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**AMERICAN COLLEGE OF SURGEONS***Inspiring Quality:**Highest Standards, Better Outcomes*

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.

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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**

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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.

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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>



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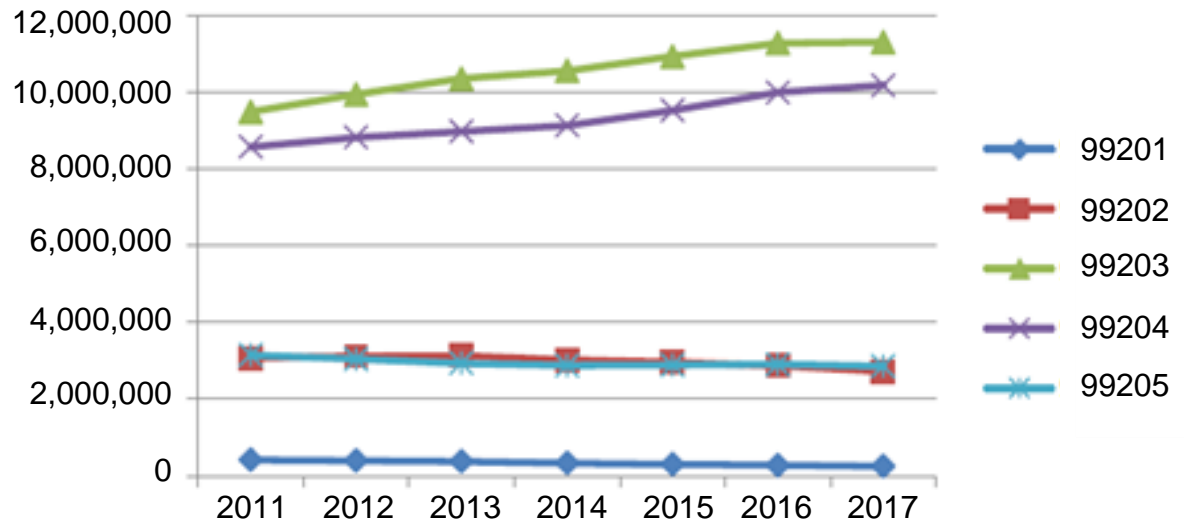
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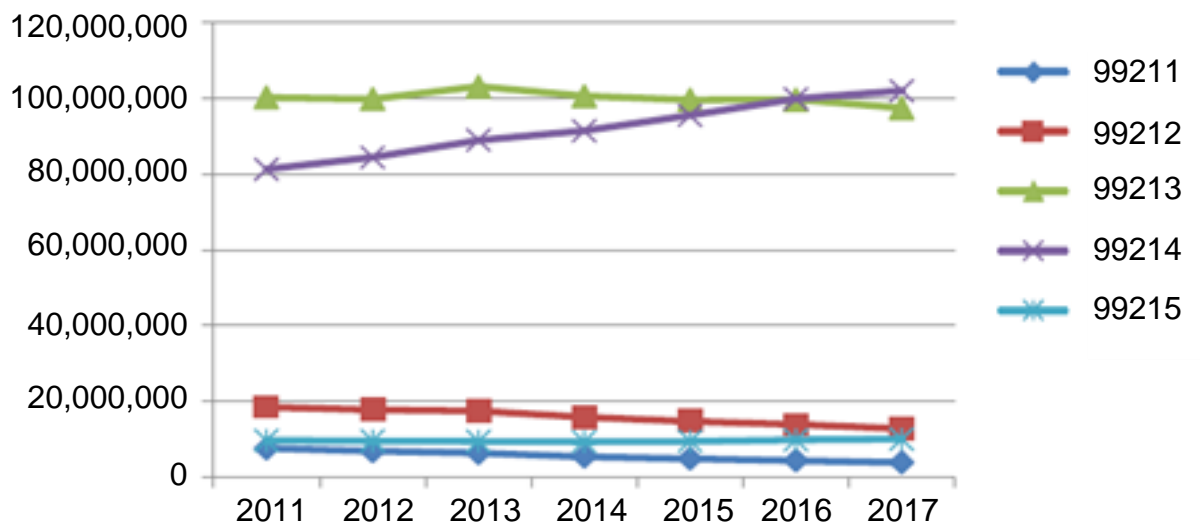
⁶ Centers for Medicare & Medicaid Services. (2019). Medicare Claims Processing Manual Chapter 12 Section 30.6.1 - Selection of Level of Evaluation and Management Service. Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>



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

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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 anesthetist, 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 anesthetists, 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,

David B. Hoyt, MD, FACS
Executive Director

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September 26, 2019

Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1715-P

P.O. Box 8016

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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 or the College), 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 26, 2019, includes the ACS' comments to the Quality Payment Program (QPP), MIPS Value Pathways (MVP) Request for Information (RFI) and other RFIs and comments to "Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm" section of the PFS. The College submitted a separate letter on September 10, 2019 which exclusively included the ACS' comments to all other proposed CY 2020 MPFS payment provisions.

CY 2020 UPDATES TO THE QUALITY PAYMENT PROGRAM

Transforming MIPS: MIPS Value Pathways Request for Information

CMS proposes to apply a new Merit-based Incentive Payments System (MIPS) framework, MIPS Value Pathways (MVP), which will start with the 2021 MIPS performance period (2023 MIPS payment year). The MVP framework aims to connect measures and activities across the four MIPS performance categories, incorporate a set of administrative claims-based population health quality measures, provide data and feedback to clinicians, and enhance information to patients. MVP is also intended to streamline MIPS reporting by limiting the number of required measures to best assess the quality and value of care within a particular specialty or condition. The details of the program will be proposed in next year's rulemaking cycle (2021).

CMS defines "value" as a measurement of quality related to cost; "value-based care" as paying for health care services in a manner that directly links performance on cost, quality, and the patient's experience of care; and "high value clinicians" as clinicians that perform well on applicable measures of quality and cost. CMS lists four guiding principles to define MVPs:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.
2. MVPs should include measures and activities that would result in providing comparative performance data that are valuable to patients and caregivers in evaluating clinician performance and making choices about their care.
3. MVPs should include measures that encourage performance improvements in high priority areas.

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4. MVPs should reduce barriers to Alternative Payment Model (APM) participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

We would like to thank CMS for being responsive to the College's feedback to better align QPP objectives to focus on a condition. As we have expressed in past letters and meetings, the QPP is not currently on the right path to define a value-expression for surgical care across stakeholders including patients, payers, and care teams. The measurement of surgical care is not currently aligned with a patient's experience of care or goals, and there is little transparency for what care will cost them. **We believe that value is an assessment or judgement that is made by the patient, and therefore must measure health outcomes that matter to the patient.** Yet, as acknowledged by CMS, the QPP measures surgeons based on primary care measures such as tobacco cessation or diabetes control. Measuring surgeons based on primary care measures disincentivizes the continued measurement of critical surgical standards for safety such as tracking preventable harm—surgical standards show little variation across providers but are the core components of a quality program. Furthermore, many of the QPP specialty measures are based on how clinical services are billed and do not map to the surgical patient or the care model, resulting in measures that are not actionable or meaningful to clinicians and difficult for patients to assess value. **We greatly appreciate that CMS is specifically addressing many of these concerns by rethinking MIPS in the MVP.**

Our MVP comments below consist of three major components. First, we discuss current work in value-based care that the College is doing with Harvard Business School's (HBS) Institute for Strategy and Competitiveness which can help guide the MVP work, we outline guiding principles for assessing surgical value in the MVP program, and we then discuss the implementation of these principles to align with the Improvement Activity (IA), Cost, Quality, and Promoting Interoperability (PI) components of the MVP.

ACS THRIVE Project: Opportunities to Align with MVPs

The RFI for MVPs is especially timely, as the College is currently collaborating with HBS Institute for Strategy and Competitiveness on a project titled Transforming Health Care Resources to Increase Value and Efficiency, or "THRIVE."¹ The fundamental goal and purpose of ACS THRIVE is to create

¹ American College of Surgeons. *American College of Surgeons and Harvard Business School's Institute for Strategy and Competitiveness partner to develop value measurement tool for hospitals.* July 2019. Retrieved from: <https://www.facs.org/media/press-releases/2019/acsthive071819>

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value for patients by delivering outcomes that matter to patients as the definition of success. **This work focuses on defining quality as the health outcomes that matter to patients and the costs of delivering these outcomes.**

ACS THRIVE: Assessing Quality and Improvement

The foundation for assessing quality for the value equation in ACS THRIVE is centered on assuring standards are applied for promoting team-based episodes of care to optimize quality and safety. In surgery, this is achieved through participation in one of the ACS accreditation and verification programs, such as the Surgical Quality Verification Program (SQVP), ACS Trauma, Bariatric, and/or Commission on Cancer accreditation. Patients benefit from this by knowing that for their condition or disease all necessary structural and process elements are aligned in a culture of continuous quality improvement throughout the care enterprise. The focus of care becomes team-based, patient-centered, and aims at improving outcomes that matter to patients. Once this foundational requirement is met, ACS THRIVE approaches quality from two directions: 1. **conformance quality**, which includes clinical standards and monitoring high risk events related to preventable harms (i.e. “do no harm”), and 2. **performance quality**, which measures the achievement of patient goals such as Patient Reported Outcomes (PROs) as seen in Figure 1 below. The current QPP program does not hit the mark on conformance or performance measurement across the phases of surgical care during the patient’s journey.

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Figure 1: Two Definitions of Quality Measurement

Clarifying the Term “Quality”

Two Definitions of Quality

- 1. Hitting the specifications**
preventable or avoidable “do no harm” → **Conformance Quality**
- 2. Superior performance**
achieving patient goals Example: patient able to walk again as a result of surgery → **Performance Quality**

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To further illustrate how this framework is developed based on patient-centricity, Figure 2 below illustrates the patient’s care journey for their diagnosis of cancer as envisioned in the ACS THRIVE project, where quality is measured with conformance measures including ACS SQVP,² clinical outcomes to monitor event rates, and performance measures which measure the achievement of patient goals.

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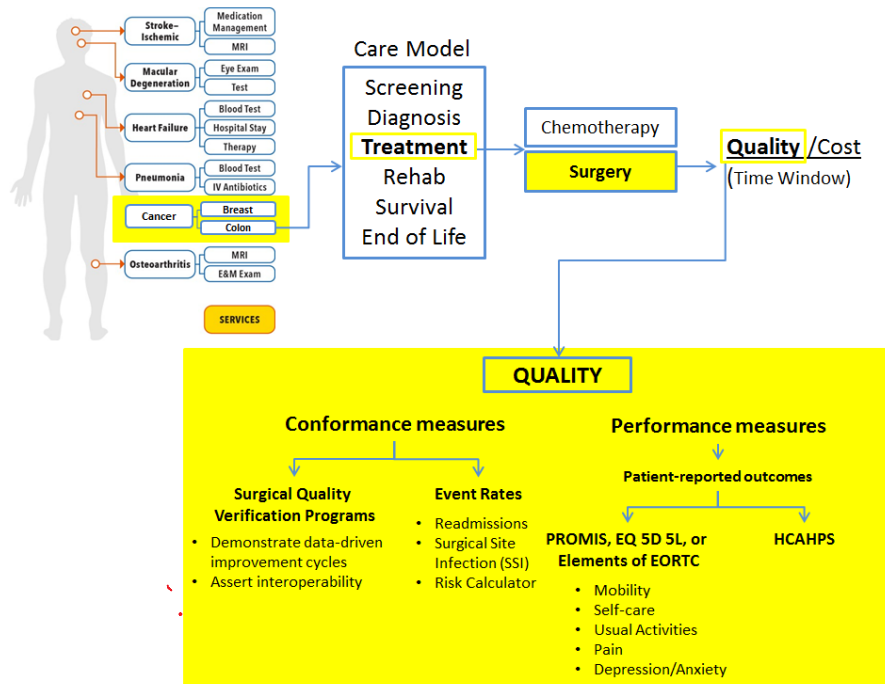
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² American College of Surgeons. “Optimal Resources for Surgical Quality and Safety.” 2017. Retrieved from: <https://www.facs.org/quality-programs/about/optimal-resources-manual>

Figure 2: Condition-based Measurement



ACS THRIVE: Assessing Cost and Price

To measure cost in the value equation, ACS THRIVE considers both the cost and price. In ACS THRIVE, cost refers to the cost of delivering outcomes (production costs) using tools such as Time-Driven Activity-Based Costing (TDABC). TDABC is a tool which provides information to understand costs or expenditures that a delivery system expends in resources, personnel, and time within a complete cycle of care.³ In order to eliminate waste, a care pathway must identify all steps that do not contribute to improved patient outcomes, redesign processes to reduce waste, and optimize interventions.

In addition to understanding production costs, ACS THRIVE highlights the clinical services and the prices for those services for the entire episode. In a fee-for-service environment, few physicians realize all of the services their patients experience, and thus have little understanding of the price for all those services—or the additive effect they have on overall total cost of care. ACS THRIVE uses episode grouper logic to provide a price for all the services in an episode of care.

³Argyris C, Kaplan R. Commentary: Implementing New Knowledge: The Care of Activity-Based Costing. *Accounting Horizons*. 1994; 8(3): 83-105.



In surgical patients, this means understanding the price of a total episode of care as well as a breakdown into preoperative price, intra-hospital price, and post discharge price.

ACS THRIVE aims to redesign the health care delivery system to deliver substantially better outcomes to patients at a lower cost to society, enabling universal access. **ACS THRIVE will help care teams and hospitals move away from fee-for-service toward shared accountability in bundled care because they will have a good understanding of all the processes of care and the cost for a condition or episode.**

We look forward to partnering with CMS to align the ACS THRIVE work with the MVP program, and develop surgical MVPs. As described by CMS, MVPs could be condition-based with multiple physicians' assigned attribution. **We encourage CMS to further emphasize the patient's journey within the MVP framework—which could measure overall care for a condition or a specific intervention for that condition as an episode.** The quality and costs of the MVP program could map to our ACS THRIVE project, ensuring consistency with the four categories of quality, cost (price), improvement, and interoperability. Based on the various types of general surgical subspecialties, a suite of general surgical MVPs might begin with Integrated Practice Units (IPUs)⁴ and/or episodes such as MVP-Hernia, MVP-Cholecystectomy, MVP-Colectomy/Cancer, and MVP-Breast/Cancer.

ACS Recommended MVP Guiding Principles

Critical to the success of the MVP program will be the willingness of CMS to allow for innovation and a truly patient-centric program. Below is a list of guiding principles which will need to be tested in a pilot. Following these guiding principles are recommendations for integrating these principles into the QPP program:

1. **Develop surgical MVPs based on clinical service lines.** We envision the implementation of the program at the hospital or Ambulatory Surgery Center (ASC) level for the key service lines each performs. The service lines would contain a suite of MVPs, and clinicians would accept assignment to the appropriate MVPs as part of team-based surgical care.

⁴ Porter ME, Lee TH. The Strategy That Will Fix Healthcare. *Harvard Business Review*. October 2013. Retrieved from: <https://hbr.org/2013/10/the-strategy-that-will-fix-health-care>.

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2. **Surgical MVPs should be rooted in a surgical verification program, such as the Surgical Quality Verification Program (SQVP).**

Verification programs pursue excellence and avoid system errors by ensuring that the resources, staff, and infrastructure are in place to provide the highest possible quality care to the patient. To meet the MVP's requirements and streamline participation, IA, PI, and Quality structural and process measures can be incorporated into verification programs. To do this, MVP measures can be consolidated into various composite measures or included as an evidence-based standard.

The SQVP is designed as an overarching assessment of a quality program which can be applied broadly across a delivery system regardless of the practice type (academic, community, or rural care delivery system). In addition to the more broadly applied verification programs, the ACS has more service line directed programs which more narrowly define the quality elements to a particular clinical domain. These include areas such as trauma, cancer, metabolic and bariatrics, frail elderly and geriatrics, pediatric surgery, complex GI, and vascular surgical service lines. Any of these programs can be applied in multiple care settings such as academics, community or rural-based care.

3. **Quality scoring based on participation in verification programs, conformance measures, and performance measures.** Scoring for quality should constitute three categories with shared attribution at the team level: participation in a verification program, conformance measures chosen from a list of CMS consistent metrics (Surgical Site Infection (SSI), Readmissions and Surgical Risk Calculator, etc.) and PROs applied as appropriate for the condition/procedure (e.g. PROMIS,⁵ elements of EORTC,⁶ or EQ 5D-5L⁷). Note that there is a proposed framework detailed below.
4. **Test the attribution methodology for assigning clinicians to MVP(s).** Many surgeons will have a single dominant domain which will map to an MVP. However, depending on their practice, surgeons may not have a single dominant domain and will fit into multiple MVPs. Therefore, CMS will need to analyze the appropriate methodology for how to determine the appropriate MVP or mix of MVPs. For example, would CMS determine which MVPs clinicians fall into based on a percentage of cases? If so, will

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⁵ <http://www.healthmeasures.net/explore-measurement-systems/promis>

⁶ <https://qol.eortc.org/item-library/>

⁷ <https://euroqol.org/docs/EQ-5D-5L-User-Guide.pdf>



that result in accurately assessing their care? This must be carefully analyzed.

