September 10, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1693-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (CMS-1693-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) proposed rule: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program published in the Federal Register on July 27, 2018.

The ACS (or the “College”) 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 proportion of our members’ performance and reimbursement is measured and paid for under the provisions contained in this rule, the College has a vested interest in CMS’ Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP), and we believe that we can offer insight to the Agency’s proposed modifications to these policies. Our comments below are presented in the order in which they appear in the rule.

PROVISIONS OF THE PROPOSED RULE FOR PFS

Determination of Practice Expense Relative Value Units

PE RVU Methodology
In the calendar year (CY) 2018 PFS final rule, CMS indicated that low volume Current Procedural Terminology (CPT) codes (i.e., those that have fewer than 100 allowed services in the Medicare claims data) would be identified using the most recent year of claims data and instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data for practice expense (PE) and malpractice (MP) relative value units (RVUs), CMS will instead use the expected specialty based on medical review and input from the American Medical Association (AMA) RVS Update Committee (RUC) and specialty societies. The Agency proposes to add 28 codes to the current list of codes that are assigned an expected specialty for CY 2019.

We agree that the use of assigned specialty overrides for low volume services would provide greater stability in the valuation of these services and would prevent year-to-year distortions and variability in PE and MP RVUs for such codes. The ACS appreciates that CMS continues to allow service-level overrides for low volume codes and thanks the Agency for its consideration of the RUC-recommend anticipated specialties for codes with Medicare utilization less than 100. We believe that the RUC, with representation from all national medical specialties and subspecialties, is the most appropriate group to review and recommend the expected specialty for low volume codes. The ACS urges CMS to continue to use the RUC as an expert panel and accept their recommendations for these 28 codes.

Changes to Direct PE Inputs for Specific Services

Standardization of Clinical Labor Tasks

Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes clinical labor tasks and assigns such tasks a clinical labor activity code. CMS states that, in reviewing the RUC-recommended direct PE inputs for CY 2019, the 3 minutes of clinical labor time traditionally assigned to the “Prepare room, equipment and supplies” (CA013) clinical labor activity were split into 2 minutes for the “Prepare room, equipment and supplies” activity and 1 minute for the “Confirm order, protocol exam” (CA014) activity. The Agency notes that these codes do not currently have clinical labor time assigned for the “Confirm order, protocol exam” clinical labor task, and indicates that the services being furnished by the clinical staff has not changed; CMS believes that this difference in clinical labor time is a result of how the information was presented on the new RUC PE worksheets versus the old worksheets. CMS thereby proposes to maintain the 3 minutes of clinical labor time for CA013 and remove the clinical labor time for CA014 wherever this pattern occurred in the RUC-recommended direct PE inputs, asserting that there is no effect on the total
clinical labor direct costs in these situations since the same 3 minutes of clinical labor time is still being used in the calculation of PE RVUs.

The ACS does not support the shift of the 1 minute of clinical labor time assigned to CA014 to CA013 and believes that CMS’ understanding of the changes in clinical labor times in the revised spreadsheet for CA013 and CA014 is incorrect. The standard clinical labor time for CA013 has always been 2 minutes; although, the RUC may have assigned extra time to CA013 for certain CPT codes reviewed between the years of 2002 and 2004 to account for additional time needed to set up extra equipment. If a code includes 3 minutes or more for CA013, such minutes were added strictly for this activity, and not for CA014.

In February 2016, the RUC PE Spreadsheet Workgroup revised the description of the imaging-specific clinical labor activity “Patient clinical information and questionnaire reviewed, order from physician confirmed and exam protoceled by radiologist” to read “Patient clinical information and questionnaire reviewed, order confirmed and exam protoceled/prepared” in order to make such activity applicable to a wider range of services. During the workgroup’s discussion, some specialties noted that if the newly-revised “Patient clinical information and questionnaire reviewed, order confirmed and exam protoceled/prepared” activity included the protocol of an exam, that clinical labor time would need to be moved to the service period of the activity because clinical staff would need to be in the treatment room to perform the task. However, if the revised activity was intended only to reflect the review of patient information, such clinical labor time could remain in the pre-service period of the activity.

To clarify that the “Patient clinical information and questionnaire reviewed, order confirmed and exam protoceled/prepared” included both the review of patient information and protocol of the exam, the RUC divided this activity into the following two line items for pre-service and intraservice clinical labor:

- **Pre-service work:** “Review patient clinical extant information and questionnaire” (CA007) – assigned 1 minute of clinical labor time
- **Intraservice work:** “Order confirmed and exam protoceled/prepared” (CA014) – assigned 1 minute of clinical labor time

The ACS wishes to remind the Agency that CA014 is not the same activity as CA013, and the time for CA014 should not be bundled into CA013 since it is a separate and distinct clinical activity.

*Equipment Recommendations for Scope Systems*
CMS seeks comment related to the creation of scope equipment codes on a per-specialty basis for five categories of scopes: (1) a rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. CMS also seeks such recommendations for a sixth category, a multi-channeled flexible video scope, which was recommended by the ACS for CY 2018. CMS specifically seeks recommendations regarding the scope equipment items that would be typically required for each category, as well as the proper pricing for each scope. CMS states that it will not finalize any scope equipment proposals until CY 2020 in order to incorporate the feedback from the RUC Scope Equipment Reorganization workgroup.

