage the patient throughout the continuum of surgical care. A nurse anesthetists' clinical background does not provide the same depth of training in clinical issues beyond those related to delivery of anesthesia care, which is most often provided under physician supervision. Specifically, CRNA training and curriculum do not extend beyond provision of anesthetics and do not include the specific skills and background essential for risk assessment, diagnosis or medical decision making outside the scope of administering anesthesia during the perioperative period.
- Expansion of procedures that can be performed in the ASC setting: Many procedures that have previously been performed in the hospital setting are now being performed in ASCs. In addition, as more complex surgical services are transitioned to the ambulatory setting, patients previously thought to be too sick to undergo procedures in an ASC are now receiving surgical care in such facilities. The transitions in site of service may be appropriate for some patients, but sicker patients with significant comorbidities must be thoroughly evaluated and their care optimized to minimize the likelihood of complications or need for transfer to an acute care hospital. Unlike patients who receive surgical care in the hospital setting, ASCs do not have the same

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backup resources necessary to manage all clinical needs. As a result, the evaluation by a **physician** anesthesiologist is essential to not only assess risk, but also to determine the appropriate perioperative management to optimize each patient's clinical care and reduce the need for transfer to the hospital setting.

The ACS does not support CMS' proposal to permit CRNAs to perform the functions of a physician in completing an anesthetic risk and pre-surgery evaluation, and we urge the Agency to not finalize this policy.

Advisory Opinions on the Application of the Physician Self-Referral Law

CMS makes several proposals related to its advisory opinion process for the physician self-referral law (i.e., the Stark law) for CY 2020. Specifically, the Agency proposes that an advisory opinion would be binding on the Secretary and that a favorable advisory opinion would preclude the imposition of sanctions with respect to the party or parties requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the advisory opinion is issued. In addition, the Agency proposes that the Secretary will not pursue sanctions against any individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion that received a favorable opinion. CMS goes further to state that if parties to an arrangement are uncertain as to whether CMS would view it as materially indistinguishable from an arrangement that has received a favorable advisory opinion, then those parties can submit an advisory opinion request to query whether a referral is prohibited under section 1877 of the Act because the arrangement is materially indistinguishable from an arrangement that received a favorable advisory opinion.

The ACS urges CMS to update its current regulations related to the Stark law, as they have failed to keep pace with innovative payment and delivery models and threaten to undermine the Agency's goal of incentivizing providers to transition to alternative payment models (APMs). We look forward to future proposals from CMS that will serve to modernize the regulations to reflect current payment innovations. **Until then, however, we support the Agency's proposed changes to the advisory opinion process.** We believe that as physicians seek to develop and participate in new models, an advisory opinion process that allows those that are in arrangements that are "indistinguishable in all material aspects" from an arrangement that has already received a favorable opinion will provide some stability in the market and help support physician efforts to move toward more value-based delivery and payment models.

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The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Ollapally, Regulatory Affairs Manager, at vollapally@facs.org, or Lauren Foe, Senior Regulatory Associate, at lfoe@facs.org.

Sincerely,

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