5. **Restructure the Promoting Interoperability performance category to enable true interoperability beyond electronic health records (EHRs).** To truly promote interoperability, CMS must incentivize the use of enhanced digital health IT capability. The functionality for digitally enhanced data aggregation should be a **minimum standard** for health IT in the MVP program. Functional EHR requirements should move toward verification and authentication of meeting national standards that enable the movement of health data across the digital environment. The goal for interoperability should be the digital transformation of data into knowledge and insights through the use of an open-source patient cloud. In this environment, Application Programming Interfaces (APIs) can flourish to deliver performance measures, inform patients, and to share knowledge with registries and other smart devices.
6. **A single source or entity to aggregate data for MVP benchmarking.** Measures should be analyzed and aggregated within a given domain or clinical service line by a single source and submitted to CMS for consistency in data interpretation. This includes standardized data definitions, standardized risk adjustment/data analytics, consistency of data ascertainment methods, and common normalization methods. It is nearly impossible (and overly costly) to create reliable and valid comparisons between care systems when multiple data aggregation systems are used for measurement. Examples include the Society for Thoracic Surgeons Registry, the ACS National Surgical Quality Improvement Program (NSQIP) and the American Academy of Ophthalmology IRIS® Registry each as single source. The importance of this cannot be overemphasized.
7. **Clinicians need to understand the cost of delivering outcomes for an episode, and the price to patients for shopability.** To move from fee-for-service into value-based care, delivery systems need support to understand both the cost and price aspects of care to optimize value. The tools for establishing production costs for facility-based care are possible using TDABC. Price models use episode groupers which are customizable by the clinicians using industry standards (such as the CMS-Episode Grouper Methodology (EGM)). CMS can enhance the CMS-EGM grouper use by moving it into position as a tool sitting over the CMS Virtual Research Data Center (VRDC).

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8. **MVPs should be reviewed and endorsed by an agent for CMS.** For surgery, a library of pilot IPU/episodes could be developed by ACS and HBS, then reviewed and endorsed by an agent for CMS. This will include the minimum criteria for quality and cost elements for CMS value-based care prior to inclusion into the CMS MVP program.
9. **Public reporting to express value with quality and cost measurement requires more research.** The current method of creating a combined score in a numeric expression which combines quality, cost, improvement, and interoperability into one number is a starting point. However, the ACS feels such expressions are not as informative to patients as creating a series of expressions using graphics or radar plots which define the various elements of interest to patients. Public education programs for learning to interpret value expressions are essential.

MVP Framework for Scoring Quality and Improvement

In order to have a patient-centric quality program, scoring for quality should constitute three categories with shared attribution at the team level for MVPs based on 1) participation in a verification program, 2) conformance measures chosen from a list of CMS consistent metrics (SSI, Readmissions and Risk Calculator, etc.) and applied as appropriate to the right condition/procedure, and 3) PROs based on the PROMIS, EORTC, EQ 5D-5L or other patient survey that is valid for differentiating outcomes for a condition or procedure.

ACS proposes that verification programs are the foundation for the MVP program, as they pursue excellence and avoid system errors by ensuring that the resources, staff, and infrastructure are in place to provide the highest possible quality care to the patient. For example, in the last decade, the U.S. has seen a dramatic improvement in perioperative mortality for patients undergoing bariatric surgery. The improvement is associated with more than 800 bariatric centers that have been verified through the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). The program measures the entirety of the care experience and the care team, linking the roles and contributions across the care team to optimize care. The result has been that one-year patient mortality decreased from 4.6 percent (1997–2000) across Medicare beneficiaries to less than 1 percent today across all patients.^{8,9} MBSAQIP Accreditation

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⁸ Flum DR, Salem L, Elrod JA, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA*. 2005;294(15):1903-1908.



programs have demonstrated safer outcomes, shorter length of stay (LOS), and lower total charges.¹⁰

Verification programs can also help to streamline MVP participation—measures can be consolidated into various composite measures or included as evidence-based standards in a verification program, which would be reviewed and endorsed by an agent chosen by CMS. Standards in verification programs include data systems that track conformance measures that are actionable and allow for the focus to shift to measuring the achievement of patient goals of care. Standards that are aligned with MVP domains can be thoughtfully integrated into verification programs for a continuous cycle of improvement for optimal patient care.

The ACS SQVP includes several quality-related domains and is applicable across surgical specialties:

SQVP Standards:¹¹

1. Institutional administrative commitment
2. Episode program and scope
3. Facilities and equipment resources
4. Personnel and services resources
5. Patient care: expectations and protocols
6. Data systems and surveillance
7. Quality improvement
8. Research: basic and clinical trials
9. Education: professional and community outreach

Figure 3 illustrates an example framework when considering implementation and scoring. This example is for illustrative purposes only, it is not meant to be a methodology for testing. Surgeon Jane Doe practices in two hospitals and two of the surgical MVPs align with her practice. In this example, she would have to meet the MVP threshold (percent of surgical cases) by totaling the volume of

⁹ Nguyen NT, Hohmann S, Slone J, Varela E, Smith BR, Hoyt D. Improved bariatric surgery outcomes for Medicare beneficiaries after implementation of the Medicare national coverage determination. *Arch Surg.* 2010;145(1):72-78.

¹⁰ Morton JM, Garg T, Nguyen N. Does hospital accreditation impact bariatric surgery safety? *Ann Surg.* 2014 Sep;260(3):504-8; discussion 508-9.

¹¹ American College of Surgeons. “Optimal Resources for Surgical Quality and Safety.” 2017. Retrieved from: <https://www.facs.org/quality-programs/about/optimal-resources-manual>



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surgical services for each of the MVPs she is eligible for (note: the appropriate methodology for how to determine the appropriate MVP or mix of MVPs must be analyzed). The MVP Score can be established with a total score by volume and weight assigned to: the SQVP Verification (or other relevant verification program), PROs, and the event rates. ACS weights the SQVP and PROs as the dominant elements. To meet the MVP's program needs, the IA and PI categories are represented within the verification program. For an initial pilot year(s), these broadly applied components—verification, performance, and conformance measures can be a starting place. In future years, more detailed metrics could be refined for each MVP if needed. Inputs for how to measure and weight the components would require guidance from a multi-stakeholder community. ACS is currently working on how to determine differing levels of verification for the purposes of incentivizing high-valued surgical care, and how to assess performance and conformance measures as part of the Total Weighted Average MVP score. **ACS continues to develop the ACS THRIVE framework and is eager to collaborate with CMS on the development of surgical MVPs.**

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Figure 3: MVP Scoring Example (for illustrative purposes)

| Jane Doe: Hosp A N=200 | | MVP – Colon Cancer | MVP – Breast Cancer |
|--|--|-----------------------------------|-----------------------------------|
| Verification Program: SQVP | Highest Weight in MVP Score | Score based on verification level | Score based on verification level |
| Performance: PROMIS, EORTC or EQ – 5D – 5 L | Medium Weight in MVP Score | Score based on performance | Score based on performance |
| Conformance: SSI/Readmit/Risk Calculator (Event rates) | Lowest Weight in MVP Score (least important) | Score based on performance | Score based on performance |
| Hospital A MVP Score (Y+Z) | | Y | Z |
| Jane Doe: Hosp B N=100 | | MVP – Colon Cancer | MVP – Breast Cancer |
| Verification Program: SQVP | Highest Weight in MVP Score | Score based on verification level | Score based on verification level |
| Performance: PROMIS, EORTC or EQ – 5D – 5 L | Medium Weight in MVP Score | Score based on performance | Score based on performance |
| Conformance: SSI/Readmit/Risk Calculator (Event rates) | Lowest Weight in MVP Score (least important) | Score based on performance | Score based on performance |
| Hospital B MVP Score (A+B) | | A | B |
| Surgeon Total MVP Score= Weighted Average of Hospital A and Hospital B | | | |

Data Integrity as a Key Focus of MVPs

ACS has stressed the importance of a “single source” or entity to aggregate data for benchmarking performance. In our experience with NSQIP and other ACS clinical data registries, we have demonstrated that it is critical for measures to be analyzed and aggregated by a single source for consistency in data interpretation, including standardized data definitions, standardized risk adjustment/data analytics, consistency of data ascertainment methods, and common normalization



methods. It is otherwise virtually impossible (and overly costly) to create reliable and valid comparisons between care systems when multiple data aggregation systems are used for measurement. It is also critical to use the appropriate measure science when determining validity and reliability. Currently, the MIPS program requires a percentage of cases over a 12-month period to determine performance for a given quality measure. This is arbitrary and has no basis in measure science, resulting in inconsistent levels of statistical power. We have proven that the data completeness requirement is not reliable for most surgical measures as a result of the number of cases a surgeon completes in a 12-month period—this is the case for clinical outcome measures that monitor low event rates such as mortality and SSI in particular. We discuss this in further detail in our comments to the 2020 QPP program.

ACS is eager to work with CMS to achieve accurate benchmarking through the appropriate use of statistical methodology. If it is not possible to achieve discernibility at the individual-clinician level, then the hospital/institution level measurement should be used as a proxy for quality. This must be determined on a measure-by-measure basis and applies to conformance and performance measurement, including PROs. It is important to recognize that we are in the early phases of understanding and implementing PROs, without the digital infrastructure to capture data from the patient at the point of care for a condition. Therefore, in the early years of MVP, we may not be able to have PROs that are condition-specific; we will need to allow time for their evolution.

MVP Population Health Quality Measure Set

As part of the MVP RFI, CMS solicits feedback on the inclusion of population health quality measures based on claims data. As discussed throughout our comments, surgeons do not find these types of measures actionable or meaningful to caring for surgical patients. It will be burdensome and frustrating for surgeons' MVP performance to be impacted by measures that are more actionable and relevant to primary care physicians. Furthermore, this policy generally seems contrary to the intent of MVP, which is to provide minimal sets of measures to eliminate burden for a specialty or condition. For example, CMS has expressed the intent to move specialists out of the CMS Web Interface in the current MIPS program where surgeons are measured based on primary care measures such as tobacco cessation or diabetes control. The framework that we present in this section which is inclusive of—participation in a verification program, conformance measures chosen from a list of CMS consistent metrics (SSI, Readmissions and Surgical Risk Calculator, etc.) and PROs applied as appropriate for the condition/procedure (e.g. PROMIS, elements of EORTC, or EQ 5D-5L)—are measures that are actionable, meaningful to clinicians and patients, and provide assurance that systems that clinicians practice in pursue excellence and

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avoid system errors by ensuring that the resources, staff, and infrastructure are in place to provide the highest possible quality care to the patient.

MVP Framework for Cost and Price

Given the innovative nature of the MVP program, the ACS encourages CMS to extend this innovation to the area of cost measurement. In addition to providing a score that CMS can use to assess the value of care provided to patients and reward physicians, cost measurement in Medicare should also provide physicians with the information they need to increase the value of that care. To provide the requisite level of information to meet both of these goals, it will likely be necessary to think of cost in terms not only of the *price* of care to CMS and the patient, but also the *cost* to the delivery system providing that care.

Cost-of-Delivering Services: TDABC

The ACS THRIVE demo will use Time-Driven Activity-Based Costing (TDABC) to thoroughly document all of the personnel, materials, and other resources used throughout an episode of care for all of the services assigned to that episode. For the core of the episode, these costs are measured on a minute-by-minute basis. For example, personnel costs are determined by calculating the annual compensation of a surgeon, nurse, anesthesiologist, or other clinician who maps to an episode and dividing by the typical annual minutes of work to establish a \$/min for each personnel type. We then track the number of minutes each person contributes throughout all phases of care and multiply that number by their unit cost. The result defines the overall personnel costs, supply costs, and so forth for the episode of care.

The purpose of looking at the *actual* cost of providing care rather than just the price, (i.e. the cost to the purchaser) is that it shines a light on hidden opportunities for cost savings, such as making sure that providers are working to the top of their license and reducing excess capacity in physical resources, allowing the delivery system to function more efficiently.

When production costs exceed patient price, either wasteful costs must be removed, or price must be adjusted. It is vital to delivery systems to understand their cost for goods and services if they are to remain a viable community asset and if they hope to increase value to the patient.

Price of Delivering Patient Outcomes

Price for the purposes of scoring the Cost category in a MIPS MVP can be determined using tools developed by the recently incorporated **PACES Center**

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for Value in Healthcare. The PACES Center’s tools are based on the CMS Episode Grouper for Medicare (EGM) and produce a patient-specific expected price with a breakdown for all services assigned to the episode within the phases: Prehospital, Hospital and Post discharge. By defining the episode of care to be measured (for cost *and* quality) and pulling in all charges related to that episode of care, PACES will help to identify other areas for improvement, such as duplication of services, by providing information on the types of services billed and the number and types of providers involved in care for the patient for that episode. Due to its thorough and iterative clinical review, comprehensive accounting of costs, ability to nest treatment episodes within condition episodes, and its automatic assignment and attribution logic, ACS continues to favor the PACES methodology to that of the current and proposed MIPS episode-based cost measures.

In order to act on CMS data in a useful way, ACS and its partners offer to: assist CMS in moving this evolution of the CMS EGM onto the Virtual Research Data Center (VRDC), pilot price modeling for surgical episodes of care, and then evaluate the utility of this informative “pricing” approach to optimize surgical care. CMS can enhance the CMS-EGM grouper use by assisting with positioning the CMS grouper within the VRDC firewall without the loss of CMS-EGM macros required to run the grouper logic as designed for CMS and optimal price modeling performance.

Participating practices armed with this information on both cost and price, along with meaningful quality measures, will be able to redesign care models to deliver the same or, preferably, better outcomes with a lower-cost mix of resources, including personnel, equipment, devices, and drugs. This is a value expression that is truly meaningful to patients. Furthermore, this information provides valuable insights not only for those in a fee-for-service environment, but also those who may wish to improve efficiency in an ACO or take on risk in a bundled payment arrangement. For that reason, this information helps to create stepping stones from fee-for-service to Alternative Advanced Payment Models (A-APMs).

Another important consideration in measuring value and incentivizing improvement is the need to assess quality and cost over the same episode of care. The MVP concept lends itself well to this as does the ACS THRIVE demo. The PACES Center for Value in Healthcare, noted above, seeks to build, maintain and promote a consensus standard for episode definition. Such a standard, if widely adopted, will reduce complexity, increase transparency and facilitate value improvement by allowing delivery systems to focus on improving care to the patient rather than focusing on which costs are in or out of episode on a payer by payer basis.

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Public Reporting to Express Value in MVPs

The current method of creating a combined score in a numeric expression which combines quality, cost, improvement, and interoperability into one number is a starting point. However, the ACS feels such numeric expressions are not as informative to patients as creating a series of expressions using graphics or radar plots which define the various elements of interest to patients. Public education programs for learning to interpret value expressions are essential.

The College believes that value is determined by an assessment that is made by the patient, and therefore must measure health outcomes that matter to the patient. Patients need information on care and outcomes that can be assessed, rather than a single score that represents the way in which CMS defines value. **Patients value aspects of care differently, and need information on multiple, meaningful, areas from which they can determine value as they define it.** To align with our recommendations for the MVP program, publicly reported information should include participation in a surgical verification program(s) for assurances in quality and safety, actionable cost measures, conformance measures, and performance measures (PROs). Information from these components will provide patients with meaningful information through which they can assess and determine value. Below are two figures that could be helpful for patients to assess the value of care. Figure 4 compares quality and cost in a bar chart for hospital based episodes. Figure 5 is a radar plot which defines the various elements of care that may be of interest to patients. These representations are for illustrative purposes only and must be tested for their ability to help patients assess value.

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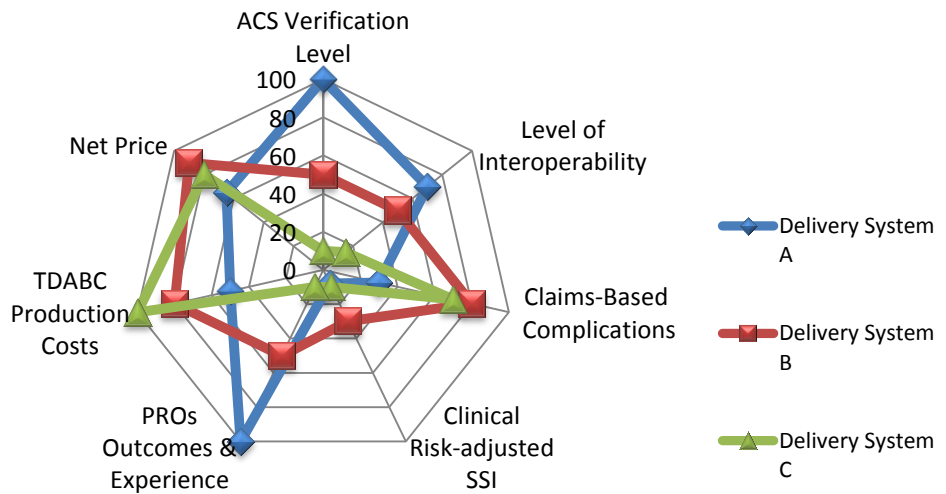
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Figure 4: Value Expression for Hospital-based Episodes



Figure 5: Radar Chart Episode Value Expression



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MVP Framework for Interoperability

CMS stated that they envision the PI category to remain a foundational element of the program, but did not offer any strategic changes to PI to best leverage health information technology (health IT) to facilitate MVPs and APMs. **The College believes that in order to advance toward MVP participation and meet goals of enhanced interoperability that the PI category must fundamentally change. We need to rethink how PI can support the data model needed for a true value-based program.**

The ACS believes it is critically important that the PI program becomes more than digitally specified measures for payment programs and moves beyond EHR-based conceptions of interoperability. The functionality for digitally enhanced data aggregation for payment performance measures should become a **minimum standard** for health IT. To truly promote interoperability, CMS must incentivize the use of enhanced digital health IT capability. This level of interoperability is critical in order to achieve the goal of value-based care. This will require the creation of a patient cloud where data can be processed, converted, and normalized, allowing for a digital transformation of knowledge—not simply the digitization of a paper record. The PI category of the overall MVP program could be integrated into the surgical accreditation and verification programs discussed above, such as the SQVP. The verification program can include the components of interoperability foundational to achieving value-based care.