We thank CMS for adding the ACS-recommended scope category for multi-channeled flexible video scopes and would like to remind the Agency that, even within its six proposed scope categories, different scopes within a single category will vary both in use and in pricing. For example, rigid scopes for sinoscopy, laryngoscopy, sigmoidoscopy, and anoscopy, which are used to examine different parts of the body, can vary in price by thousands of dollars. Within the flexible scope category, the price difference between scopes can be $10,000. We also believe that, based on length and numbers of channels, scopes differ in the amount of supplies and time necessary to properly clean and maintain the equipment. The College appreciates that CMS will delay implementation of any changes to the valuation of scopes until CY 2020 to allow the opportunity for the RUC Scope Equipment Reorganization Workgroup, which represents all medical and surgical specialties that utilize scopes and related equipment, to provide guidance on the correct categorization, pricing, and coding for these equipment items.

Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) provides that the Secretary of the Department of Health and Human Services (HHS) may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include types and prices of PE inputs. CMS indicates that their authority under section 1848(c)(2)(M) of the Social Security Act, as added by the PAMA, has allowed the Agency to enter a market research contract with StrategyGen to conduct an in-depth and robust study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. CMS notes that these supply and equipment prices were last systematically developed in 2004-2005. StrategyGen submitted a report to CMS with updated pricing
recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs.

CMS specifies that the StrategyGen team included researchers, attorneys, physicians, and health policy experts and that the resources and methodologies used included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. The primary and secondary resources StrategyGen used to gather price data and other information included: telephone surveys with vendors for top priority items (Vendor Survey); physician panel validation of market research results, prioritized by total spending (Physician Panel); the General Services Administration system (GSA); an aggregate health system buyers database with discounted prices ( Buyers); publicly available vendor resources such as Amazon Business and Cardinal Health ( Vendors); and the Federal Register, current DPEI data, historical proposes and final rules, and other resources such as AMA RUC reports ( References). In order to guide StrategyGen’s research, equipment and supplies were prioritized by CMS based on four total spend categories (top, high, medium, and low total spend) for equipment and supply codes.

While the ACS thanks CMS for its extensive description of StrategyGen’s research processes and findings, no details were provided about the pricing source(s) and manufacturers for any supply or equipment item—the Agency only made public the methodology and results of its contractor’s market study. We are extremely disappointed that although CMS attends every RUC meeting, including each PE Subcommittee meeting, the agency never indicated to RUC members or specialty society representatives that the Agency had entered into a contract to conduct research on market pricing of supplies and equipment. In addition, the CY 2018 PFS proposed and final rules did not alert stakeholders that CMS anticipated to contract with StrategyGen for such research and to subsequently make pricing changes based on the contractor’s findings, which CMS proposes to implement over four years (CYs 2019-2022) because of the wide swings in pricing. The College expresses deep concern with the lack of transparency in StrategyGen's recommendations and CMS’ conduct for such a major revision to DPEIs. As such, we cannot support the implementation of the proposed pricing updates for any supply or equipment item. Below, we identify just a few significant errors or questionable recommendations that should have been caught during an internal validation process.

Patient gown (SB026): This supply item is among the list of supplies with the highest utilization, as it is included in every E/M visit and most every non-facility procedure and imaging service. We can only believe that StrategyGen and its
subcontractors misunderstood that this is a "disposable" gown, as we find it unlikely that any office would pay $3.54 per unit for this item.

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<td>SB026</td>
<td>Gown, patient</td>
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Pack, E/M visit (SA047): This pack consists of ten individual items shown in the second table below. It is not a "pack" that is wrapped and opened for single use, but instead a convenient grouping of items that will typically be used at a stand-alone E/M visit. We do not understand how the StrategyGen-recommended price ($7.750) can equal less than the sum of the StrategyGen-recommended price ($8.418) of the component items.

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<td>SB036</td>
<td>Paper, Exam Table</td>
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<tr>
<td>SB022</td>
<td>Gloves, non-sterile</td>
<td>pair</td>
<td>2</td>
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<tr>
<td>SM025</td>
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<td>item</td>
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<td>$0.533</td>
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<tr>
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Total: $2.984 $8.418

Pack, pelvic exam (SA051): This pack consists of specific individual items as shown in the second table below. Similar to the E/M pack, it is not a "pack" that is wrapped and opened for single use, but instead a convenient grouping of items that will typically be used for a pelvic exam. We do not understand how the StrategyGen-recommended price ($20.160) can be so significantly greater than the sum of the StrategyGen recommended price ($2.940) of the component items.
Since CMS has not made public the specific details (source and manufacturer) for individual supply and equipment items or packs, kits, rooms, and lanes needed by stakeholders to provide recommendations in response to this proposed rule, the ACS urges CMS not to finalize any DEPI updates before providing such details and allowing time for stakeholders to review the invoicing that StrategyGen used to develop its pricing recommendations.

### Determination of Malpractice Relative Value Units

In the CY 2018 PFS proposed rule, CMS sought input from stakeholders on use of the most recent MP premium data collected by its contractor, Acumen, to update the specialty risk factors used in calculation of the MP RVUs prior to the next 5-year update (CY 2020). In both our September 11, 2017 CY 2018 PFS proposed rule comment letter and a separate, MP RVU-specific letter sent to HHS and CMS on September 28, 2017, the ACS strongly opposed CMS’ proposal to update the MP RVUs for CY 2018 using the Acumen data that was collected for an update to the GPCIs and urged CMS to suspend utilization of the new MP premium information to allow time for the Agency to collect more accurate and complete data using Acumen or other sources.