To achieve data exchange and interoperability goals in the short-term and strategically shift the PI category as part of the MVP Program, ACS recommends the below steps. These components could be an attestation-based category that would be consistent across all of the MVPs:

- **Require the use of open APIs using FHIR-based standards when ONC finalizes Cures regulations.** When the ONC finalizes the 21st Century Cures rule, the standards for implementing APIs using FHIR based standards will be clearly defined. We strongly encourage CMS to work with ONC to include the same standards as an attestation for the PI category, in which clinicians would attest to using APIs that adhere to the ONC standards. As the program progresses, the attestation could move from a yes/no to a scaled attestation, creating incentives for clinicians who are super-utilizers of these standards to facilitate care.
- **Incentivize bi-directional data exchange with patient cloud(s) built on open-source standards-based architecture through attestation.** This cloud-based architecture will send and receive data to and from EHRs, third-party applications, registries, Health Information Exchanges (HIEs),

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and patient-generated health data (PGHD). We encourage CMS to include attestation of bi-directional exchange with a patient cloud environment as part of the PI program. Similar to the above, this attestation could also advance to a scaled attestation as the use of these tools matures.

- **Require the certification of digital health solutions and systems by a neutral certifying body for public assurance that applications are accurate and secure.** There are two important components to this: 1) CMS should work with the ONC to determine criteria and a process for certification of third-party applications to ensure appropriate clinical logic, technical specifications, and privacy standards, and; 2) Attestation from PI eligible clinicians to the use of **certified** third-party applications and devices as the final (3rd) attestation in the PI category.
- **Establish neutral governance of architecture and standards to ensure vendor-agnostic solutions and to avoid intellectual property being owned by single vendors.** CMS and ONC should work to develop and maintain a neutral governance of open-source standards through a public/private partnership, similar to Logica Health (formerly the Health Services Platform Consortium) or the Sequoia Project. The Sequoia Project will develop and enforce the Common Agreement for data exchange through the Trusted Exchange Framework and Common Agreement (TEFCA).¹² Although this would not be component of the PI category, neutral governance is foundational to ensure that the above PI attestations do not result in undue burden on clinicians or health care organizations.
- **Identify alternatives to a Universal Patient Identifier (UPI) to ensure appropriate patient matching and increase patient safety.** Inaccurate patient matching leads to endless patient safety concerns, and enhanced interoperability will only increase these risks. In the absence of a legislative fix mandating the creation of a UPI for this issue—which is the ideal solution—we encourage CMS to work with the ONC and the private sector to continue to explore alternative solutions for this problem. A standard algorithm hosted in a cloud platform that assesses and determines patient matches based on identifying information, such as name, date of birth, Payer ID, or other unique identifiers could be a stop-gap solution.

Through the above components and national standards for data exchange, physicians will be able to improve quality and advance care through the access to

¹² <https://sequoiaproject.org/>

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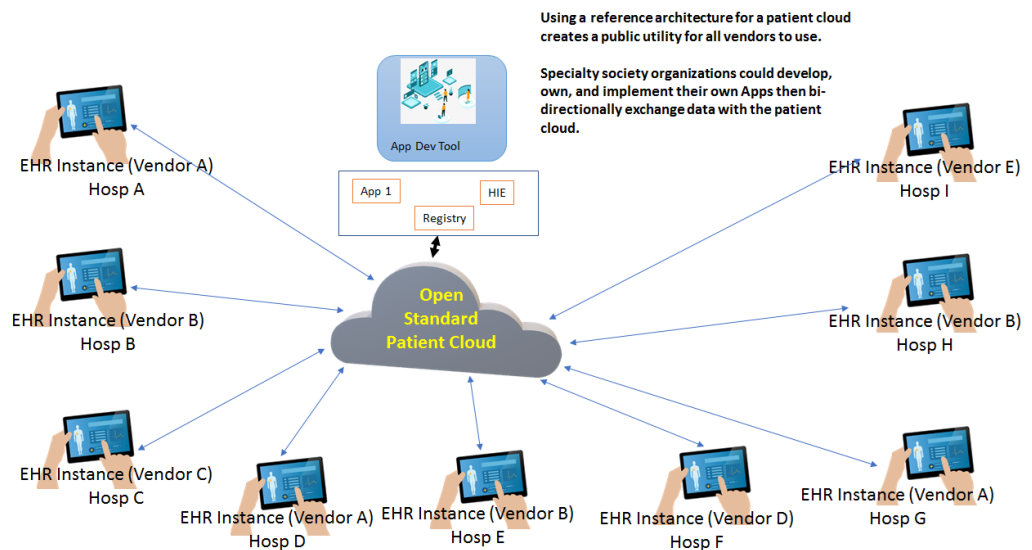
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more complete and integrated patient information, and benefit from the insights gained through processing and translation of data that can occur within the patient cloud platform. As illustrated in Figure 6, this advanced model of interoperability allows for the digital transformation of data into knowledge and insights, as it is able to take in huge amounts of data, process it, display it, and share it with a variety of different endpoints and systems. These data could inform and enable a culture of continuous quality improvement focused on providing high-value care. By re-imagining PI through the five components above, healthcare will be poised to advance its use and integration of digital tools, making the use of “big data,” artificial intelligence (AI), machine learning (ML), and Internet of Things (IoT) a possibility. A redesigned PI program is absolutely critical for the transformation from fee-for-service toward value-based care as envisioned in the future MVP program and APMs.

Figure 6: Advanced Model of Interoperability



MIPS Performance Category Measures and Activities

Quality Performance Category

Contribution to Final Score

CMS previously finalized that the Quality performance category will comprise 50 percent of a MIPS eligible-clinician’s final score for the 2020 MIPS payment year (2018 performance) and 45 percent of the MIPS final score for the 2021 MIPS

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payment year (2019 performance). The Bipartisan Budget Act of 2018 (BBA) requires that 30 percent of the MIPS final score be based on performance in the Quality performance category by year six of MIPS (2022 performance), but allows for the category weight to be adjusted for the first through fifth years. Using the authority granted in the BBA, CMS proposes to weight the Quality performance category at 40 percent of the final MIPS score for the 2020 performance year (a 5 percent decrease from the 45 percent weight in the 2019 performance year). The Agency also proposes setting the Quality category weight at 35 percent of the final score for the 2021 MIPS performance year, and 30 percent of the final score for the 2022 MIPS performance year to meet the timeline and requirement in BBA.

While we understand that the proposed weights for Quality and Cost for the upcoming years are required by statute, these categories still do not provide meaningful and actionable metrics for clinicians—in order to achieve value, it is **absolutely critical that clinicians have the capability to receive key indicators of the care they provide and act on that information to improve. This should be the primary focus of a quality program.** For example, the current Medicare Spending Per Beneficiary (MSPB) measure does not produce actionable data.

Quality Data Submission Criteria

Submission Criteria for Groups Electing to Report the Consumer Assessment for Healthcare Providers and Systems (CAHPS) for MIPS Survey

Currently, the CAHPS for MIPS Survey is the primary mechanism in MIPS to capture patient experience. If a group or virtual group chooses this reporting option and administers the survey, it is counted as a quality measure, and is available for attestation as an Improvement Activity. CMS states that through user-testing, patients and caregivers regularly request mechanisms that provide more patient reported information, such as publicly reported narrative reviews of individual clinicians and groups. Based on this feedback, CMS requests comments on the addition of patient narratives to the CAHPS for MIPS survey, including whether the survey should collect data at the individual eligible clinician level.

The College agrees with CMS that patient-generated data could have great value in MIPS. **The ACS appreciates CMS' efforts to provide more information to patients but we do not support the continued use of the Clinician and Group (CG) CAHPS survey. The CG CAHPS survey or "CAHPS for MIPS" falls short of the type of patient feedback that is meaningful to specialists, and therefore does not provide relevant information to patients on specialty care.** Additionally, CAHPS surveys are retrospective and therefore do not provide an

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opportunity to drive improvement or inform care during the patient's journey. CAHPS surveys also have many implementation challenges. There has consistently been a low survey response rate, which is an indication that CAHPS surveys are limited in their ability to capture a meaningful sample of patients—this may also indicate that the administration of these surveys lack meaning and are too burdensome. CAHPS has also not been able to keep up with current health IT opportunities.

Instead of the continued focus on modifications to CG CAHPS, we believe it is time to revisit patient reported data and urge CMS to work with stakeholders to develop a framework that focuses on measuring how well patients' goals are met for a condition or episode through the use of validated PROs. More specifically, **we encourage CMS to pilot PRO tools as a foundational element of successful quality improvement programs. We hypothesize that PROs tailored to a condition or episode allow clinicians to better understand the elements of care their patients value most, and empower patients to work with care teams to communicate goals and engage in shared decision making prior to and during care.** Collecting PROs in more frequent, but brief, occurrences throughout episode(s) of care can provide meaningful information to physicians throughout the patient's care journey and enhance patient-clinician communication—including progress on patient goals, post-surgical recovery, pain management, and rehab and therapy, to name a few.

CMS also requests feedback on adding narratives to the CAHPS for MIPS survey and on whether the survey should collect data at the individual eligible clinician level. **To restate our feedback above, we strongly recommend that the inclusion of patient narratives should be tested prior to large scale implementation and for use in a pay-for-performance program**—and it is unclear how and whether CMS would incorporate patient narratives as part of the MIPS Quality score. In addition, we ask for clarity on how CMS plans to manage false or inappropriate narratives. For example, could a false narrative misguide patients? How would a physician appeal a false narrative? Will false narratives become a disruption to the trust in a physician-patient relationship, or worse, create defamation suits? We also ask CMS for examples of where raw patient narrative data has been used successfully to drive improvements in care.

Although the validated PROs we discussed above still need to be piloted prior to use in the QPP program, there is well established evidence in the literature detailing the benefits of PROs. There is also a need for increased PRO use in order to understand how to best incorporate results into value-based payment programs.

It is also crucial for CMS, along with stakeholders, to leverage digital health platforms to collect information from patients. By leveraging health IT, patients

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can be asked fewer questions more frequently through easily accessible platforms (such as smart phones), rather than distributing a large retrospective survey after the completion of care. This format also allows physicians to gather real-time data directly from patients to inform care decisions at various points of treatment, and increase communication between patients and physicians, while reducing administrative burden. **Utilizing a standardized, open source patient-cloud as the centralized, standard platform would allow PRO implementations through open APIs across all EHR platforms.** Responses from patients would flow back to the EHR through an open API in the patient-cloud and allow for PRO communication to be pulled by the EHR and displayed internally to present patient reports to the clinical teams. These cloud-based patient reports could also be sent to other third-party applications. In the patient-cloud, data from multiple sources could be aggregated and analyzed, and the open architecture allows for widespread, vendor-agnostic use of successful survey tools. With a patient-cloud, and with permission from the patient, any EHR can deliver a report to any entity—the patient portal, another EHR, CMS, etc. The College continues to develop and test open source patient-clouds and inclusions of care tools such as PROs for surgical care. We are eager to collaborate with CMS on these efforts.

Managing Customer Experience and Improving Service Delivery

CMS seeks comment on the seven domains identified in the *President's Management Agenda—OMB Circular No. A-11 section 280—Managing Customer Experience and Improving Service Delivery*. Domains include:

1. Satisfaction
2. Confidence
3. Quality
4. Ease/Simplicity
5. Efficiency/Speed
6. Equity/Transparency
7. Employee Helpfulness.

The President's Management Agenda offers guidance on how customer experience should be measured in the federal government. CMS asks if additional elements, questions, or context informed by these domains should be added to the current CAHPS for MIPS survey.

The College acknowledges that these domains may be important when measuring patient experience and satisfaction, but—as discussed above—CAHPS already has low response rates with little valuable information on specialty care. If CMS chooses to test this, instead of adding additional questions or elements to the

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survey, we recommend CMS examine sampling methodologies, such as computer adaptive testing (CAT). Choosing the correct sampling methodology would allow for shorter surveys that would keep patients engaged, but still provide the ability for statistically significant response rates.

Data Completeness Criteria

The Agency has incrementally increased the data completeness threshold since Year 1 of the QPP. In Year 1 (CY 2017) and Year 2 (CY 2018), CMS maintained a data completeness threshold that required physicians to submit quality measure data for 50 percent of all patients, unless reporting via Medicare Part B claims, which required 50 percent of all Medicare Part B patients. CMS states that the data completeness threshold was retained at 50 percent for the first two years to allow time for MIPS eligible clinicians to adjust to the program, but believes it is important to incorporate higher data completeness thresholds over time to ensure a more accurate assessment of a MIPS eligible clinician's performance.

Therefore, the threshold was increased to 60 percent of all patients (all payer) in Year 3 (CY 2019). For Year 4 (CY 2020), CMS proposes to adopt a higher data completeness threshold of 70 percent of the MIPS eligible clinician's or group's patients that meet the measure's denominator criteria. CMS explains that they believe the increase in the data completeness threshold is reasonable based on CY 2017 average data completeness rates. The rates showed that on average, small practices reported 74.76 percent of data, individual clinicians reported 76.14 percent, and groups reported 85.27 percent. However, CMS did not include information on whether these percentages represent all reporting mechanisms combined or if these are a subset, such as claims. We seek further clarity on whether these numbers represent all MIPS eligible clinicians across reporting options.

The College does not support the increase of the data completeness threshold based on an arbitrary percentage with no demonstration of statistical reliability. We seek clarification from CMS on any evidence that demonstrates that this policy has the ability to differentiate performers based on the proposed data completeness threshold. We also seek clarity on the level of statistical reliability that 70 percent data completeness achieves for the diversity of MIPS measures.

In our decades of experience in quality measurement, increasing data submission thresholds based on a percentage of cases applicable to all quality metrics has not demonstrated variation in one clinician and/or group from another clinician and/or group, unless the goal is to identify the bottom 3-5 percent of clinicians (poor performers). In other words, ACS has not generally been able to determine statistically relevant differences across average and high performing clinicians on

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an individual level of measurement. Challenges related to measuring the performance of individual clinicians results in data being heavily skewed towards high performance, which decreases the ability to show variance among physicians. Our work has shown that reliability must be determined on a measure-by-measure basis, taking into account event rates for a specific procedure.

For example, with the use of high quality clinical data from ACS NSQIP, when measuring aspects of rare event rates to create discrimination, ACS has demonstrated that the needed case volume is too high for most surgeons to be accurately ranked solely by their individual outcomes. In a NSQIP study by Hall et al, the sample size needed to achieve good statistical reliability (0.7) for surgical site infection (SSI) for colectomy was 254 cases, and 1,985 cases for mortality.¹³ Outliers could not be identified for mortality. The high case volume required is especially difficult given the regulatory requirements of the MIPS program, which only allow for a maximum of 12 months of a data and an arbitrary sample size based on a percentage of cases that fit into a measure numerator. Simply put, based on our experience, a MIPS clinician's payment should not be impacted based on surgical outcomes because they are not reliable and can misclassify care. We have only found that we are able to reliably identify 3-5 percent of the bottom performers—all other performance cannot be reliably measured.

We encourage CMS to explore a policy that determines whether a MIPS clinician is not statistically proven to be a poor performer (bottom 3-5 percent). If CMS cannot demonstrate statistical reliability beyond poor performance, then perhaps CMS should consider outlier status for poor performance to be one contributor to a quality score and seek other more pertinent aspects of measurement to score clinicians. These could include hospital or system level measures, adequacy of their infrastructure through verification, and conformance with quality improvement standards and more specialty-focused PROs.

CMS may also wish to rethink its overall data strategy and the role of data completeness for future consideration. Having longitudinal data beyond 12 months may give CMS new directions for channeling its efforts about data completeness. The clinical data ecosystem is moving beyond simple interoperability within individual clinical EHRs. Many aspects of the health IT world are working to promote patient-clouds built with inputs from multiple

¹³Hall BL, Huffman KM, Hamilton BH, Paruch JL, Zhou L, Richards KE, Cohen ME, Ko CY. Profiling individual surgeon performance using information from a high-quality clinical registry: Opportunities and limitations. *JACS*. 2015;221(5):901–913. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/26363711>.

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EHRs into one canonical data model upon which many APIs can act. Most other industries have already made this switch. The elastic cloud environments, big data, ML/AI, and IoT have created an environment which will greatly enhance access to information and improve health and healthcare. Other federal agencies are actively pursuing enriched data strategies, such as the Food & Drug Administration (FDA). Realizing larger data availability and greater scales of data completeness will increase sampling in such a way to enhance reliability, validity, and allow for predictive modeling. CMS, through rule-making, could play a major role in removing barriers from EHR data blocking by enhancing the patient-cloud architecture. The focus requires investing in securing privacy so as to enable the data availability for building an open-source cloud platform. The current EHR models create highly siloed customized data models such that every EHR instance (even for the same vendor) is an island unto itself. As such, we are left with a lack of interoperability. By allowing data migration into trusted cloud platforms with a single, common data model, we enable big data exposure to ML/AI and create highly complex performance metrics to inform clinicians and patients.

Selection of MIPS Quality Measures

Call for Measures and Measure Selection Process

Each year, stakeholders are encouraged to identify and submit quality measures during the annual Call for Measures process. Measures are considered for inclusion in MIPS for the performance period beginning two years after the measure is submitted. Measure stewards are asked to consider various factors before submitting measures:

- Measures are not duplicative of an existing or proposed measure.
- Measures that are beyond the measure concept phase of development, with a strong preference for measures that have completed reliability, feasibility, and validity testing.
- Measures that are outcomes-based rather than process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnoses and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.
- Measures that address significant variation in performance and are not considered topped out.

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In addition to these previously finalized factors, CMS proposes to require measure stewards to link MIPS quality measures to existing and related MIPS cost measures and IAs, as applicable and feasible, beginning with the 2020 Call for Measures process.

The College thanks CMS for acknowledging our concerns in previous years about the siloed-nature of MIPS, and introducing the MVP concept to take steps toward creating a more cohesive, streamlined program. The ACS supports a model that ties quality measurement, cost, and improvement activities together, as these are essential elements of a system focused on measuring value and creating a culture of continuous quality improvement. Although we agree with the concept of aligning MIPS categories, there are two key issues we believe are needed in order to achieve a cohesive program:

- 1) **There are very few measures in MIPS that map to the surgical patient and therefore, most existing measures do not provide meaningful and actionable information to surgeons for quality and cost—information that is required for quality improvement actions.**
- 2) **While we agree that measure stewards should identify improvement activities and cost measures that align with quality measures, it is important that it is clarified that this is the role of the measure steward which includes physicians and clinical expert representatives and not the measure methodologist alone.** Measure stewards can oversee a process in which clinicians identify which improvement activity and cost measure are appropriately relevant to the quality measure they steward.