In this proposed rule, CMS notes that it did not finalize its proposal to use the updated MP premium data in 2018 and acknowledges that it did not have sufficient data to calculate accurate MP RVUs for certain specialties because of changes in MP insurers’ premium coding and rate filing processes. CMS seeks additional comment regarding the next MP RVU update—which must occur by CY 2020—and specifically asks for recommendations on how the Agency can improve the way that specialties in the state-level raw rate filings data are

<table>
<thead>
<tr>
<th>CMS Code</th>
<th>Description</th>
<th>Unit</th>
<th>Quantity</th>
<th>CMS Current Price</th>
<th>Extended Price</th>
<th>Recommended Price</th>
<th>Final Price</th>
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<table>
<thead>
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<th>CMS Code</th>
<th>Description</th>
<th>Unit</th>
<th>Quantity</th>
<th>CMS Current Price</th>
<th>Extended Price</th>
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<th>Extended Price</th>
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<tr>
<td>SJ032</td>
<td>Lubricating jelly (K-Y) (5gm ouo)</td>
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<td>0.066</td>
<td>0.540</td>
<td>0.540</td>
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<tr>
<td>SB006</td>
<td>Drape, non-sterile, sheet 40in x 60in</td>
<td>item</td>
<td>1</td>
<td>0.222</td>
<td>0.222</td>
<td>0.130</td>
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<tr>
<td>SK052</td>
<td>Pad, feminine mini</td>
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</table>

**Total**

1.172

2.940
crosswalked for categorization into the CMS specialty codes that are used to develop specialty-level risk factors and MP RVUs.

The College remains concerned that the existing MP premium data collection and calculation processes employed by CMS and Acumen are neither transparent nor precise and that any MP RVU updates made using the most recent premium data will unfairly reduce payments for providers who regularly furnish surgical services. Our specific concerns with CMS’ MP RVU update methodology, along with our recommendations to improve this methodology, are described below.

Calculating National Average Premiums

Acumen was charged with collecting MP premium data and evaluating options for calculating a national average for each specialty. For CY 2018, CMS asked Acumen to test a new method in which premiums were geographically normalized before identifying the national average. Per the advice of Acumen, CMS incorporated population estimates from the American Community Survey, which collects nationwide population data at the county level, as weights for calculating specialty premiums.

To assess the effect of these changes, Acumen examined the differences among four calculation options for comparison and validation purposes. These calculation options included:

- **Option 1**: Sum all county-level price adjusted premiums, weighted by share of total population
- **Option 2**: Sum all county-level price adjusted premiums, weighted by the share of work and PE RVUs
- **Option 3**: Sum all county-level price adjusted premiums, weighted by the share of total RVUs
- **Option 4**: Sum the ratio of each total RVU weighted specialty premium to each MP RVU-weighted MP GPCI.

Acumen indicated that its review did not show any substantial differences in national average premiums (shown in the table below) when comparing each option.¹

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National Average Premium Distributions across Options

<table>
<thead>
<tr>
<th>Metric</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
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<tr>
<td>Minimum</td>
<td>$2</td>
<td>$122</td>
<td>$122</td>
<td>$98</td>
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<tr>
<td>Average</td>
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<td>$12,280</td>
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<td>Maximum</td>
<td>$81,170</td>
<td>$79,919</td>
<td>$79,823</td>
<td>$80,793</td>
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</table>

Following this analysis, Acumen recommended and CMS agreed to utilize Option 1, which weights national average premiums with population estimates. The ACS disagrees with the assumption that the differences between these four options were not substantial. We believe these data clearly show that Option 1 (population weighting) is different from Options 2 through 4 (RVU weighting) given the significant differences in the minimum national average premium between population and RVU weighting.

Using population to weight the national average premiums is incorrect. This method does not reflect differences in the risk of specific services among different areas of the country. Risk-of-service, not population, reflects how services differ in their contributions to MP premiums. For example, if a provider often performs a complex, difficult surgical procedure, this would have a larger impact on the provider’s premium risk classification than if the provider instead often performs elective surgery or non-surgical services. Therefore, we believe the premiums should be normalized using surgical and non-surgical work RVUs for each geographic area. Since work RVUs reflect differences in time, intensity, and difficulty among procedures—which are directly correlated with malpractice risk—we believe that they are the best available proxy for weighting geographic differences to calculate national average premiums. The College urges CMS to use work RVUs instead of population to weight geographic differences to calculate national average premiums for the 2020 MP RVU.

Calculating Specialty Risk Factors

Acumen recommended, and CMS agreed, to maintain the current process of normalizing each specialty premium to the value of the specialty with the lowest premium, which has been implemented in all prior MP RVU updates. To calculate specialty risk factors, Acumen solicited MP premium data for CY 2018 from all 50 States, the District of Columbia, and Puerto Rico for all physician and non-physician practitioner (NPP) specialties and for all risk classifications (i.e., surgical, non-surgical, other) available. However, Acumen noted that not all specialties had distinct premium data in the rate filings they obtained. Additionally, for some specialties, MP premiums were not available from the rate
filings in any state. Therefore, for specialties for which Acumen did not obtain premium data for at least 35 states, and for specialties for which Acumen did not obtain distinct premium data in the any of the state rate filings, Acumen crosswalked the premiums for these specialties to a similar specialty that the contractor determined had comparable risk.

The ACS has several concerns about the validity of the premium data that Acumen used to calculate the specialty risk factors that were in turn used to compute the proposed MP RVUs in the CY 2018 PFS. Most importantly, we question the reliability of the MP RVU calculation methodology, as nearly 40 percent of specialties were crosswalked to other specialties because of insufficient premium data. We believe it was Acumen's obligation to find sources to obtain robust data and we question why the contractor imposed a threshold of 35 states as the minimum for having “sufficient” data. We outline our specific concerns about each individual methodology issue below.

- **Blending All Available Premium Data:** For 24 specialties, there was wide variation across the rate filings in terms of whether surgery class premiums were reported and which categories were reported (e.g., major surgery, minor surgery, no surgery). Although Acumen set a minimum threshold of 35 states in order to calculate premium data, they set a lower threshold of only 25 states to calculate separate surgical and non-surgical risk factors.

For specialties with enough surgical/non-surgical premium data from at least 25 states (e.g., family practice), separate surgical and non-surgical MP premiums were calculated. For specialties where “major surgery” was the dominant premium class (e.g., general surgery, cardiac surgery), only one MP premium (surgical) was calculated. For all other specialties that did not have substantial data for the “major” and “no surgery” classes, or for specialties for which the “major surgery” class was not the dominant class, Acumen blended the available premium data into one general premium rate using a weighted average “blended” premium at the national level based on the percentage of work RVUs correlated with the surgery class premiums within each specialty. For example, the surgical premiums for a given specialty were weighted by that specialty’s work RVUs for surgical services; the non-surgical premiums for that specialty were weighted by the work RVUs for non-surgical services; and the unspecified premiums for that specialty were weighted by all work RVUs to create a single premium rate. We do not believe that a single premium that blends insufficient data for surgical, non-surgical and unspecified premiums accurately and fairly contributes to the final calculation of MP RVUs. This methodology will overpay providers whose practices furnish more non-surgical services and underpay providers whose practices furnish more surgical services.
As shown in the table below, which includes data taken from the Acumen interim report and the CY 2018 PFS proposed rule, the “blended” proxy for the surgical premiums for dermatology, gastroenterology, cardiology, endocrinology, and nephrology are significantly less than the 2017 rates and also significantly less than those for general practice or family practice. Additionally, in 2015, cardiology premium data were collected from 41 states for “major surgery”; in 2018, cardiology premium data were only collected from 12 states for “major surgery.” We do not believe this difference is due to a decrease in the number of interventional cardiologists performing surgery; rather, this is likely due to a difference in the data collection process and/or a change in practice from individual to group or institutional employment, which would make it more difficult to obtain premium data. This difference is presumably also found in the other specialties with “blended” data premium rates. We urge CMS and Acumen to increase collaboration with state and national medical societies to obtain separate surgical and non-surgical premium data. We recommend that CMS continue to use the previous surgical and non-surgical premium data until more data can be obtained instead of using “blended” premiums for MP RVU calculations as proposed for CY 2018.

### Changes in Normalized Premium Rates for Selected Specialties from CY 2017 to CY 2018 (Proposed)

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<tr>
<th>Specialty Code</th>
<th>Specialties Crosswalked to Allergy/Immunology</th>
<th>2006 AMA PPI Premium Rate</th>
<th>2018 (proposed) Non-surgical Normalized Premium Rate</th>
<th>2018 (proposed) Surgical Normalized Premium Rate</th>
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<tr>
<td>03</td>
<td>Allergy/Immunology</td>
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</table>


1. Crosswalking Non-Physician Providers (NPPs) to Other Specialties:
Since CY 2010, CMS has crosswalked certain NPP specialties to the physician specialty with the lowest MP premium—allergy/immunology.\(^3\) We do not believe that crosswalking NPP specialties to allergy/immunology is relative or supported by data. The American Medical Association’s (AMA) Physician Practice Information (PPI) 2006 national survey data, which included PE and MP insurance premium rates from 51 specialties and are used by CMS for calculating PE RVUs, have shown that many NPP specialties have significantly lower MP premiums than allergy/immunology.\(^4\) For example, as shown in the table below, the PPI data indicate that NPP specialties such as physical therapy and occupational therapy, which together account for approximately 10 percent of all Medicare claims, have premium rates that are less than 20 percent of the allergy/immunology premium rate. We are concerned that, if such data had been finalized, the large discrepancies between the PPI survey data and MP premium rates proposed in the CY 2018 PFS would have resulted in overcompensation for NPPs. The ACS believes that the continued application of these unsubstantiated crosswalks may significantly impact the MP RVUs for all other specialties due to budget neutrality. We urge CMS to review the collected data, however minimal, for these specialties to determine if the crosswalk to allergy/immunology is supported before implementation of crosswalks to the lowest physician premium specialty for future MP RVU calculations. If this methodology is not supported for the calculation of NPP premium rates, we recommend that CMS work through the national and state NPP societies to obtain more MP premium data.

<table>
<thead>
<tr>
<th></th>
<th>Occupation</th>
<th>MP Premium</th>
<th>PE Premium</th>
<th>Other</th>
<th></th>
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<tbody>
<tr>
<td>67</td>
<td>Occupational Therapist</td>
<td>$ 1,821</td>
<td>$8,201</td>
<td>$8,201</td>
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<tr>
<td>68</td>
<td>Clinical Psychologist</td>
<td>$1,466</td>
<td>$8,201</td>
<td>$8,201</td>
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<tr>
<td>80</td>
<td>Licensed Clinical Social Worker</td>
<td>$1,115</td>
<td>$8,201</td>
<td>$8,201</td>
<td></td>
</tr>
</tbody>
</table>

\(^3\) Centers for Medicare and Medicaid Services. Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Proposed Rule; July 2009.