Proposed changes to quality measures

Each year CMS proposes to add, modify, or remove quality measures for inclusion in MIPS for the upcoming performance year. This proposed rule includes updates to new and existing specialty-specific measure sets for the 2020 MIPS performance year. Our comments on the addition of a quality measure and modifications are discussed below.

Proposed for Addition:

Multimodal Pain Management

CMS proposes the addition of the *Multimodal Pain Management* measure beginning with the 2020 MIPS performance year. This process measure accounts for the percentage of patients, aged 18 years and older, undergoing selected surgical procedures whose pain was managed with multimodal pain medicine.

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ACS has consistently promoted the use of multi-modal analgesia as a way to reduce opioid prescribing and improve patient outcomes. Multimodal pain management is an essential element of Enhanced Recovery After Surgery (ERAS) and is defined as “the use of multiple, simultaneous mechanisms of pain control acting synergistically to improve analgesic effect and reduce the focuses of any single agent.”¹⁴ Multi-modal pain management techniques are tied to the reduction of unnecessary opioid-use, excessive post-operative prescriptions, and length of stay. **The College supports the addition of this measure in MIPS and thanks CMS for acknowledging it as a high priority measure.**

General Surgery Specialty Set

For General Surgery Specialty Set in the 2020 Performance year, CMS proposes to remove two measures: *Medication Reconciliation Post-Discharge* and *Sentinel Lymph Node Biopsy for Invasive Breast Cancer*; and add two measures: *Anastomotic Leak Intervention* and *Adult Immunization Status*.

- Removal of *Sentinel Lymph Node Biopsy for Invasive Breast Cancer*

Sentinel Lymph Node Biopsy for Invasive Breast Cancer measures the percentage of clinically node negative breast cancer patients before or after neoadjuvant systemic therapy, who undergo sentinel lymph node (SLN) procedure. CMS proposes the removal of this measure based on extremely topped out status, noting that it is a standard clinical practice. The College has strongly opposed the removal of measures based solely on extremely topped out or topped out status, as discussed below. Assessing value of care for a patient differs from placement of a measure into a payment program—there are more aspects to quality than just payment. Value includes the major aspects of quality which are fit for care are being delivered.

Quality includes multiple measures which reside in a culture of quality improvement and safety. Conformance measurement tracks “defect free care” by identifying events that are avoidable or preventable, such as wound infection, readmissions, and other adverse events. Conformance measurement is only one aspect of quality measurement and relies heavily on event rate reporting. When CMS removes a valued measure such as *Sentinel Lymph Node Biopsy* because it is “topped out” the Agency is sending the wrong message to the field. ACS would rather build on topped out measures so that patients are subjected to all the proper

¹⁴ Beverly, A., Kaye, A.D., Ljungqvist, O., Urman, R.D. Essential Elements of Multimodal Analgesia in Enhanced Recovery After Surgery (ERAS) Guidelines. *Anesthesiology Clinics*, 2017;35(2):e115-e143.

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aspects of a care model in support of quality. For example, consider a breast cancer care measure set which includes sentinel node biopsy for invasive cancer and the sentinel node biopsy rate during breast conserving operations for Ductal Carcinoma in Situ—which should be the inverse of the rate of node biopsy with invasive cancer of the breast. Together, these measures reflect the role of sentinel node biopsy in breast cancer care. In other words, it is more important to drive better care than it is to drive better payment. Therefore, **ACS supports the continued inclusion of the *Sentinel Lymph Node Biopsy for Invasive Breast Cancer* measure because it identifies a process essential to the optimal care of a specific cancer patient.** There are many more aspects of optimal breast cancer care to include. If measures were all-inclusive of the key aspects of care, patients would benefit from knowing all the structure and processes were followed, so the focus would shift to improving outcomes.

- Addition of *Adult Immunization Status*

The *Adult Immunization Status* measure determines the percentage of patients 19 years or older who are up-to-date on recommended routine vaccines. The Agency proposes this as a new quality measure in MIPS for the CY 2020 reporting period, and also proposes to include the measure as part of the General Surgery specialty set, citing that it is “clinically relevant to the clinician type.” Currently, this measure is only validated and endorsed at the level of the health plan, and not the individual level. CMS states that they believe the health plan level version of the measure can be easily adapted to the clinician level by revising the measure analytics to assess the proportion of patients who have been administered the vaccines.

The College does not support the inclusion of this measure in the *General Surgery Specialty Set* because it does not aid surgical teams in providing improved surgical care and it adds an unnecessary task to a surgeon’s workflow that provides little value to surgical patients or their goals for surgery. We believe this measure is more appropriate for measurement of primary or chronic care. Additionally, the 2018-2019 Measure Application Partnership (MAP) did not support the inclusion of this measure in rulemaking, calling for additional specification and testing of the measure for clinician-level analysis. MAP states that the measure specifications require more detail to account for variability of benefits (i.e., reimbursement for vaccinations), vaccine shortages, data availability/feasibility, and more clarity into the timeframe of

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reporting. MAP also noted that the composite measure required internal harmonization of its component parts.¹⁵

- Addition of *Anastomotic Leak Intervention*

The *Anastomotic Leak Intervention* measure identifies the percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery. CMS proposes the addition of this measure to the *General Surgery Specialty* set for the 2020 performance because they believe it is clinically relevant to general surgeons. The College generally supports the inclusion of this measure, as it a foundational conformance measure that identifies adverse events for the specified procedures and provides relevant and actionable data for surgical practice. However, **in order to reliably and validly measure anastomotic leak intervention, we need a single source to collect, analyze, and aggregate data. ACS has found that measuring the same quality measure, with the same measure specification across registries does not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation, including the lack of standardized data definitions, lack of standardized risk adjustment/data analytics, inconsistency of data ascertainment methods, and lack of common normalization methods.**

This was demonstrated when ACS harmonized the SSI NSQIP measure with the CDC National Healthcare Safety Network (NHSN) SSI measure. After harmonization of measure specifications, results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry. Through further study, ACS found that this discrepancy was not because NSQIP participants had poorer surgical outcomes, instead, the discrepancy was due to the lack of standard processes used to track patients and collect data for use in the NHSN registry when compared to NSQIP. An SSI in the outpatient setting would usually be missed under the current NHSN practices, but captured in NSQIP.¹⁶

¹⁵ National Quality Forum (NQF). 2018-2019 MAP Final Recommendations. Retrieved from:

<https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244>

¹⁶ Ju MH, Ko CY, Hall BL, Bosk CL, Bilimoria KY, Wick EC. A Comparison of 2 Surgical Site Infection Monitoring Systems. *JAMA Surg.* 2015;150(1):51-57.

doi:10.1001/jamasurg.2014.2891. Available at <https://www.ncbi.nlm.nih.gov/pubmed/25426765>.



Global and Population-Based Measures

In the MVP RFI, CMS discusses its intention to include Global and Population-Based administrative claims-based quality measures as part of the proposed MVP framework. The Agency states that increasing the number of population health measures that utilize administrative claims data in the MIPS program, in conjunction with reducing the number of required condition and specialty specific measures would reduce burden associated with quality reporting, help improve patient outcomes, and increase alignment with APMs and other payer performance measurement. Therefore to align with the MVP implementation timeline and allow for the measure to be tested and reviewed by the MAP, CMS proposes the addition of one administrative claims-based quality measure, *All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions*, beginning with the 2021 MIPS performance period.

ACS does not support the inclusion of this measure because surgeons do not find global and population-based measures actionable or meaningful when caring for surgical patients. It will be burdensome and frustrating for surgeons' performance to be impacted by measures that are more relevant and actionable to primary care physicians. The proposal of this measure generally seems contrary to the intent of MVP, which is to provide minimal sets of measures to eliminate burden for a specialty or condition. For example, CMS has expressed the intent to move specialists out of the CMS Web Interface in the current MIPS program because surgeons and other specialists are measured based on primary care measures such as tobacco cessation or diabetes control.

The framework ACS proposes in the MVP section of this comment letter is inclusive of: participation in a verification program, conformance measures chosen from a list of CMS consistent metrics (SSI, Readmissions and Surgical Risk Calculator, etc.) and PROs applied as appropriate for the condition/procedure (e.g. PROMIS, elements of EORTC, or EQ 5D-5L). This framework includes measures that are actionable and meaningful to clinicians and patients. It also provides assurance that the systems clinicians practice in pursue excellence and avoid system errors by verifying that the resources, staff, and infrastructure are in place to provide the highest possible quality care to the patient.

Topped Out Measures

In the CY 2019 QPP final rule, CMS finalized that once a measure reaches extremely topped out status (measures with average mean performance within the 98th and 100th percentile range), it may be proposed for removal in the next rulemaking cycle regardless of how long it has been in the topped out measure

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lifecycle. The ACS has expressed concern about this policy and the removal of measures based on topped out status in our comments on the CY 2018 and CY 2019 QPP Proposed and Final Rules. In this proposed rule, CMS states that stakeholders have expressed concern that physicians' ability to self-select measures they expect to perform well on may contribute to many measures' topped out status. Based on this concern, CMS seeks comment on whether they should increase the data completeness threshold for quality measures that are identified as extremely topped out, but retained in the program due to the limited availability of quality measures.

The ACS continues to oppose the topped out measure policy and believes the policy is extremely flawed. The general removal of measures based on mean performance does not account for variation in performance among sub-populations, does not consider how a measure supports quality improvement, and therefore its removal may have unintended consequences on patient safety. A highly reliable quality system attempts to identify all critical measures and seeks topped out performance in all of them. High value process measures are crucial to a coordinated surgical team because they tell an important story as part of the care continuum. For example, the *Patient-Centered Surgical Risk Assessment and Communication* measure is considered topped out by CMS and could eventually be removed from the program under the topped-out measure removal policy. Yet, assessing and discussing risk with patients prior to operating is essential for both patients and their surgeons as they explore treatment options and prepare for surgery. Tools that assess surgical risk, such as the Surgical Risk Calculator, are not only important to the surgeon when deciding on surgery, but also facilitate the informed consent discussion and patient-centered decision making. The topped out measure policy does not take these important factors into consideration. If the MIPS program is truly focused on improved quality, it is critical to incentivize the use of high value process measures, such as the standards used in ACS accreditation and verification programs (Trauma Verification, Commission on Cancer Certification, Bariatric Accreditation, and the ACS Optimal Resources for Surgical Quality and Safety standards). These programs use high value process measures to ensure that clinical teams have the appropriate resources to deliver optimal care. The measures in these programs should not be disincentivized by the MIPS program.

Additionally, while we appreciate CMS' efforts to respond to stakeholder concern with self-selection, the College does not believe increasing the data completeness threshold for extremely topped-out measures addresses the reliability and validity issues with topped out measures. We believe this proposal is inherently flawed. Under this proposal, MIPS clinicians and groups who score well will likely continue to report on the measure, while those who do not are even more likely avoid it so this proposed policy won't achieve the goal of

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getting a more complete picture of performance. As long as payment is tied to performance on specific measures and valuable, actionable data is not produced through program participation, payment will drive participant's reporting strategies and physicians will "study to the test." Physicians will continue to select measures they know will best position them to score well in the program and lead to positive payment adjustment.

There are more aspects to quality than just payment. When CMS removes a valued measure because it is "topped out" the Agency is sending the wrong message to the field. ACS would rather build on topped out measures so that patients are subjected to all the proper aspects of a care model in support of quality. In other words, it is more important to drive better care than it is to drive better payment.

In addition, CMS seeks comment on potential alternative solutions in addressing extremely topped out measures. **High-value topped out measures should be included in a composite that encompasses the various phases of surgical care or as part of the list of structural measures in a verification program, such as the ACS SQVP.**¹⁷ Composites could also be used as CMS chooses measures for the various MVP pathways. The ACS encourages CMS to work with stakeholders to identify episode- or specialty-specific measures that provide high-value information to physicians and their patients, and develop a framework that would allow for "topped-out" or "extremely topped out" measures to be retained. An example of this is a suite of measures for a condition or related to a procedure. When considering quality care for breast cancer, we believe three separate aspects of care are helpful to the patients and the care team: the disutility of care (events or complications); quality of the patient's overall health and achievement of patient goals; and survival and disease control. **To drive better quality in breast cancer care requires a suite of measures which, when combined together are "topped out" and help to ensure patients receive the highest quality of care.** Patients deserve to be informed in order to optimally shop for care. CMS' approach for removing topped out silos of disaggregated measures does not inform patients or drive care teams to improve. ACS feels patients deserve more than metrics used in payment models.

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¹⁷ American College of Surgeons. "Optimal Resources for Surgical Quality and Safety." 2017. Retrieved from: <https://www.facs.org/quality-programs/about/optimal-resources-manual>



Removal of Quality Measures

CMS continues to prioritize the reduction in the number of measures in MIPS. To achieve this, the Agency has established criteria that allow quality measures to be removed through notice and comment rulemaking. In addition to the previously established removal criteria, CMS proposes to remove MIPS quality measures that do not meet case minimum and reporting volumes for two reporting periods. The Agency discusses MIPS quality measures that have had low reporting rates from year to year, and the difficulty in determining benchmarks for measures with low reporting rates. **The ACS does not support the removal of measures based on these criteria. Instead, we recommend that CMS offer incentives for reporting these measures, especially measures that focus on specific specialties or conditions.** Measures developed with a specific specialty or condition in mind may not be reported as robustly as measures that can be applied to various categories of MIPS-eligible clinicians, therefore contributing to a low reporting rate. While some specialty measures may have low reporting rates, this does not necessarily indicate a low value measure. For example, a specialty measure could be reported by a small number of clinicians, such as pediatric specialists, and yet that small number represents a significant percentage of those caring for the patients to which the measure applies. **Removing measures based on this criterion could lower the number of meaningful measures available to specialties, and force them to report measures that do not fit in their work flows and provide little value to their practice or patients.**

Request for Information on Potential Opioid Overuse Measure

CMS developed an eCQM to address concerns about unsafe opioid use titled *Potential Opioid Overuse*. The intent is to assess patients on long-term and high-dose opioid prescriptions in order to find alternate therapies and methods for pain management. The measure evaluates the patient population over 18 years old with prescriptions for opioids that are longer than 90 days (with no more than a 7-day gap between prescriptions or prescription refills) on a daily dose of 90 MMEs or higher.

The College appreciates the intent of the measure, and believes that it is important to understand the patient population on long-term, high-dose opioids in order to prevent Opioid Use Disorder (OUD) and find effective pain management strategies and therapies. However, similar to the concerns that CMS identified when the measure was piloted, the ACS believes that it will be challenging to capture and report the data-elements related to prescription start and stop and patient initiation (both date and time beyond the general prescription length, as well as patient pick-up). These data are within pharmacy systems and/or e-prescribing systems (such as Surescripts)—not only from physician prescriptions,

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meaning the data in a physician's EHR would be incomplete for reporting this measure.¹⁸

Similar to the Prescription Drug Monitoring Program (PDMP) measure that CMS made optional for the 2020 reporting period, **this measure should be implemented after PDMPs are standardized and better integrated with EHRs, pharmacy systems, and other external data sources.** When PDMPs are in advanced stages of use, these data will be more readily available and inclusive of all prescriptions and their associated sigs (instructions for use) for the patient, from all prescribers. However, regardless of technical capacity and utilization, data on patient habits collected from this measure will be limited. In order to understand use, Patient Reported Outcomes (PROs) must also be incorporated to understand actual patient use of filled prescriptions. With PROs, patients can share actual use of prescribed opioids, which can be supplemented with pharmacy data to create a more complete picture.

Further, from a surgical perspective, patients should not be on an opioid prescription post-surgery for more than 7 days without a clinical indication. As most surgical pain is highly tolerated after three days and with non-steroidals after 7 days, post-surgical patients should not be on opioid medications beyond 7 days, unless there is another underlying chronic pain diagnosis. To capture surgery patients and their post-surgical pain management and related opioid use, the College recommends a new measure, *Observed versus expected opioid usage in post-surgical cases*, which is detailed in the Promoting Interoperability section.

Cost Performance Category

General Comments

The purpose of measuring both quality and cost in Medicare is to be able to assess the value of care provided to Medicare patients and provide physicians with the information they need to increase the value of that care. To achieve higher value, quality measurement and cost measurement should occur for the same episode of care. While this does not appear feasible for 2020 under the current MIPS structure using existing measures, ACS is hopeful that the newly proposed MVP option could allow for measurement of both cost and quality across a single episode of care.

For the Cost category of MIPS to be meaningful, the measures used must be not only reliable, but also actionable. That is, they should provide information on how

¹⁸ <https://surescripts.com/enhance-prescribing/>



a physician or care team currently uses resources and allow for comparisons with others who may be more efficient. Broad cost metrics such as those currently applied to most MIPS participants, do not break down all the services billed related to the patients' experience in a care model. ACS defines costs related to the five phases of surgical care: preop, periop, intraop, postop and post discharge. We are able to consolidate these into costs defined more simply as prehospital, hospital-related services, and post discharge. Further breakdown of all the services, adjusted for the patient's co-morbid conditions, allows the clinicians to benchmark prices, identify wasteful expenditures, and create alternative solutions. Without this level of detail, cost or price becomes a burden and therefore unmanageable. Clinicians do not possess the resources to dissect their patients' total cost, and therefore must rely on payors to provide benchmark comparisons of these complex expenditures. In addition, the knowledge around cost must be presented in such a way as to avoid disruptions to clinical care or to patients.

Cost measures should be designed around the patient and include all care provided for a given condition, or intervention. This information should then be combined with quality measurement that demonstrates the outcomes of that care. This allows MIPS participants to understand how their care decisions result in spending and outcomes that differ from those of similar clinicians and allows them to take actions that improve their MIPS performance, and ultimately the value of care they provide. ACS continues to offer to work with CMS to define price representations to clinicians which would enable surgeons to carry out their clinical responsibilities while acting on these fiscal matters.

ACS THRIVE

ACS and the Harvard Business School (HBS) Institute for Strategy and Competitiveness recently introduced the ACS THRIVE initiative. ACS THRIVE is designed to help hospitals and surgical practices improve patient outcomes while lowering the cost of delivering care as reimbursement shifts to bundled payments—an approach that increases transparency and accountability. This newly designed value-measurement process will be piloted at 10–15 U.S. hospitals, focusing on measuring the full cycle of care—including its key surgical, medical, behavioral, and social elements—for three surgical conditions.

ACS THRIVE will look at surgical spending from two different perspectives:

- **Cost**, defined as the resources used to produce the care provided, and;
- **Price**, defined as how much is spent on that care by the patient and payer

To determine the cost of care, the project will use TDABC to thoroughly document all of the personnel, materials, and other resources used throughout an

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episode of care for all the services assigned to that episode. For the core of the episode these costs are measured on a minute by minute basis. For example, personnel costs are determined by the annual compensation of a surgeon, nurse, anesthesiologist, or other clinician who maps to an episode and dividing by the typical annual minutes of work to establish a \$/min for each personnel type. We then track the number of minutes each person contributes throughout all phases of care and multiply that number by their unit cost. The result defines the overall personnel costs, supply costs and so forth for the episode of care. The purpose of looking at the actual cost of providing care rather than just the price, (i.e. the cost to the purchaser) is that it shines a light on hidden opportunities for cost saving such as making sure that clinicians are working at the top of their license and reducing excess capacity in physical resources, allowing the delivery system to function more efficiently. When production costs exceed patient price, either wasteful costs must be removed or price must adjust. It is vital to delivery systems to understand their cost for goods and services if they are to remain a viable community asset.

Price information for an episode will be determined using tools developed by the recently incorporated **PACES Center for Value in Healthcare**. The PACES Center's tools are based on the CMS EGM and are capable of producing a patient-specific expected price with a breakdown for all services assigned to the episode within the phases: prehospital, hospital and post discharge. PACES yields highly actionable knowledge to the care team so that actions can be taken to reduce wasteful aspects of the care model. By pulling in all charges related to an episode of care, PACES will help to identify other areas for improvement such as duplication of services. Duplication of services will be identified by providing information on the types of services billed and the number and types of clinicians involved in care for that episode. **Due to its thorough and iterative clinical review, comprehensive accounting of costs, ability to nest treatment episodes within condition episodes, and its automatic assignment and attribution logic, ACS continues to favor the PACES methodology to that of the current and proposed MIPS episode-based cost measures.** In order to act on CMS data in a useful way, ACS and its partners offer to assist CMS in moving the CMS EGM onto the VRDC to pilot price modeling for surgical episodes of care and evaluate the utility of this informative “pricing” approach to optimal surgical care.

Participating practices armed with this information on both cost and price along with meaningful quality measures can redesign care models to deliver the same or, preferably, better outcomes with a lower-cost mix of resources—especially personnel, equipment, devices and drugs. This is a value expression that is truly meaningful to patients.

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While this level of detailed cost measurement may not be feasible in the current MIPS framework, the results from the ACS THRIVE pilot will be used to create a scalable approach that other hospitals can use to measure and improve value. The method will include risk-adjusted benchmarks, so hospitals can compare their value with one another to generate system-wide improvement. The lessons learned will hopefully lead to best practices that can then benefit a wider range of practices and delivery systems. If elements similar to these were incorporated into the proposed MVP in 2021, they would be strong foundation for the future transition to higher value care in MIPS and a stepping stone toward participation in Advanced APMs.

Weight in the Final Score

CMS proposes to increase the weight of the Cost category to 20 percent of the final MIPS score in 2020 (for the 2022 payment year), 25 percent in 2021, and 30 percent in 2022 and subsequent years.

The ACS recognize that CMS is concerned about facilitating a smooth transition from the current 15 percent weight of the cost category to the required 30 percent weight for the 2024 payment year. **However, despite the proposed changes and addition of new episode-based measures, there will not be sufficient information available to provide accurate, actionable information for surgeons and other participating clinicians to reduce costs and improve the value of care provided.** Accurate and actionable measures are of the utmost importance. That is, the information generated by available cost measures must be both reflective of the true cost of care provided to the patient, and actionable by participating clinicians over a reasonable timeframe. **Despite the imperative for a smooth transition to the full 30 percent weight for the Cost performance category in 2024, the ACS continues to question the utility of the currently available and proposed cost measures in MIPS. Therefore, we encourage CMS to maintain the weight of the Cost category at 15 percent of the final MIPS score for the 2020 performance period to focus on improvements to the Cost category, as well as for program stability during the development of MVPs.**

Attribution of Cost Measures

In response to concerns about the current cost measure attribution methodology, CMS proposes a new approach to cost measure attribution by including attribution methodology in the specifications of each measure. Under this proposal, each cost measure would be attributed according to the measure specifications for the applicable performance period, and could allow for different considerations and methodologies depending on whether a participant reports data as an individual clinician or a group under MIPS.

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The ACS appreciates CMS’ recognition of the shortcomings of the current methodology for attribution of cost measures. However, this proposal falls short of achieving the shared accountability needed to incentivize greater care coordination and fails to adequately recognize the team-based nature of care. Patients and payers have a shared interest in better understanding the *total cost* experienced in treating a condition or keeping a patient healthy. Cost measurement should facilitate this understanding by measuring cost around the patient and scoring clinicians based upon their role and their success in providing high value care by keeping down costs and providing high quality care.

To appropriately measure and attribute costs in a way that incentivizes value, ideally all charges associated with a given episode of care for a specific patient should be aggregated and apportioned to clinicians in a manner which moves away from fee-for-service accountability and toward shared accountability in a bundled service. Since much of surgical care has moved from long stays in a facility to shortened stays, and increased prehospital and post hospital care, the complexity of the modern care model calls for rethinking a fee-for-service approach to resource accountability. Yet, many of the attribution strategies from fee-for-service are continued when they no longer align with the complex structure of modern care. We encourage CMS to consider alternatives that could achieve this, such as the methodology used by the PACES Center for Value in Healthcare. The PACES Center’s methodology is based up on the EGM which was developed under contract with CMS for this purpose. **The ACS encourages CMS to consider patient-centered, shared attribution for measures in the MIPS cost category.**

MSPB Measure

CMS proposes to modify the Medicare Spending Per Beneficiary (MSPB) specifications by changing the attribution methodology to distinguish between medical episodes and surgical episodes. The revised attribution methodology is intended to account for the team-based nature of care provided when managing medical conditions during an inpatient stay and allows for attribution to multiple clinicians to ensure all clinicians involved in a beneficiary’s care are appropriately attributed.

As noted above, the ACS agrees with the intent of better measuring the entire care team involved in providing care to the patient. However, **we disagree with the decision to split surgical episodes from medical episodes.** Surgical intervention is frequently the continuation of care for an ongoing medical condition. For example, a patient might suffer from a massive upper gastrointestinal hemorrhage. This patient will have a primary care clinician, an intensivist, and a

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gastroenterologist carrying for them with the surgical consultation on the side, in case the hemorrhage is not controlled. Or a patient with new onset, severe ulcerative colitis will have an entire team trying to reverse the condition of the colitis and avoid an emergency surgical resection. In both instances, at certain points, these patients are at risk to a surgical hand-off to assume the lead role in care and save a life. Is it CMS' contention that the best ways to manage costs are to pull the teams apart and assign services as medical and others as surgical? ACS opposes this approach in principle.

The best quality and cost management comes from a patient-focused approach with the entire team jointly aware of the structure, the processes, and the outcomes of care and associated costs. Rather than create a divisive culture, ACS prefers a culture of inclusion and team-centered care with shared accountability. CMS already possesses the cost logic in its CMS EGM (the Medicare Grouper) to create a series of episodes nested in episodes. In complex cases, such as the cases discussed above, patients can have all their co-existing episodes of care defined with all associated services and attributable team members with the CMS EGM. This way, the care teams can assess all the services which apply to their episodes and evaluate those costs for their overall impact on the quality of care—as a team. Additionally, from the patient's perspective, all of their physicians and clinicians are involved in treating the same underlying condition. Therefore, the care team measured and attributed a score should include the full range of clinicians involved.

In summary, it is counterproductive to institute payment policies that disincentivize providers from working together to provide the highest value care. Furthermore, there could be unintended consequences if clinicians are influenced by where costs will accrue and be attributed when making decisions to delay or expedite a surgical procedure. **The ACS appreciates CMS' recognition of the team-based nature of care but cautions against the decision to completely split medical and surgical procedures. Instead, CMS should consider alternate methodology that allows for treatment or procedure episodes “nested” within condition episodes to more accurately measure the cost of treating a patient.**

New Episode-based Cost Measures.

CMS has worked with a measure development contractor, Acumen, to continue the development of episode-based cost measures. For 2020, CMS proposes to add ten newly developed episode-based cost measures shown in CMS Table 37 below to the MIPS cost category.

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TABLE 37: Episode-Based Measures Proposed for the 2020 Performance Period and Future Performance Periods

| Measure Topic | Episode Measure Type |
|---|-----------------------------------|
| Acute Kidney Injury Requiring New Inpatient Dialysis | Procedural |
| Elective Primary Hip Arthroplasty | Procedural |
| Femoral or Inguinal Hernia Repair | Procedural |
| Hemodialysis Access Creation | Procedural |
| Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation | Acute inpatient medical condition |
| Lower Gastrointestinal Hemorrhage* | Acute inpatient medical condition |
| Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels | Procedural |
| Lumpectomy Partial Mastectomy, Simple Mastectomy | Procedural |
| Non-Emergent Coronary Artery Bypass Graft (CABG) | Procedural |
| Renal or Ureteral Stone Surgical Treatment | Procedural |

*This measure is being proposed only for groups. Please reference section III.K.3.c.(2)(b)(vi)(B) of the proposed rule.

ACS continues to urge CMS to view the issue of cost in patient-centric terms as the Agency seeks to meet the requirements of MIPS set forth under MACRA. This means that in addition to its use in determining MIPS physician payment, cost information should be available and presented to the patient and should include all services the patient is likely to receive from all parties involved in a given episode of care. This information would be more representative of the way patients experience care and more meaningful in the creation of a value expression when coupled with quality information for the same episode of care.

As noted in previous years, the ACS remains concerned that the methodology used in these cost measures may be too narrow to provide actionable data and insights to participating physicians. If a measure focuses too narrowly on a very small sliver of care, it may provide predictability, but at the cost of missing the opportunity for savings by eliminating low-value or duplicative services that could be identified with a broader scope. For the Cost category of MIPS to be meaningful, the measures used must be not only reliable, but also actionable. That is, cost measures should provide information on how a physician or care team currently uses resources to allow for comparisons with others who may be more efficient. In surgery, for example, the ACS defines costs related to the five phases of surgical care: preop, periop, intraop, postop and post discharge. We are able to consolidate these into costs more simply as prehospital, hospital-related services, and post discharge. A further breakdown of all the services, adjusted for the patient’s co-morbid conditions, allows the clinicians to benchmark prices, identify wasteful expenditures, and create alternative solutions. Without this level of detail, cost or price becomes a burden and therefore unmanageable. Broad cost metrics such as those used in MIPS do not breakdown all the services billed related to the patients’ experience in a care model. The ACS encourages CMS to consider the work being done jointly by ACS and the Harvard Business School, described above on, measuring cost in the ACS THRIVE initiative for an example of the potential for actionable cost measurement. **CMS should be focused on actionable cost measurement in the QPP. This requires**

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providing a full picture of cost to allow clinicians and their patients to make informed decisions on their care in order to increase value and generate savings.

Improvement Activities Performance Category

Improvement Activities Data Submission

Group Reporting

In the CY 2017 QPP final rule, CMS established that if at least one clinician within the group is performing a MIPS Improvement Activity (IA) for a continuous 90 days in the performance period, the group may report on that activity. In this proposed rule, CMS states that by the 2020 performance year clinicians should be familiar with the IA category and how they are expected to report. The Agency does not believe increasing the minimum threshold for groups reporting IA's will present additional burden or complexity because of the wide range of options and large number of IAs available to clinicians. Therefore, beginning with the 2020 performance year, CMS proposes to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent. In conjunction, CMS proposes to require that 50 percent of a group's NPI perform the **same** activity for the **same** continuous 90 days in the performance period for the group to receive credit for the activity.

The College opposes both aspects of this proposed policy, and believes that if adopted, the number of meaningful IA's available for reporting will be limited and therefore burden on physicians will increase. Groups can be composed of many types of MIPS-eligible clinicians whose workflows and improvement indicators differ greatly. Requiring multi-specialty groups to report the same IA's would greatly reduce the number of meaningful IAs available and would result in groups choosing IAs that simply satisfy MIPS requirements rather than IAs that directly improve and enhance the care they provide. The proposed policy does not take into account that a single physician may have chosen an IA that helps them improve quality. As a result of the newly proposed policy, clinicians will be required to complete the same activity their group chooses regardless of relevance to their quality improvement targets. **Instead, we recommend that CMS allow individuals in groups the freedom to choose IAs they deem most meaningful. While this may mean all clinicians in a practice are reporting the same activity based on the composition of the practice, the College strongly believes that this should not be a requirement.**

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Improvement Activities Inventory

For the 2020 MIPS performance period and future years, CMS proposes to add seven removal factors for consideration when removing improvement activities. CMS explains that adding removal factors for this category will provide transparency and align with the removal factors in the MIPS Quality performance category.

- Factor 1: Activity is duplicative
- Factor 2: There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice
- Factor 3: Activity does not align with current clinical guidelines or practice
- Factor 4: Activity does not align with at least one meaningful measures area
- Factor 5: Activity does not align with the quality, cost, or PI performance categories
- Factor 6: There have been no attestations of the activity for 3 consecutive years
- Factor 7: Activity is obsolete

Based on the proposed removal factors, CMS also proposes to remove fifteen, modify seven existing, and add two new IAs. The proposed removal of IAs is contingent on the removal factors being finalized. Many of the changes in the IA inventory aim to combine duplicative activities.

For the 2020 performance period, the Agency proposes the addition of two activities: Participation in a *Qualified Clinical Data Registry (QCDR) that promotes use of patient engagement tools* and *Use of QCDR data for ongoing practice assessment and improvements*—these two activities would replace nine existing IAs focused on the use of QCDRs. The College thanks CMS for their efforts to consolidate activities to eliminate redundancy and create a more focused activity list. However, consolidating these measures will leave clinicians participating in QCDRs with only two medium-weighted QCDR participation-related IAs. **Therefore, we recommend CMS increase the weights of the *Participation in a QCDR that promotes use of patient engagement tools* and *Use of QCDR data for ongoing practice assessment and improvements* activities from medium-weighted activities to high-weighted activities. In addition, we ask that the two new QCDR activities not be limited just to QCDRs, but be expanded to include participation in nationally validated and risk-adjusted clinical data registries led by clinicians with demonstrated quality improvement.** Expanding the definition to include registries such as National Surgical Quality Improvement Program (NSQIP) will recognize and incentivize

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the use of registries which have demonstrated quality improvement but do not fit the QCDR definition.

For future rulemaking, we strongly encourage CMS to offer full credit in the IA category for participation in a national verification program, such as the Surgical Quality Verification Program (SQVP).¹⁹ This aligns with the approach outlined in the MVP framework proposal, where CMS discusses incorporating attestation to participation in specialty accreditation programs, such as the ACS Commission on Cancer accreditation program, as a way to satisfy the improvement activity requirement. Verification programs pursue excellence and avoid system errors by ensuring that the resources, staff, and infrastructure are in place to provide the highest possible quality care to the patient. The SQVP is designed as an overarching assessment of a quality program which can be applied broadly across a delivery system regardless of the practice type (academic, community, or rural care delivery system). In addition to the more broadly applied verification programs, the ACS has additional service line directed programs which more narrowly define the quality elements to a particular clinical domain. These include areas such as trauma, cancer, metabolic and bariatrics, frail elderly and geriatrics, pediatric surgery, complex GI and vascular surgical service lines. Any of these programs can be applied in multiple care settings such as academics, community or rural based care to pursue excellence in care.

Promoting Interoperability

Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

CMS proposes changes to the PI category of MIPS. The proposed changes were done with the overarching goals of decreasing administrative burden, streamlining reporting, increasing access to health information through technology for patients, enhanced interoperability, and the continued use of Certified Electronic Health Record Technology (CEHRT).

The ACS believes it is critically important that the PI program becomes more than digitally specified measures for payment programs and functional EHR requirements. To encourage interoperability, CMS must incentivize the use of advanced digital health IT capability and the meeting of national standards that

¹⁹ American College of Surgeons. "Optimal Resources for Surgical Quality and Safety." 2017. Retrieved from: <https://www.facs.org/quality-programs/about/optimal-resources-manual>

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allow for the movement of health data across the digital environment. As specified in the ONC proposed rule on the 21st Century Cures Act, interoperability is no longer only about EHRs. To implement the provisions in the Cures Act, interoperability must move beyond the focus of EHRs, including measures that track the simple electronic sending and receipt of Summary of Care documents (CCDAs) or patient access. Rather, EHRs, health IT vendors, and users of these products need to demonstrate meeting national standards. These standards—such as Fast Healthcare Interoperability Resources (FHIR) based APIs and US Core Data for Interoperability (USCDI) extracts—support exchangeable knowledge artifacts, which support better patient care through the digitization of knowledge, including clinical decision support, patient alerts, and shared goals across the care team. Incentivizing early adoption of these standards will encourage early uptake and utilization of digital standards to build a foundation for providing value-based care.