## Comparison of AMA PPI and CY 2018 (Proposed) MP Premium Amounts for Selected Specialties

<table>
<thead>
<tr>
<th>Specialty Code</th>
<th>Specialties Crosswalked to Allergy/Immunology</th>
<th>AMA PPI Premium Rate</th>
<th>Non-surgical Normalized Premium Rate</th>
<th>Surgical Normalized Premium Rate</th>
</tr>
</thead>
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<tr>
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<tr>
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</tr>
</tbody>
</table>

Given each of the issues described above, the ACS strongly urges CMS to withhold any modifications to the MP RVU update methodology until more robust data are collected to ensure that premiums and RVUs can be determined correctly for each specialty and premium class. We wish to highlight that Section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) directed HHS to establish a process under which CMS would be required to accept and use, to the maximum extent practicable, data collected or developed by entities and organizations to supplement the data CMS normally collects in determining PE RVUs. The College believes that medical specialty societies are well positioned to survey their members at the practice level to gather accurate and precise MP premium data, and encourages CMS to employ a process similar to that enacted in the BBRA for PE RVUs in order to establish a pathway for such societies to collect and submit data to the Agency to enhance what information CMS and its contractor already compile for the calculation of MP RVUs. The ACS stands

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3 BBRA, P.L. 106-113, Section 212.
ready to work with CMS to ensure that separate and valid surgical and non-surgical premium data for all specialties are obtained to determine resource-based MP RVUs.

**Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services**

CMS states that, for CY 2019, the Agency aims to increase access for Medicare beneficiaries to physician services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology. CMS thereby proposes to create two new Healthcare Common Procedure Coding System (HCPCS) codes for communication technology-based services that would be paid under the PFS similar to face-to-face physician services. Further, these proposed new codes would not be subject to the limitations placed on Medicare telehealth services in section 1834(m) of the Social Security Act.

**Brief Communication Technology-based Service**

**Coding and Billing:** CMS proposes to pay separately, beginning January 1, 2019, for a newly defined type of physician service furnished using communication technology. This service would be reported using HCPCS code GVC11 (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion). GVC11 and would be reported when a physician or other qualified health care professional (QHP) has a brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient’s condition necessitates an office visit. When the brief communication technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or QHP, this service would be bundled into that previous E/M service and would not be separately reportable. In instances when the brief communication technology-based service leads to an in-person E/M service with the same physician or QHP within the next 24 hours or soonest available appointment, this service would be bundled into the pre- or post-visit time of the associated E/M service and also would not be separately reportable. CMS also proposes that GVC11 only be furnished to established patients because the Agency believes that the clinician should have an existing relationship with the patient and basic knowledge of the patient’s medical condition and needs in order to perform this service.
Valuation: CMS proposes a work RVU of 0.25 for GVCI1 based on a direct crosswalk to CPT code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion).

Patient Consent: CMS states that it expects that this service would be initiated by the patient and notes that many beneficiaries would be financially liable for sharing in the cost of these services. The Agency believes it is important for patients to consent to receiving these services, and specifically seeks comment on whether it should require, for example, verbal consent that would be noted in the medical record for each service.

The ACS does not support separate billing and payment for GVCI1 for CY 2019. Although CMS states that this service is not meant to substitute for an in-person service currently separately payable under the PFS, and therefore should not be subject to the statutory limitations governing other telehealth services, the College disagrees and believes that the Agency should apply all requirements and restrictions placed on payment for Medicare telehealth services in section 1834(m) of the Social Security Act—including the definition of an eligible telehealth originating site and limitations on beneficiary charges—to this code. We also assert that brief communication technology-based services should be given new, precise CPT codes and assigned relative values by the RUC as literature and evidence support new technologies. Specifically, we wish to highlight the following issues related to the valuation and utilization of GVCI1:

- CMS proposes to base the code descriptor and valuation for this code on 99441 (a telephone E/M service); however, GVCI1 does not describe an E/M service, and instead may only be used to evaluate the status of a patient. Additionally, the code descriptor for the crosswalk code includes the word “guardian,” which is not a HIPPA-compliant term. While “guardian” is not included in the descriptor for GVCI1, we ask CMS to clarify whether a person other than the patient may use this service, and, if so, we question how a clinician furnishing a “virtual check-in” can verify that the individual with whom they are electronically communicating has legal authority to discuss the patient’s condition.

- The College agrees that patients should be informed that they may be responsible for a cost-sharing amount, but wonder how this would be communicated to the patient (e.g., an electronic document providing all required advance beneficiary notice legal information that the beneficiary
must either accept or decline). CMS itself questions which types of communication technologies could provide a level of clinician-patient interaction sufficient enough to determine if the patient’s condition warrants an in-person office visit, and if such services were provided electronically, verbal consent would not be applicable. As mentioned above, in instances during which a patient is not the person communicating with the clinician, who would be responsible for giving consent? We cannot envision a legally binding consent process where an established patient is providing consent for future, yet-to-be determined services that might or might not be necessary, and therefore are concerned about a clinician’s potential liability in the face of difficulty obtaining patient consent for these services. Likewise, we do not believe that patient initiation of a request can alone be considered consent to the submission of a claim for this service.

Given these concerns, the College urges the Agency to delay implementation of and reimbursement for a brief communication technology-based evaluation service until the CPT, RUC, and other stakeholders are given the opportunity to determine the appropriate description, reporting guidelines, and valuation of such services.

Remote Evaluation of Pre-Recorded Patient Information

Coding and Billing: CMS proposes to pay separately, beginning January 1, 2019, for remote services using “store and forward” communication technology that provides for the “asynchronous transmission of health care information.” This service would be reported using HCPCS code GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). GRAS1 would be reported for a remote provider's evaluation of patient-transmitted information conducted via pre-recorded video or image technology to determine whether an office visit or other service is warranted. When the review of the patient-submitted image and/or video results in an in-person E/M office visit with the same physician or QHP, this remote service would be bundled into that office visit and therefore would not be separately billable. In instances when the remote service originates from a related E/M service provided within the previous 7 days by the same physician or QHP, this service would be bundled into that previous E/M service and also would not be separately billable.
CMS notes that code GRAS1 is distinct from code GVCII1 in that this service involves a clinician’s evaluation of a patient-generated still or video image, and the subsequent communication of the resulting response to the patient, while the brief communication technology-based service describes a service that occurs in real time and does not involve the transmission of any recorded image.