Proposed Changes to Measures for the e-Prescribing Objective

As part of the Electronic Prescribing objective in the MIPS reporting period in 2019, CMS included two opioid measures: *Query of the PDMP* and *Verify Opioid Treatment Agreement Measure*. Both measures were optional for CY 2019, and *Query of the PDMP* was previously finalized to be required in CY 2020 Quality Payment Program Rule. However, CMS proposes the below changes for these measures for CY 2020:

- *Query of PDMP Measure*: Based on comments and stakeholder concerns regarding the lack of integration between EHRs and PDMPs and challenges in documenting the review of the PDMP, CMS is proposing to not require this measure for CY 2020. Instead, this measure is proposed to remain optional in CY 2020 and eligible for 5 bonus points, and will be attestation only.
- *Verify Opioid Treatment Agreement Measure*: CMS is proposing to remove this measure in CY 2020 due to feedback from stakeholders on the challenges with documentation that prevent the ability to adequately report on this measure.

ACS supports both of these proposed changes because these measures are challenging to electronically report due to the additional documentation and verification with an external system requirements, which create undue administrative burden. Additionally, ACS recommends postponing the creation of new MIPS measures that require integration with PDMPs until after the finalization of the 21st Century Cures regulations, which will affect the integration of PDMPs and EHRs. Future considerations for the development of new measures

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should also account for updates and standardizations made to state-level PDMPs through the implementation of programs included in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

Health Information Exchange Objective

CMS proposes a modification to the exclusion and a re-distribution of points earned for both of the measures that are part of the Health Information Exchange objective: *Support Electronic Referral Loops by Sending Health Information* and *Support Electronic Referral Loops by Receiving and Incorporating Health Information*. CMS proposes that beginning with the 2019 measurement period, the exclusion for both measures will be for any MIPS eligible clinician who has fewer than 100 transitions of care, referrals, **and** initial patient visits (meaning an encounter in which the clinician has never yet encountered the patient) **cumulatively**. In prior program years, the exclusion was understood to mean 100 or fewer transitions of care only. Further, if a clinician is exempt from either or both of these measures, the 40 points (20 points for each measure) will be redistributed to the *Provide Patients' Electronic Access to their Health Information*.

The College appreciates these clarifications, and supports the continued focus on interoperability. **However, given the proposed rules from ONC and CMS on the 21st Century Cures Act, it is important that this objective and the contained measures encourage advanced methods of health information exchange, including APIs. Both *Referral Loops* measures refer only to summary of care documents (CCDAs) being exchanged, and should be updated to include more advanced methods of exchanging, such as through an API.** The *Provide Patients Access* measure already accounts for granting patients' access to their data through APIs.

Additional Considerations

Hospital-Based Eligible Clinicians in Groups

CMS defines a hospital-based individual eligible clinician as a clinician who furnishes 75 percent or more of professional services at an inpatient hospital, outpatient hospital, or emergency room. CMS proposes to change the definition of a hospital-based group so that such a group would be identified as hospital-based and eligible for reweighting of the Promoting Interoperability category if more than 75 percent of the NPIs in the group meet the definition of a hospital-based individual MIPS eligible clinician. For those individual eligible clinicians and hospital-based groups that meet the definition of hospital-based, the Promoting

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Interoperability category will be at a zero percent weight, and the associated PI points will be distributed to the quality performance category. **The College supports this proposal and thanks CMS for the adjustment.**

RFI on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Performance Category

CMS seeks comment on the addition of new opioid use disorder prevention and treatment measures for inclusion in the PI performance category. Specifically, CMS asks for measures that consider the following aspects:

- *Include evidence of positive impact on outcome-focused improvement activities, and the opioid crisis overall;*
- *Leverage the capabilities of CEHRT where possible, including: near-automatic calculation and reporting of numerator, denominator, exclusions and exceptions to minimize manual documentation required of the provider; and timing elements to reduce quality measurement and reporting burdens to the greatest extent possible;*
- *Are based on well-defined clinical concepts, measure logic and timing elements that can be captured by CEHRT in standard clinical workflow and/or routine business operations. Well-defined clinical concepts include those that can be discretely represented by available clinical and/or claims vocabularies such as SNOMED CT, LOINC, RxNorm, ICD-10 or CPT;*
- *Align with clinical workflows in such a way that data used in the calculation of the measure is collected as part of a standard workflow and does not require any additional steps or actions by the health care provider;*
- *Are applicable to all clinicians (e.g., clinicians participating as individuals or as a group, or clinicians located in a rural area, designated health professional shortage area (HPSA), designated medically underserved area (MUA), or urban area);*
- *Could potentially align with other MIPS performance categories; and*
- *Are represented by a measure.*

ACS Proposed Measure 1: Observed versus expected opioid usage in post-surgical cases

ACS appreciates the opportunity to propose opioid measures for future program inclusion. We recommend developing a measure titled *Observed versus expected opioid usage in post-surgical cases*. This measure concept would track the expected versus observed opioid usage, defined per surgical type and case, based on morphine equivalent dose (MED) over a 30-day period. CMS could identify

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expected opioid usage per surgical case based on existing claims and pharmacy data, while patient-reported and pharmacy data would provide actual opioid usage post-surgery. Studies have found that 6% of patients become persistent opioid users following surgical procedures.²⁰ The ACS is dedicated to helping surgical patients manage pain safely, and to set expectations for pain management. This measure would help physicians understand the volume of patients who exceed expected and recommended opioid doses post-surgery, and work to determine alternative pathways to better manage post-surgical pain in these patients.

Proposed Measure 2: Screening for Substance Use Disorder in pre-operative appointments

The ACS believes that measuring rates of Substance Use Disorder (SUD) screening in pre-operative appointments will better allow surgeons and care teams to work with patients on post-operative pain management and pain management techniques, and we propose the creation of a measure called *Screening for Substance Use Disorder in pre-operative appointments*. By understanding a patient's history and propensity towards SUD, the care team is better able to engage the patient in realistic expectations for pain and pain management post-operatively. Measuring this screening alongside collecting patient feedback through PROs not only engages patients early on and keeps them engaged throughout their surgical episode, it allows the care team to create a care plan that is right for the patient, and design patient-specific goals for recovery.

RFI on NQF and CDC Opioid Quality Measures

CMS proposes adding the below NQF and CDC OUD measures to the PI performance category in future reporting years. CMS seeks comment on the use cases for health IT implementation for the actions within the measures.

NQF:

- Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940)
The proportion of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120 mg Morphine Equivalent Dose (MED) for 90 consecutive days or longer.

²⁰ Brummett CM, Waljee JF, Goesling J, et al. New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults. *JAMA Surgery*. 2017;152(6): e170504. Retrieved from: <https://jamanetwork.com/journals/jamasurgery/fullarticle/2618383>

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- Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950)

*The proportion of individuals without cancer receiving prescriptions for opioids from 4 or more providers **and** from 4 or more pharmacies.*

- Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951)

*The proportion of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120 mg MED for 90 consecutive days or longer, **and** receiving prescriptions for opioids from 4 or more providers **AND** from 4 or more pharmacies.*

The ACS supports the above measures, given the definitions and exclusions of patients with cancer and patients receiving palliative care but recommends delaying implementation. In response to the solicitation for health IT use cases for the above measures, pharmacy and PDMP data will be vital in ensuring complete and accurate data. Better integrated pharmacy, PDMP, and EHR data will allow for streamlined reporting with little administrative burden on physicians. With implementation of the ONC and CMS proposed interoperability rules over the next several years, there will be a shift in data exchange as standards become required. At the end of the implementation timeline from the final rules, the EHR will have the technical ability to incorporate PDMP and pharmacy data, creating a complete record of patient medications. In this future state, the reporting for the above measures will be more accurate, complete, and contain important external data elements. As such, **the ACS supports these measures but recommends delaying the use of them until implementation of the updated technical standards, including for the integration of PDMPs and EHRs from the 21st Century Cures proposed rules and the SUPPORT Act, are complete.**

CDC:

- Check PDMP Before Prescribing Opioids (Measure 2)
The percentage of patients with a new opioid prescription for chronic pain with documentation that a PDMP was checked prior to prescribing.
- Evaluate within Four Weeks of Starting Opioids (Measure 4)
The percentage of patients with a follow-up visit within four weeks of starting an opioid for chronic pain.
- Check PDMP Quarterly (Measure 11)
The percentage of patients on long-term opioid therapy who had documentation that a PDMP was checked at least quarterly.

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- Counsel of Risks and Benefits Annually (Measure 12)
The percentage of patients on long-term opioid therapy for whom the clinician counseled the patient on the risks and benefits of opioids at least annually.

The ACS appreciates additional CDC opioid measures being considered for inclusion in the Program. However, the Program proposed the *Query the PDMP* measure as a bonus measure in 2020 due to the challenges with collecting accurate data. Because of similar concerns on data availability and PDMP integration, **the ACS does not support the inclusion of Measures 2 and 11 until PDMPs are more standardized and better integrated into EHR systems.**

Measures that prevent Opioid Use Disorder (OUD) and ensure appropriate treatment for patients with OUD should focus on patient engagement and utilize digital knowledge to optimize patient-centered care. Instead, many measures focus on the digitization of micro-events (such as a prescription, or the dosage of the prescription). ACS strongly supports the adoption of measures that empower patients and caregivers to better understand pain expectations and pain management, supported by technology to aid in patient-specific care plans. Successful care pathways for pain management are individualized for the patient and help the care team set realistic goals and expectations with frequent check-points throughout the care continuum. Incorporating PDMPs, CDC recommendations for opioid dosing, and multi-modal analgesics for pain management are all tools that the care team can use to meet patient goals and in executing the care plan. The proposed measures the College recommends above (*Observed versus expected opioid usage in post-surgical cases* and *Screening for Substance Use Disorder in pre-operative appointments*) provide meaningful and longitudinal information to care teams when making these determinations alongside their patients.

RFI on a Metric to Improve Efficiency of Providers within EHRs

CMS is seeking feedback on possible measures to demonstrate provider efficiency as a result of health IT. Specific questions are as follows:

- *What are useful ways to measure the efficiency of health care processes due to the use of health IT?*
- *What are measurable outcomes demonstrating greater efficiency in costs or resource use that can be linked to the use of health IT-enabled processes? This includes measure description, numerator/denominator or “yes/no” reporting, and exclusions.*

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- *What do stakeholders believe may be hindering their ability to achieve greater efficiency (e.g., product, measures, CMS regulations)? Please, provide examples.*
- *What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability Program) that can increase the efficiency of health care provider interactions with technology systems, for instance, alternate authentication technologies that can simplify health care provider logon? How could we reward health care providers for adoption and use of these technologies?*
- *What are key administrative processes that could benefit from more efficient electronic workflows, for instance, conducting prior authorization requests? How could CMS measure and reward health care providers for uptake of more efficient electronic workflows?*
- *Could CMS successfully incentivize efficiency? What role should CMS play in improving efficiency in the practice of medicine? The underlying goal is to move to a more streamlined, efficient, easier user experience, whereby providers can input and access a patient's data in a reliable, timely manner. CMS seeks feedback on the best way(s) to get there.*

The ACS offers recommendations below on the above questions for processes, electronic workflows, digital tools, and integration that would improve physician efficiency within EHRs. **The College believes that attestation and incentivizing the below advanced capacities would be more beneficial than developing measures.**

- *Technologies, capabilities, and system features that would increase efficiency:* The ACS supports the CMS goal of efficient and effective use of technology to improve quality of care, decrease costs, and reduce administrative burden. We believe that incentives for physicians and systems for early adoption of APIs and standards, such as FHIR and USCDI, would encourage early uptake of these standards, promote data exchange across the care continuum, and allow for EHRs to incorporate external data for a complete patient record. Additionally, integration of digital tools and external data within the surgical workflow could be incentivized to encourage early adoption of technology, and increase efficiency of EHRs for surgery. Examples of surgical specific enhancements that could be incentivized include: risk calculation within EHRs, electronic workflow integration of the ERAS protocols, telehealth and other digital care service options, electronic Prior Authorization process, and Electronic Prescribing for Controlled Substances (EPCS). Incentivizing these types of digital services can result in increased use of these technologies to optimize patient care, and encourage physicians and hospitals to be innovative in their care options.

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CMS' efforts should focus on the entire digital workflow and avoid being constrained by EHRs. A patient-cloud example which demonstrates a clinician and patient workflow solution for surgical care is Meges Health's "iPostop" solution. This is a platform-based digital workflow which begins preoperatively for countless surgical procedures. In this instance, the platform surrounds the patient with the care team, which includes the surgeon and the supporting cast of nurses and office staff. Numerous events are tracked up to the day of an operation. Once the operation is complete, patients are often discharged early. With iPostop, a digital connection remains constant with periodic check-ins by the patient, the staff, or the surgeon. This allows for asynchronous engagement of patients in clinical workflow solutions which are not possible within everyday EHRs. It is these solutions which require customization, governance, and updating by the clinical teams constantly. These solutions are digitally bolted onto the EHRs.

- ***Inclusion of Cost Data:*** Specific technologies and features to improve efficiency include better incorporation of cost data within existing workflows to support resource use stewardship. Price information for an individual patient that is integrated into physicians' clinical workflow through APIs would be useful information for both patients and clinicians in making clinical and care decisions. **We urge CMS to work with ONC and to support the development and use of platforms such as the product created by Gemini Health, which aims to reduce health care costs through drug cost transparency at the point of care in a clinical workflow integrated within EHRs.**²¹ The ability to access patient-specific drug and alternative cost and coverage information at the point of care increases patient and care giver activation and shopability, reduces pharmacy call backs, and prior authorizations. However, if patients have increased information about comparative treatment options and medications, protections should be put in place to ensure that clinicians are not required to provide alternatives that the clinician does not deem appropriate, nor should clinicians be held liable for refusing to offer such alternatives.

Additionally, the behavior economics behind price transparency needs to be considered by CMS. When patients have been on medication for years, and suddenly a clinician is "rewarded" for changing the medication, how does a clinician explain the change to patients without seeming self-

²¹ <http://www.gemini.health/our-solutions/>

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serving? What some payers have done is to create a shared savings aspect of this to the patients. We encourage CMS to create a drug cost report available to both clinicians and patients, including options for less costly alternatives. And, when cost savings occur, exploring incentives for patients, such as reduced co-pays, would encourage further adoption.

Better understanding of total cost and resource use for episodes of care through the integration of external data would allow for better decision making along the care continuum. This process could be aided through integration of the patient workflow within the clinician workflow, including the collection of PROs in more frequent, but brief, occurrences throughout their episode of care. Patient portals and third-party applications connected to EHRs through APIs could create additional options for PROs to become a part of clinical decision making.

- *Increased Efficiency for Prior Authorization Through Electronic Workflow:* Surgeons across the country are facing setbacks in furnishing services to patients due to prior authorization processes that are antiquated, overly stringent, and inappropriately utilized by insurers. While many aspects of the clinical workflow have become automated, prior authorization remains a manual, paper-based task for many physicians. The exorbitant amount of time and resources practices must devote to prior authorization is due in part to the lack of automated prior authorization processes that integrate with EHRs. The encumbrance of inefficient prior authorization requirements represents unnecessary hours of lost clinical productivity, increased practice costs, and delays or interruptions in medically-necessary treatment. **In the limited cases where prior authorization is truly necessary, all processes needed to obtain prior authorization for medical services should be made available in EHRs or through connected digital technologies at the point of care to provide physicians with the real-time coverage information they need when making treatment decisions.** The majority of prior authorizations end up approved. If a clinical practice has a track record which exceeds a threshold, then it should not require prior authorization for the majority of its scheduled patient care. If retrospective review of the practice demonstrates the practice no longer meets the threshold, then prior authorization could be instituted on the key services ordered.
- *Streamlining standards and encouraging open source systems to ease burdens of interoperability:* **Further reducing administrative burden, streamlining systems for sending and reporting data to HIEs, registries, and other databases through open source digital standards**

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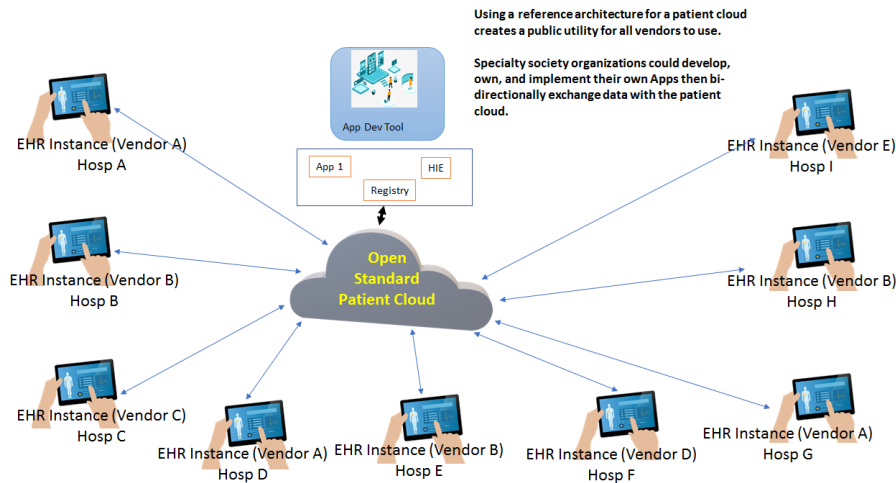
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that meet criteria for clinical interoperability would better utilize existing technology and create efficiencies. This would greatly aid in data liquidity, to largely eliminate data blocking and enable patient cloud environments. Further, updated standards should include the ability for EHRs to ingest external data after clinical reconciliation, allowing for a complete health record for the patient within a physician’s single system. Requiring data be sent and received in a single, standard format will better enable bidirectional exchange, particularly when facilitated through a single cloud platform. Demonstrated in the cloud ecosystem example provided below in Figure 6, data can be processed, converted, and normalized in the cloud platform, before the cloud sends data to third-parties (registries, apps, state HIEs, or other EHRs). This framework will eliminate the need for EHRs to establish multiple connections to exchange data with a variety of external parties. This ecosystem simplifies data exchange through standards and plug-and-play connectivity.

Figure 6: Advanced Model of Interoperability



RFI on the Provider to Patient Exchange Objective

In the CY 2019 PFS proposed rule, CMS suggested creating a set of health IT related activities to replace traditional measures in future program years. One example is for MIPS clinicians to receive credit for implementing and maintaining an open API to allow patients to access health information through a patient portal or other third-party application.

Since this proposal, both ONC and CMS released proposed rules on the 21st Century Cures Act. These rules focused on creating standards for data exchange,

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including FHIR-based APIs, which are meant to lessen the burden and complexity of data exchange. If these provisions in the Cures rules are finalized, these standards will be incorporated into the 2015 CEHRT definition, making them a requirement for participation in the PI category. CMS requested feedback on functionality and standards for data exchange using FHIR-based APIs.

Immediate Access

CMS seeks comment on whether data from clinicians should be available to the patient no later than one business day after it is available in the EHR. Given the intended burden reduction coming from the utilization of APIs and standards, CMS asks if this makes providing patients access to their health information an easier task, and therefore possible to do within one business day. The College is concerned that this standard could disincentivize physicians to complete a patient's chart. Further, it is important that physicians are able to view and discuss results with patients before that data are available to patients. As an alternative, **ACS believes two business days is a more realistic ask for data to be available for patients, as this allows time for physicians and the care team to discuss any sensitive results with patients before it is available electronically.**

Persistent Access

CMS is seeking comment on whether patients should have unimpeded access to their health information without re-authorization before subsequent use of a third-party application containing their health information. While **ACS agrees with CMS that patients should have routine access to their health information, it is critical that this apply only to certified applications. As the FDA has a certification and regulatory process in place for mobile applications, the ACS strongly recommends that these criteria be adjusted and adopted in order to authenticate application developers. Additionally, just as critical is the 1) certification of the clinical logic used to ensure that the products are safe, accurate, and in alignment with clinical guidelines, and 2) privacy certification to ensure that apps meet privacy standards. We encourage CMS, in collaboration with ONC, to leverage the expertise of professional society organizations to certify the clinical logic. In addition, ACS suggests that an EHR vendor's API check for the below three "yes/no" adoption & implementation attestations as a part of the certification requirements:**

- (1) *Industry-recognized development guidance* (e.g., Xcertia's Privacy Guidelines);
- (2) *Transparency statements and best practices* (e.g., Mobile Health App Developers: FTC Best Practices and CARIN Alliance Code of Conduct); and,
- (3) *A model notice to patients* (e.g., ONC's Model Privacy Notice).

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The certified app could then be acknowledged or listed by the health IT developer (e.g., in an “app store,” “verified app” list). EHR vendors could also publicize app developers’ attestations.

Furthermore, ACS supports policies that require patients seeking access to their data using the app to initially authenticate themselves (using previously issued credentials by a health care provider or trusted source) and authorize: 1) the app to connect to the FHIR server; and 2) specify the scope of the data the app may access. Once all of these processes have been completed, the ACS agrees with persistent access for patients to their own data.

Standards-based API

CMS asks for comment on a PI bonus measure for the use of a certified FHIR-based API before the ONC’s final 21st Century Cures Act compliance date to incentivize early adoption. **The College agrees incentivizing early adoption of FHIR-based API standards could be beneficial. However, as mentioned in the comments above, before using in a care setting, it is vital to ensure third-party applications connected to EHRs are certified to ensure both technical and clinical validation and verification.** Further, as it will likely require resources for physicians and practices to upgrade to this technology before it is required, it is important to work with the ONC to ensure that adoption and implementation is feasible for a variety of practice sizes, including rural and small practices with limited resources.

Available data

The ONC proposed an additional requirement for EHR vendors in the 21st Century Cures rule. In addition to the FHIR-based API standards, the ONC introduced the concept of Electronic Health Information (EHI) exports. EHI is defined as all of the data that the health IT system produces and electronically manages for a patient or group of patients. This applies to the system’s entire database, including but not limited to clinical, administrative, and claims/billing data. The definition also includes the oldest EHI available on that patient to the most recent, no matter the specific electronic format (e.g., PDFs are included). The goal of EHI exports is that patients would be able to request and receive *all of the information within their EHR patient record*. Additionally, vendors would need to be able to do this same export for every patient and every data point within the system. CMS seeks feedback on whether there should be a PI measure that requires clinicians to use technology certified to this EHI standard.

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Specifically, CMS asks:

- Do stakeholders believe that incorporating this alternative measure will be effective in encouraging the availability of all data stored in health IT systems?
- In relation to the Provider to Patient Exchange objective as a whole, how should a measure focused on using the proposed total EHI export function in CEHRT be scored?
- If this certification criterion is finalized and implemented, should a measure based on the criterion be established as a bonus measure? Should this measure be established as an attestation measure?
- In the long term, how do stakeholders believe such an alternative measure would impact burden?
- If stakeholders do not believe this will have a positive impact on burden, in what other way(s) might an alternative measure be implemented that may result in burden reduction? Please be specific.
- Which data elements do stakeholders believe are of greatest clinical value or would be of most use to health care providers to share in a standardized electronic format if the complete record was not immediately available?

The ACS supports the concept behind this proposal, which aims to provide patients and health IT users, including physicians, a means to efficiently export the entire electronic health record for a single patient or all patients in a computable, electronic format. We also support that this criterion could provide additional assurances that a health IT developer supports, and does not inhibit, the access, exchange, and use of EHI. Importantly, this proposal also supports longitudinal data record development, which will help to foster better care coordination and more efficient care over time.

However, we are concerned that the ONC's proposed definition of EHI is too ambitious and fails to recognize important attributes that must first be in place to ensure successful implementation. We are also concerned that CMS is considering related policies before the ONC releases the 21st Century Cures final rule. **For example, in the ONC proposed rule, the agency did not propose that the export must be executed according to any particular standard. It is only proposed to require that the export must be accompanied by the data format, including its structure and syntax, to *facilitate* interpretation of the EHI. It is critical that there are standards to export data in order to ensure the data are pulled consistently from every system and that it could then be imported and integrated into other systems as needed.**

Therefore, the ACS strongly recommends uniform standards that certified health IT developers would have to adhere to in order to ensure that data can

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not only be exported, but also imported by the receiving entity. The initial data set subject to this requirement should be limited to USCDI standards, as this will result in a much more manageable mandate for health IT developers and help to minimize potential unintended consequences. The College is also concerned that by using a measure to encourage early adoption of this standard that practices and physicians that have the resources to afford an early upgrade to their EHR will be at a scoring advantage. Because it is likely that upgrading to these standards will be expensive, particularly while they are new, practices and physicians with limited resources may not be able to afford moving to these standards. As such, **for measurements relating to EHI, ACS supports providing incentives based on attestation for progress towards standard system extracts based on open-source, non-proprietary USCDI standards. Due to existing concerns with the proposed definition of EHI, further suggestions of measures or the burden of those measures is unwarranted until a final, and updated, definition of EHI is published.**

Bidirectional Exchange

CMS also asks for feedback on general questions related to data exchange and the use of health IT:

- Do stakeholders believe that CMS should consider including a health IT activity that promotes engagement in the health information exchange across the care continuum that would encourage bidirectional exchange of health information with community partners, such as post-acute care, long term care, behavioral health, and home and community-based services to promote better care coordination for patients with chronic conditions and complex care needs? If so, what criteria should CMS consider when implementing a health information exchange across the care continuum health IT activity in the Promoting Interoperability Program?
- What criteria should CMS employ, such as specific goals or areas of focus, to identify high priority health IT activities for the future of the program?
- Are there additional health IT activities CMS should consider recognizing in lieu of reporting on existing measures and objectives that would most effectively advance priorities for nationwide interoperability and spur innovation?

The College appreciates CMS' focus on utilizing data exchange to improve the quality of patient care and reduce physician burden. There has been great progress made in the implementation of digital health services through EHRs and advances in interoperability through ONC and CMS proposed 21st Century Cures rules. However, **the College believes it is time to recognize EHRs as one data source**

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among many for an individual patient. Patients exist in multiple bits and bytes in disparate EHR systems. The best way to create a digital account for a patient is the movement of pertinent patient knowledge into a semantically interoperable, digital information system as a service in a patient cloud. The patient cloud aggregates data to create a single, unique, and more complete patient medical record, providing physicians with the information they need to deliver the highest quality care while keeping costs low, and gives the patient agency over their own data. Further, this better enables and facilitates the sharing of health information between physicians and levels of care; physicians would be able to pull needed data and patient health information from the cloud to their system, rather than needing to initiate exchange from another physician and their system. This infrastructure streamlines care coordination and care management, reduces clinician burden, and ensures more complete and accurate patient data within the longitudinal health record.

We should be cautious in recognizing EHRs as the single source of patient truth; the EHR data models are constructs from decades past, built initially for billing, and can no longer serve as the sole digital architecture representing the workflows of tomorrow. They will remain a point of data entry at a care site, but need to connect to patient-cloud platforms to share clinical information, expand data liquidity, and make patient health information more accessible by both patients and clinicians. Patients do not live in one health system or one EHR; they live in five, six, or more EHRs. They have data in third-party applications, wearable devices, and payer claims. The next generation of digital health services has to create a single, unified patient record in a cloud platform. Using a Linux-like architecture²² for an open-standard cloud architecture creates a patient unified record upon which all EHRs can provide data, all smartphones can interact, and all API developers can drop in their services for patients and clinicians. The patient cloud would work as an aggregator, able to pull data through APIs from any database with patient information, and then process, convert, and exchange data as appropriate—much like the way the banking industry has made it possible for individuals to withdraw money from any ATM, or transfer money to any external account. With shared standards, any digital information company can apply the standard and create a semantically interoperable cloud. The free market can then employ these standards and avoid overbearing, inefficient, and costly duplicative services. Digital services like third-party applications and wearable devices can also build upon these clouds to further accelerate the advancement of the industry. **The ACS supports attestation and incentivizing the use of a patient cloud based on shared standards and built on an open platform to facilitate data exchange**

²² <https://www.linux.com/what-is-linux/>

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with open APIs, rather than the creation of additional process-based measures and objectives that attempt to reward connections between disjointed platforms and systems.

Patient Matching

CMS seeks additional feedback on strategies and innovative solutions to support the private sector with patient matching, particularly in light of increased interoperability and the challenges that come with the absence of a UPI. Inaccurate patient matching can lead to adverse events, compromised safety and privacy, inappropriate and unnecessary care, unnecessary burden on both patients and physicians to correct misidentification, time consuming and expensive burden on health systems to detect and reconcile duplicate patient records and improper record merges, increased health care costs, and poor oversight of fraud and abuse. Inaccurate data matching poses a significant risk to patient safety because information may be unavailable when needed or records may be merged incorrectly, leading to inappropriate treatment choices. Errors in individual data matching will be compounded with the expansion of electronic health information sharing.

In the absence of a legislative fix mandating the creation of a UPI for this issue, the ACS recommends that CMS work with the ONC and private sector to continue to explore alternative solutions for this problem. A standard algorithm hosted in a cloud platform that assesses and determines patient matches based on identifying information, such as name, date of birth, Payer ID, or other unique identifiers could be a stop-gap solution. Further, standard requirements for patient identifiers as part of the USCDI, such as number of characters and inclusion of hyphens, dashes, and apostrophes, could aid in this issue by standardizing the name field in EHRs and third-party applications. Without a UPI, these algorithms and work-arounds for patient matching require multiple other sources of personal information in order to more accurately match patients, putting privacy and security at risk. Patients are identified by their birthday, all their previous addresses, colors of car purchases, credit ratings and more, which is a further invasion of privacy. Therefore, these options will not solve this problem completely, and ACS encourages a larger legislative fix for this issue, as it will only grow in size as digital technology continues to increase in scope and practice.

RFI on the Integration of Patient- Generated Health Data into EHRs Using CEHRT

As wearable devices and third-party health applications become increasingly common and available, the data generated from these products could introduce

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new ways to monitor and manage patient care between visits. While challenges with receiving and incorporating this information remain, CMS is interested in feedback on how the Promoting Interoperability Program could incorporate measures, activities, and elements that further the use and best practices on PGHD.

CMS asks for feedback specifically on the below questions:

- What specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings are most promising for improving patient outcomes? For instance, use of PGHD for capturing advanced directives and pre/post-operation instructions in surgery units.
- Should the Promoting Interoperability Program explore ways to include bonus points for health care providers engaging in activities that pilot promising technical solutions or approaches for capturing PGHD and incorporating it into CEHRT using standards-based approaches?
- Should providers be expected to collect information from their patients outside of scheduled appointments or procedures? What are the benefits and concerns about doing so?
- Should the Promoting Interoperability Program explore ways to reward health care providers for implementing best practices associated with optimizing clinical workflows for obtaining, reviewing, and analyzing PGHD?

ACS believes that the most beneficial PGHD are in the form of PROs. The integration of the patient experiences and milestones within the clinician workflow, including the collection of PROs in more frequent, but brief, occurrences throughout their episode of care, can provide meaningful information to physicians about progress on care goals, post-surgical recovery, pain management, and rehab and therapy. Patient portals and third-party applications connected to EHRs through APIs could create additional options for PROs to become a part of clinical decision making, and develop a simple interface for users to respond to questions and share data back to their physicians.

Incentives and bonus points are productive ways to encourage early adoption of PROs and use of PGHD incorporation into CEHRT. In early stages, attestation, rather than measurement, is a more effective way to measure uptake of PGHD, allowing physicians to test and become more comfortable with PGHD implementation before using measurement to affect reimbursement. **It is also critical that the applications and devices used to capture PGHD are certified, to ensure that 1) they use data-exchange standards and 2) that the data are**

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validated and the clinical algorithms are verified before incorporation into the EHR. It will be important to learn from these early adopters, as the use and incorporation of PGHD into the EHR and clinical workflows remains in early stages. There are many lessons to be learned regarding the appropriate incorporation and utilization of these data.

Additionally, given the proliferation of wearable devices and third-party applications and the challenges with these data, **physicians should not be required to collect or share data with any device or application requested by a patient. And, there should be a certification process in place for these applications to ensure that the third-party is a safe steward of patient data, as discussed in more detail in the *Persistent Access* section of this letter.** However, regardless of certification, there should not be a requirement to collect this data from patients, but rather it should be an option for patients and physicians to utilize devices and applications as a care management tool to maintain communication and care between visits. It is also important to recognize that not all patients have the resources, capacity, or ability to utilize technology that generates these data, and others will choose not to do so. As such, it cannot be required of physicians to use technology that patients may not be willing or able to utilize for care purposes.

As stated above, the ACS supports the concept of incentives to encourage early adoption of reviewing and incorporating PGHD. As the use of this data by clinicians remains new, evidence-based best practices are not yet well known. It is important that CMS and the ONC work together to understand the challenges physicians face as PGHD becomes more common, including challenges with volume of data, questions of accuracy, and increased communication and questions from patients. Working with physicians through these challenges to establish best practices will be an important step as the industry moves beyond adoption. ACS encourages CMS to work with specialty societies to develop these best practices.

RFI on Engaging in Activities that Promote the Safety of the EHR

CMS is seeking comments for strategies to further mitigate risks to patient safety stemming from technology implementation and usage, specifically on options that reduce clinical errors. CMS references the ONC SAFER guidelines as a possible tool to utilize for health care organizations to complete and receive points towards their Promoting Interoperability score. While the SAFER guides are comprehensive, several of the assessments contain information that should be the responsibility of the vendor to meet and complete, rather than the hospital, specifically the items in the High Priority Practices Checklist. This highlights that health IT safety is not just the responsibility of the user, but also of the vendor.

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Any strategy or program that incorporates safety standards should share responsibility with the appropriate party, including third-party developers, vendors, physicians, and patients. Additionally, the SAFER criteria were last updated in 2016, and should be made current if they are used in the PI program to ensure that they include patient safety threats that stem from increased interoperability and expanded use of new technologies.

MIPS Final Score Methodology

Performance Category Scores

Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

In the CY 2019 Final Rule, CMS finalized the following data completeness requirements: For the 2020 MIPS performance period, measures that are submitted, but do not meet the data completeness threshold (i.e., 70% of all data, as proposed for 2020), even if they have a measure benchmark and/or meet the case minimum will receive zero points towards their Quality Category score. Small practices will continue to receive 3 points. **Although this policy was previously finalized, we urge CMS to reconsider assigning zero points for measures that do not meet data completeness starting in the 2020 performance year.** Due to the complexity and associated burden of participating in the MIPS program, we believe it is important to recognize clinicians who make an effort to report, versus those who report no data, especially considering the increase to the 70% data completeness proposed requirement.

Modifying Benchmarks to Avoid the Potential for Inappropriate Treatment

CMS proposes to adjust benchmarking methodology for measures that CMS determines have the potential to encourage or result in inappropriate treatment. Instead of using average performance scores to develop benchmarks, CMS will use a flat benchmark where the top decile is equal or higher than 90%. **The College seeks clarity on why exclusions are not used as part of the measure definition to exclude patients with diagnoses or co-morbidities that have different standards of care.** Because reasons for inappropriate treatment are rare for the initial two measures proposed to use this new methodology (MIPS 1: Diabetes, Hemoglobin A1C Poor Control $\geq 9\%$ and MIPS 236: Controlling high Blood Pressure), it seems that the measure steward addressing and expanding exclusions would solve the issue of inappropriate care.

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Calculating the Final Score

Reweighting Performance Categories due to Data that are Inaccurate, Unusable, or Otherwise Compromised

Redistributing Performance Category Weights

CMS proposes, beginning with the 2018 MIPS performance period/2020 MIPS payment year, to reweight the performance categories for a MIPS eligible clinician who it determines has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents, if CMS learns the relevant information prior to the beginning of the associated MIPS payment year. CMS also proposes that for the 2020 performance year there will not be any points redistributed to the Improvement Activities performance category in any scenario. In cases where both Quality and PI categories need to be redistributed, all points would be redistributed to Cost, weighting the Cost category at 85% and Improvement Activities at 15%.