**Valuation:** CMS proposes a work RVU of 0.18 for GRAS1 based on a direct crosswalk to CPT code 93793 (Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed). CMS states that work described by GRAS1 and 93793 are similar in kind and intensity.

The ACS does not support separate reporting and payment for GRAS1 for CY 2019. Although CMS states that this service is not meant to be a substitute for an in-person service currently separately payable under the PFS, and therefore should not be subject to the statutory limitations governing other telehealth services, the College disagrees and believes that the Agency should apply all requirements and restrictions placed on payment for Medicare telehealth services in section 1834(m) of the Social Security Act—including the definition of an eligible telehealth originating site and limitations on beneficiary charges—to this code. If We assert that “store and forward” telecommunication evaluation services should be given new, precise CPT codes and assigned relative values by the RUC as literature and evidence support new technologies. Specifically, we wish to highlight the following issues related to the code descriptor and valuation assigned to GRAS1 by CMS without input from the RUC:

- The code descriptor for GRAS1 does not state who is interpreting the patient-submitted videos/images or who is following up with the patient. The descriptor is also vague in what constitutes a recorded video or image; for example, is an uploaded cellphone photograph of an elevated blood pressure reading significantly different than that same patient sending their blood pressure numbers via email or calling and leaving a voicemail with the numbers verbally? **The ACS believes that CMS has not clearly described (1) which providers will be completing the remote evaluation and follow-up in the code descriptor and (2) what types of patient-submitted videos/images are applicable to this service.**

- The crosswalk code (93793) used for the valuation of GRAS1 includes 6 minutes of clinical staff time during the service period to greet the patient, provide gowning, ensure appropriate medical records are available, review
home care instructions, and coordinate visits/prescriptions. CMS states that GRAS1 will include these same 6 minutes of clinical staff time, but does not provide any details as to why this amount of time is necessary. The ACS questions what clinical staff activity, if any, would be performed for this non-face-to-face technology-based code.

Given the concerns described above, the College urges the Agency to delay implementation of, and reimbursement for, GRAS1 until the CPT, RUC, and other stakeholders are given the opportunity to determine the appropriate utilization and valuation of services including remote evaluation of patient-transmitted video or photo information.

Interprofessional Internet Consultation

CMS proposes to pay separately, beginning January 1, 2019, for six interprofessional consultation Category I CPT codes (994X6, 994X0, 99446, 99447, 99448, and 99449) that describe assessment and management services conducted through telephone, internet, or electronic health record (EHR) consultations furnished when a patient’s treating physician or other QHP requests the opinion and/or treatment advice of a consulting physician or QHP with specific specialty expertise to assist with the diagnosis and/or management of the patient’s problem. The Agency states that the resource costs associated with seeking or providing such a consultation are bundled under current payment policy, and asserts that specialist input is often sought through scheduling a separate visit for the patient when a phone or internet-based interaction between the treating clinician and the consulting clinician would have been sufficient.

While the College appreciates CMS’ recognition that team-based approaches to patient care are often facilitated by EHR and other telecommunication technologies, we believe that the Agency must address program integrity issues associated with the utilization of interprofessional internet consultations before separate payment is made for such services. **We remain concerned that CMS has not established criteria through which the Agency and its contractors will determine if an interprofessional consultation was sought for the purpose of treating a Medicare beneficiary rather than for the benefit of the clinician (e.g., information shared as a professional courtesy or as continuing education).** In circumstances under which a clinician finds it appropriate to seek assistance from a consultative clinician, we believe that it is important for the treating clinician to contact the patient to make them aware that their health information will be shared with another clinician who may be outside of that patient’s typical care team. **The ACS urges CMS to provide guidance on how clinicians may indicate that a separate and distinct interprofessional consultation occurred in the medical record for auditing purposes, as well as**
clear directions for how to properly document the medical necessity of such services to avoid claims denials.

CMS also acknowledges that these interprofessional internet consultation services are furnished without the beneficiary being present, and thereby proposes to require the treating clinician to obtain verbal beneficiary consent in advance of these services, which would be noted by the treating clinician in the medical record. The Agency states that obtaining advance consent includes ensuring that the patient is aware of applicable cost sharing. The College agrees that patients should be informed that they may be responsible for a cost-sharing amount, but wonder how this would be communicated to the patient (e.g., an electronic document providing all required advance beneficiary notice legal information that the beneficiary must either accept or decline). CMS itself questions which types of communication technologies could provide a level of clinician-patient interaction sufficient enough to determine if the patient’s condition warrants an in-person office visit, and if such services were provided electronically, verbal consent would not be applicable. As mentioned above, in instances during which a patient is not the person communicating with the clinician, who would be responsible for giving consent? Further, does the specialist being contacted for the consultation also need to obtain consent and notify the patient of potential cost-sharing for their services? We cannot envision a legally binding consent process where an established patient is providing consent for future, yet-to-be determined services that might or might not be necessary, and therefore are concerned about a clinician’s potential liability in the face of difficulty obtaining patient consent for these services. Likewise, we do not believe that patient initiation of a request can alone be considered consent to the submission of a claim for this service.

Given the concerns described above, the College urges CMS to delay separate reimbursement for these interprofessional consultation codes until the Agency has evaluated and resolved the program integrity issues associated with such services.

Prevention of Opioid Use Disorder

CMS seeks suggestions for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. Specifically, the Agency solicits comment on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives, such as those related to payment or coverage. The United States faces a significant opioid epidemic, and the ACS applauds the CMS’ efforts to obtain stakeholder input on how
the Agency might promote the development and use of non-opioid analgesics and other pain management alternatives.