While ACS supports policies that prevent the use of inaccurate, unusable, or compromised data, ACS strongly opposes the redistribution of Cost at 85 percent and IA at 15 percent because the target of the MIPS program should be quality improvement based on quality metrics, with cost information for resource stewardship, supported by data systems in PI. In no instances should Cost be weighted so heavily that lower cost is the driving incentive to perform well in MIPS—this could lead to detrimental impacts on patient care. The MIPS final score should reflect real improvement activities that have demonstrated improvements in care with outcome measures of quality (conformance and performance) and price (cost), supported by PI which should be weighted the lowest (least important).

MIPS Payment Adjustments

Establishing the Performance Threshold

Based on data from the 2017 reporting period, CMS proposes to raise the performance threshold to 45 points for the 2020 reporting period and to 60 points for the 2021 performance year. CMS explains that the Agency sees these increases as both necessary and consistent, as the threshold increased 15 points from the 2018 to 2019 performance year.

The College understands the need to increase the performance threshold from year to year. **However, data from the 2017 performance period is not an**

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accurate representation of current actual performance, as the program was drastically different in the 2017 “test” period. Using more recent data to assess current performance would be a better measurement to determine the updated threshold. Lastly, due to the programmatic changes proposed for the 2021 performance period through the MVP program, the College recommends not finalizing a performance threshold for that period until the MVP program is better defined.

Third Party Intermediaries

Proposed Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

CMS proposes that QCDRs and Qualified Registries (QRs) must be able to support and report on all three categories within the MIPS program (Quality, Improvement Activities, and Promoting Interoperability) by the 2021 reporting period. QCDRs and QRs that **only** support participants and/or groups that are exempted from the Promoting Interoperability category are exempt from this proposed requirement. CMS asks for comment on this proposal, and specifically asks if the exceptions should be narrowed or broadened for the cases in which QCDRs and QRs would be required to support and report on the Promoting Interoperability category.

The ACS acknowledges that this proposal is intended to reduce reporting burden for participants and align with the future MVP programs. **Accordingly, the College believes that the current exception is appropriate. However, given other challenges and considerations, the timeline and expectations for this proposal should be adjusted to align with the increased interoperability standards within the ONC and CMS’ 21st Century Cures Act rules.** We discuss concerns about the challenges of implementing these changes in the following section.

CMS also proposes that health IT vendors are only required to submit data for **one** category: Quality, Improvement Activities, or Promoting Interoperability. The College believes that health IT vendors should be held to the same standards as QCDRs and QRs, particularly considering that EHRs contain much of the data needed to report on any of the three categories, and as such, CEHRT should be able to support and report on all three performance categories.

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Qualified Registries

Requirement to Support All Three Performance Categories Where Data Submission is Required

Beginning with the 2021 performance period and beyond, CMS proposes that QRs must be able to support and report on three of the four MIPS performance categories: Quality, Improvement Activities, and PI. QRs would be required to attest at the time of self-nomination.

The College generally agrees with the intent of this proposed change, as an effort to reduce administrative burden for physicians, to streamline reporting requirements, and to develop the infrastructure needed for MVPs. However, **we urge CMS to consider the resources and timeline to implement this change prior to the finalization of the 21st Century Cures rules.** For the QRs that do not currently support PI, they would be required to not only develop these measures within the database, but it would also necessitate that additional data points from the EHR, and, possibly, third-party application(s) that support patient portals and data exchange, be incorporated as well. Due to the many different EHRs that send data to registries through a variety of different mechanisms, ranging from interface to extract to CCDA and, in some cases, manual data entry, health care organizations and physicians would need to individually update their unique connection and data exchange methodology from their EHR to their QR.

Further, **the College seeks clarification on the methodology through which QRs would be required to report on PI measures. Because these measures are assessing processes that are often external (i.e., from the EHR) or require the integration of third-parties—such as a regional or state Health Information Exchanges (HIEs), third-party patient portal applications, or state-supported public health registries—the integration of these data into the registry database could be challenging.** In the case of the EHR sending data to a regional HIE for the Referral Loop measures, how would a QR support the reporting of this measure or even accurately validate a clinician's completion of this activity? Is the expectation that the EHR sends the registry the HIE data to process and report? Or is the expectation that the registry should instead receive data directly from the regional HIE to report this measure? In the case of the latter, this could mean connecting to dozens of third-parties to directly receive data on PI measures.

While the above scenario demonstrates the varying and complicated methodology through which the registry does, and could, receive information, the lack of semantic standards between EHRs presents challenges for sending and reporting these data. Between EHR vendors, and

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even between instances of the same EHR, there is great variation in documentation and in the data points utilized to complete similar workflows. Due to customization and the variations in implementations, there are multiple options through which physicians can document within systems. While this flexibility is beneficial to physicians and the care team, it complicates sending data to external systems. In each instance and in each system, all of the data points that are relevant to the measure(s) would need to be determined, ensure that these data are included in the methodology through which the data is sent to the registry, and the various data points would need to be mapped accordingly within the registry database to guarantee accurate and appropriate reporting of the data.

While the ACS understands and appreciates the intent of this proposed requirement, the above considerations present the many challenges with implementing PI measures within existing QRs. This requirement could present an unanticipated burden on physicians and health care organizations to work with multiple vendors to determine the strategies with which they can exchange data between systems. **The fast timeline for these changes—that they would need to be in place at the start of the 2021 reporting period—does not allow either vendors or QRs the time to test and pilot the best strategies for data exchange and processing.** Further, **because timelines are not in sync with the interoperability timelines proposed by both the ONC and CMS in the 21st Century Cures proposed rules, there could be new data exchange requirements, including EHI extracts, USCDI data-models, and FHIR-based API standards, that would also need to be met by vendors.** Incidentally, the requirements from the 21st Century Cures rules could create standardized, more streamlined, and lower-cost options for EHRs and other third-party applications to exchange and share data with QRs, making the options discussed above for the 2021 reporting period an expensive and complex short-term solution. Therefore, **this requirement should not be considered until after the final 21st Century Cures rules are published and the updated standards are implemented.**

As discussed in the *RFI on a Metric to Improve Efficiency of Providers within EHRs* section, in order to better utilize health IT to advance the quality of patient care, it is time to think beyond traditional EHR-centric solutions and point-to-point data exchange. To further reduce administrative burden and streamline systems for sending and reporting data to registries, open source digital standards that meet criteria for clinical interoperability must better utilize existing technology in order to create efficiencies. The figure below demonstrates that with standards in place, registries could receive necessary data through a cloud platform, where the data can be processed, converted, and normalized as needed, eliminating the need for EHRs or other third-parties to establish multiple connections and sort through specific data points in order to exchange data with a variety of external parties. This ecosystem simplifies data exchange through

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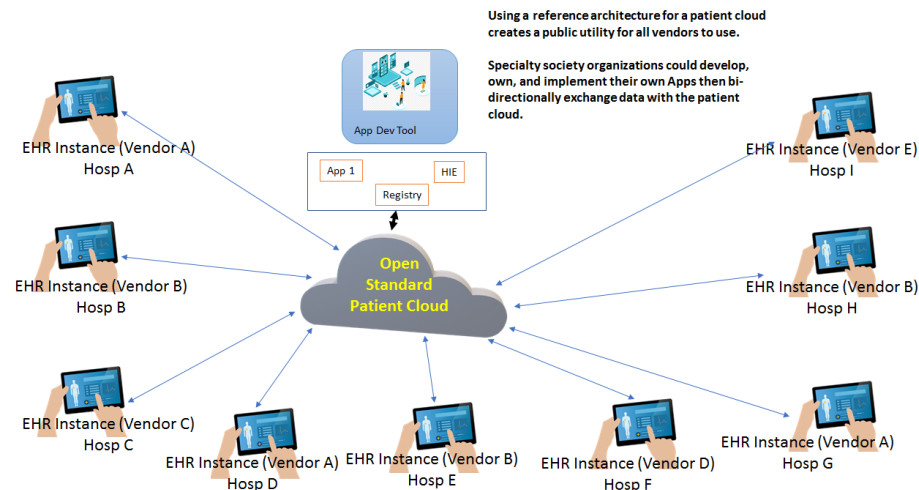
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standards and plug-and-play connectivity, better enables Qualified Registries to report data on all three performance categories, and creates the true “one-stop-shop” that is CMS’ goal.

Figure 6: Advanced Model of Interoperability



Enhanced Performance Feedback Requirement

CMS proposes that for the 2021 reporting period and following years, QRs would be required to share feedback and benchmarking to their participants on how the individual compares to other registry participants on a given measure within the same registry at least four times a year. While the ACS agrees that performance data and benchmarking are important aspects of a culture of continuous quality improvement for physicians, the **College has concerns with this proposal. Because QRs would only be able to provide data from their registry participants, this would not provide participants with feedback on their performance from a programmatic perspective as a single registry does not represent a participant’s entire peer cohort. This is a particular issue for QRs since measures are universally used by other registries; versus a QCDR, which relies on many measures that are unique to the registry.** As the MIPS reimbursement adjustments are done based on overall participant performance, providing registry-specific comparative performance feedback could be misleading for those who would rely on feedback reports to predict their potential reimbursement.

CMS asks for feedback on if eligible clinicians and groups should be able to submit data to a QCDR or QR throughout the performance period, starting April

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1, and before the close of the period on December 31. This would allow QCDRs to have additional time to provide feedback and benchmarking to participants before the data submission deadline.

The College supports participants submitting data throughout the performance period and prior to the end of the period on December 31. However, we are concerned about the current QCDR and QR data submission deadline. Given the requirements that QCDRs and QRs must complete the randomized audit and detailed audit of the data, if required, prior to submitting the data to CMS, in order for validation to be complete and fully address any found errors, the current submission date of March 31 does not allow for enough time to complete a thorough data validation. **The ACS asks for the submission date to CMS to be April 30, which would allow QCDRs and QRs to have enough time to complete validation and associated follow-up between participants submitting complete data on December 31 and the final submission to CMS.** Two months is not a long enough time period to provide results of the executed data validation plan.

Public Reporting on Physician Compare

Final Score, Performance Categories, and Aggregate Information

Quality

CMS seeks feedback on publishing responses from patient narratives, as well as a single “value indicator” on the Physician Compare website. CMS explains that the “value indicator” would be reflective of the cost and quality performance categories, as well as patient experience and satisfaction.

As discussed in the *CAHPS for MIPS* section above, the ACS has concerns about the inclusion and validity of patient narratives. The College strongly recommends that the inclusion of patient narratives be tested prior to large scale implementation and for use in a pay-for-performance program—it is unclear how and whether CMS would incorporate patient narratives as part of the MIPS Quality score. In addition, we ask for clarity on how CMS plans to manage false or inappropriate narratives? For example, could a false narrative misguide patients? How would a physician appeal a false narrative? Will these false narratives become a disruption to the trust in a physician-patient relationship, or worse, create defamation suits? We also ask CMS for examples of where raw patient narrative data has been used successfully to drive improvements in care. **Although the validated PROs we discussed above still need to be piloted prior to use in the QPP program, ACS supports testing PROs.**

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It is also crucial for CMS, along with stakeholders, to leverage digital health platforms to collect information from patients. By leveraging health IT, patients can be asked fewer questions more frequently through easily accessible platforms (such as smart phones), rather than distributing a large retrospective survey after the completion of care. This format also allows physicians to gather real-time data directly from patients to inform care decisions at various points of treatment, and increase communication between patients and physicians, while reducing administrative burden. **Utilizing a standardized, open source patient-cloud as the centralized, standard platform would allow PRO implementations through open APIs across all EHR platforms.** Responses from patients would allow flow back to the EHR through an open API in the patient-cloud and allow for PRO communication to be pulled by the EHR internally to present patient reports to the clinical teams. Cloud-based patient reports could also be sent to other third-party applications. In the patient-cloud, data from multiple sources could be aggregated and analyzed, and the open architecture allows for widespread, vendor-agnostic use of successful survey tools. With a patient-cloud, with permission from the patient, any EHR can deliver a report to any entity—the patient portal, another EHR, CMS, etc. The College continues to develop and test open source patient-clouds and inclusions of care tools such as PROs for surgical care and is eager to collaborate with CMS.

As for the proposal regarding the value indicator, **the College believes that value is determined by an assessment that is made by the patient, and therefore must measure health outcomes that matter to the patient. Patients need information on care and outcomes that can be assessed, rather than a single score that represents the way in which CMS defines value. Patients value aspects of care differently, and need information on multiple, *meaningful*, areas from which they can determine value as they define it. As detailed in the MVP RFI, the College provides an explanation of a system that measures value through verification programs, actionable cost and quality measures, and PROs. Information from these components will provide patients with meaningful information through which they can assess and determine value.**

Advanced APMs

General Comments

The ACS applauds the increase in the number of QPP-eligible clinicians who were Qualified Participants (QP) in Advanced APMs between 2017 and 2018. However, we note that it will become more difficult for surgeons and other clinicians to achieve QP status as participation thresholds increase. The ACS therefore remains concerned with the general lack of physician-focused payment models in MACRA both in MIPS as MIPS APMs and in the Advanced APM

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track of participation. The Physician-focused Payment Model Technical Advisory Committee has received more than 30 proposals from stakeholders for APMs, many of which have been reviewed favorably and recommended for testing or implementation. Unfortunately, this has not resulted in the expected or intended buildup of a library of payment models for physicians to test.

MVPs as a Pathway to A-APMs

The newly proposed MVPs proposal could help create the currently missing link between fee-for-service payment in MIPS and transition to Advanced-APMs. To meet this underlying goal of MACRA, two conditions must be met. First, we must create the destination for physicians who are willing and ready to take on risk in Advanced APMs. As noted above the expected proliferation of new and innovative payment models has yet to take hold. This will create a cooling effect—the introduction of new and innovative models must be a priority. Second, MVPs will need to start providing clinicians with the meaningful, actionable data they require in both cost and quality to allow them to understand current delivery patterns and how they compare to high performing practices. This will allow practices and delivery systems to design improvements and innovations that will help them succeed in the MIPS fee-for-service environment and beyond.

The ACS continues to be supportive of a data-driven value transformation in health care delivery as witnessed by our century of quality improvement, our recent work in development of an A-APM proposal recommended by the PTAC, and further noted in our response to the MVP RFI. We are encouraged by CMS' apparent openness to innovation from stakeholders and strongly encourage the Agency to work with ACS and other stakeholders to facilitate this transformation.

Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm

Revision(s) and Addition(s) to Denial and Revocation Reasons in §§ 424.530 and 424.535

CMS regulations set forth a number of reasons why a provider or supplier's enrollment in Medicare may be either revoked or denied. In this section, CMS proposes a new revocation reason and a new denial reason to permit CMS to revoke or deny, as applicable, a physician's or other eligible professional's enrollment if he or she has been subject to a prior action with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm from a state oversight board, federal or state health care program,

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Independent Review Organization (IRO) determination(s) , or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. **We urge CMS to not finalize this ill-defined and overly broad proposal that could have a devastating impact on physicians, and to instead focus on ways to identify and discipline the truly bad actors.**

We support CMS' goal to ensure that unqualified or potentially fraudulent individuals or entities are precluded from participating in federal healthcare programs. We are concerned, however, that CMS has introduced the subjective term of "patient harm" as a reason for revocation or denial of participation without providing a definition for this term. Also, CMS does not provide a clear definition of prior actions taken by state oversight boards or other governmental bodies that count for the purposes of this new revocation and denial authority other than listing the following examples:

- License restriction(s) pertaining to certain procedures or practices;
- Required compliance appearances before state oversight boards;
- Required participation in rehabilitation or mental/behavioral health programs;
- Required abstinence from drugs or alcohol and random drug testing;
- License restrictions on the ability to treat certain types of patients (for example, cannot be alone with members of different genders after a sexual offense charge);
- Administrative/money penalties; or
- Formal reprimands.

While we take these and any offense resulting in patient harm seriously, if an infraction were, under this proposal, to result in the significant and potentially career-ending step of revocation or denial of enrollment, CMS should be much more specific, clear, and focused on what would qualify as "patient harm," and what types of "prior actions" would trigger this authority.

CMS does not address the reality of the impact on a physician's practice of a denial or revocation to participate in Medicare. Such a revocation would lead to a mandated cross-termination of participation in Medicaid and most payers will also remove a physician from their provider network when CMS takes this action. Thus, if a physician agreed to abstain from drugs or alcohol and be subject to random drug testing to simply provide evidence that no addiction exists, CMS now gives itself the authority to revoke that physician's enrollment in Medicare, which includes a mandated cross-termination in Medicaid, with most payers also following suit. This action is contrary to CMS' efforts to reduce physician burnout, drop out, and suicide. Physicians with substance abuse disorders or mental health illnesses should feel that it is safe to report the issue and seek help,

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100+years

and this new policy could discourage such clinicians from accessing treatment and support. In addition, adoption of this policy would be completely at odds with the nationwide effort to reduce the stigma associated with seeking treatment for substance use disorders.

We are also extremely concerned that CMS buried such a major change to the denial and revocation authority in the annual physician fee schedule under the opioid treatment program section. The proposed rule gives the appearance of potentially only applying to “high risk” Medicare-enrolled opioid treatment programs; however, the proposed change impacts all clinicians in all settings.

CMS should not finalize this proposal, which represents an ill-defined, broad, and unprecedented overreach, and which puts physicians’ careers in jeopardy. We urge the agency to instead focus on ways to identify and discipline the truly bad actors using data analytics, continued dialogue, and other methods.

We appreciate the opportunity to comment on this proposed rule. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Jill Sage, Quality Affairs Manager, at jsage@facs.org.

Sincerely,

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