The use and abuse of prescription opioids has increased dramatically in recent years and has become a major public health concern. Addressing this crisis requires a collaborative effort among healthcare providers, insurers, consumers, and all levels of government to appropriately alter prescribing practices, enhance prescriber and patient education, improve drug dispensing guidelines, and integrate programs that monitor patients’ purchase of controlled substances into the clinical workflow. We believe that the magnitude and scope of the opioid crisis warrants urgent action and stand ready to represent the surgeon’s voice as CMS searches for effective solutions to prevent further harm from prescription opioid abuse.

The College, with its 100 year history in establishing standards for the national improvement of surgical care, is committed to the implementation of a multimodal plan focused on policy, physician education, and patient/caregiver education to address opioid abuse. We put the welfare of our surgical patients above all else, and we believe that surgeons, as prescribers, can play a role in optimizing pain management strategies that will decrease frequent and prolonged opioid use. Pain is an inevitable, but undesirable, consequence of surgery, and while opioid-based pain control for the postoperative patient is a therapy supported by numerous national medical specialty societies, these prescriptions carry risks, which include chronic usage, addiction, and overdose. In the midst of this opioid epidemic, surgeons have a major responsibility to understand and mitigate the risks associated with prescribing opioids and to participate in a broader solution that removes barriers to non-opioid alternative access and utilization.

**ACS Guiding Principles to Prevent Opioid Abuse and Addiction**

The ACS seeks to assure that surgical patients continue to have adequate pain control and receive the proper postoperative care needed to restore their overall health and avoid prescription opioid-related complications. We believe that surgeons have a responsibility to minimize their patients’ postoperative pain while addressing the societal imperative to avoid overprescribing, and in 2017 developed the following five principles to guide our efforts in preventing opioid abuse and addiction in surgical patients:

1) **Promote the use of prescription drug monitoring programs (PDMPs) through the following activities:**
   - Set expectation that PDMPs are fully functional and interoperable with electronic health records
• Establish state/federal grant programs to enhance PDMPs
• Reduce barriers to PDMP access by nonphysician licensed independent practitioners and physicians’ designated agents

2) **Support research and training, developed in collaboration with specialists in pain management, for safe prescribing practices of opioids and non-opioid analgesics through the following activities:**

- Identify patients at high risk for opioid addiction, substance use disorder, or an opioid-related adverse drug event
- Establish guidelines for acute pain management of the opioid-addicted patient
- Set expectations and educate patients and caregivers prior to surgery, during discharge, and throughout follow-up
- Provide evidence-based education and evaluation training programs on opioid and non-opioid alternatives for pain management for the entire surgical team—surgeons, residents, and other health professionals
- Strengthen postoperative surveillance by both patients and providers to expand the evidence on use, response to alternative therapies, and potential issues with long-term use in acute surgical and palliative care patients

3) **Recognize and address issues specific to military veterans by establishing the following programs:**

- Fully functional opioid tracking system for Veterans Affairs (VA) patients
- A system to track prescriptions issued at all federal facilities, including the VA, to outside treating providers and pharmacists
- Expansion of the VA Opioid Safety Initiative

4) **Change the direct relationship between provider reimbursement and patient pain control through the following efforts:**

- Detach questions regarding pain management on patient satisfaction surveys from physician reimbursement
- Examine the impact of insurer and state-based government regulations on prescribing practices and patient experience

5) **Support patient safety legislation that includes the following provisions:**

- Exemptions for the postoperative and/or injured surgical patients who are expected to require opioid analgesics for more than seven days
- Exceptions from prescriber mandates for patients undergoing cancer treatment, cancer rehabilitation, and palliative care
• E-prescribing of controlled substances to improve tracking, reduce opportunities for fraud, and limit episodes where patients in pain are without relief
• Partial filling of opioid prescriptions
• Disposal programs to prevent misuse or diversion of unfinished prescriptions

Using these principles, the ACS encourages CMS to engage the physician community in advancing opioid-sparing, multimodal pain management techniques that leverage local anesthetics, enhanced recovery after surgery (ERAS) protocols, and other non-opioid treatment options. We stand ready to work with the Agency to enhance pain management programs that allow for early intervention with non-opioid therapy (e.g., regional nerve blocks, gabapentin, high-dose non-steroidal anti-inflammatory drugs) and facilitate the frequent review of a postoperative pain control plan during a patient’s hospital stay and following discharge. Specifically, to eliminate barriers to the use of non-opioid alternatives by physicians, we ask that CMS provide separate reimbursement for opioid-sparing therapies administered by surgeons during the perioperative period; these therapies are often cost prohibitive for physicians and facilities under current Medicare policy because the fees associated with the provision of non-opioid medications—which may be significantly more expensive than a prescription opioid—are bundled into the overall payment for “supplies” related to surgical procedures, such that a surgeon who administers a non-opioid medication receives the same fixed Medicare payment as a surgeon who prescribes opioids for post-operative pain, regardless of the difference in the cost of the two drugs.

In addition, the ACS would like to offer assistance to the CMS in its efforts to identify and evaluate evidence-based practices to optimize the health of patients with pain. In the absence of data that indicates appropriate drug threshold amounts, the ACS is developing a mechanism by which to obtain real time feedback from patient to provider about patterns of medication usage. Strong for Surgery, an ACS quality program, empowers surgeons and practices to integrate checklists into the preoperative phase of clinical practice for elective operations. The checklists are used to screen patients for potential risk factors (e.g., smoking, malnutrition, diabetes, medication misuse) that can lead to surgical complications, and to provide appropriate interventions to ensure better surgical outcomes. Strong for Surgery targets areas known to be highly influential determinants of surgical outcomes. The ACS intends to release a new opioid sparing checklist,

along with a web-based application to record responses and serve as a communication tool between the patient and provider, within the Strong for Surgery program mid-2018. Over time, Strong for Surgery data can be used to identify trends in prescription opioid usage, successes and challenges with patient learning, and real-time behavior feedback. Enabling surgeons to be directly involved in messaging about risk factors allows them to play a much greater role in reducing complications and treat the total health of the patient, and the ACS believes that Strong for Surgery, which has demonstrated efficacy in reducing smoking rates among preoperative patients, would be an appropriate tool to screen patients for factors that can lead to opioid abuse and a mechanism to tailor postoperative pain management programs to patients with varying levels of risk.7

We have also created additional resources related to opioid use and surgery, which may be accessed by the public on the ACS website at https://www.facs.org/education/opioids.

**Potentially Misvalued Services under the PFS**

**Update on Global Surgery Data Collection**

As required by the Medicare Access and CHIP Reauthorization Act (MACRA), CMS implemented a process for collecting data on the number and level of post-op visits related to 10- and 90-day global codes. CMS provided several reporting statistics in the proposed rule from states where reporting was required. Of the clinicians who were required to report CPT code 99024 for post-operative visits based on the policy effective July 1, 2017, only 45 percent reported one or more visits during the first six-month period ending December 31, 2017. Among 10-day global procedures performed in that window, only 4 percent had one or more matched visits reported with CPT code 99024. CMS indicated that it is possible that clinicians are not consistently reporting post-operative visits but did not rule out the possibility that post-operative visits are not being provided if not reported, especially in the case of 10-day global procedures.

The ACS and a number of other surgical specialty societies worked diligently to inform our members of the global codes data collection reporting requirements leading up to July 1, 2017 and afterwards. Despite our best efforts, however, it is highly unlikely that all clinicians who are required to report are doing so for every post-operative visit for every procedure. Anything short of perfect reporting will result in inaccurate data that should not be used to revalue global codes. We

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believe that CMS has met the MACRA requirements to collect data on the number of post-operative visits. CMS has indicated that it will soon be surveying three additional codes for data related to the level of visits—we believe this will satisfy the data collection portion of the law. MACRA also requires that CMS “improve the accuracy” of global codes based on the data that are collected or other available data.\textsuperscript{8} The College does not believe that the data that have been collected can be used to improve the accuracy of the existing codes, and we urge CMS not to proceed with revaluing global codes at this time.

\textit{Transfer of Care}

Under current policy, in cases where clinicians agree on the transfer of care for the postoperative portion of the global period, the surgeon bills only for the surgical care using modifier 54 (\textit{surgical care only}) and the clinician who furnishes the postoperative care bills using modifier 55 (\textit{postoperative management only}). The global surgery payment is then split between the two clinicians. However, clinicians are not required to report these modifiers unless there is a formal transfer of postoperative care. CMS seeks comment on whether the Agency should require use of these modifiers in cases where the surgeon does not expect to perform the postoperative office visits, regardless of whether or not the transfer of care is formalized. We believe that surgeons understand correct reporting of modifiers 54 and 55 and document transfer of care appropriately, and thereby do not think that this policy should be changed.

\textit{Valuation of Specific Codes}

\textit{Fine Needle Aspiration (CPT codes 10021, 10X11, 10X12, 10X13, 10X14, 10X15, 10X16, 10X17, 10X18, 10X19, 76492, 77002 and 77021)}

CMS proposes to accept the RUC-recommended work RVUs for seven of the ten fine needle aspiration (FNA) CPT codes reviewed (work RVU of 0.80 for 10X11, work RVU of 1.00 for 10X13, work RVU of 1.81 for 10X14, work RVU of 1.18 for 10X15, work RVU of 1.65 for 10X17, and recommended contractor-priced status for 10X18 and 10X19). CMS also proposes to accept the RUC-recommended work RVUs for the three associated imaging codes reviewed (work RVU of 1.50 for 77021, work RVU of 0.67 for 76942, and work RVU of 0.54 for 77002). The ACS appreciates that CMS recognizes that the RUC-recommended work RVUs are the correct values for these FNA biopsy codes and associated imaging codes relative to other codes in the PFS.

\textsuperscript{8} 42 U.S.C. 1395w-4(c)(8)(C).
CPT code 10021(*Fine needle aspiration biopsy; without imaging guidance; first lesion*): CMS disagrees with the RUC-recommended work RVU of 1.20 for 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). CMS asserts that the work RVU as recommended by the RUC does not reflect this decrease in time, and thereby proposes a work RVU of 1.03 based on a direct crosswalk to 36440 (*Push transfusion, blood, 2 years or younger*). CMS also disagrees with the RUC-recommended work RVU of 1.63 for 10X12 and instead proposes a work RVU of 1.46 based on the recommended interval of 0.43 additional RVUs for ultrasound guidance when performed with a fine needle aspiration biopsy.

**We do not support CMS’ proposed value for 10021 for the following reasons:**

- **Crosswalk code:** Code 36440 is not a service with similar work when compared with 10021. Code 36440 is used to report a push transfusion of blood through an already established access in a vessel, which does not carry the same risk and intensity as 10021, which involves accessing a lesion in the neck multiple times to aspirate biopsy specimens.

- **Changes in service time:** CMS is using outdated information to track changes in time for 10021. In 1995, the RUC surveyed 88170 (*Fine needle aspiration with or without preparation of smears; superficial tissue (e.g., thyroid, breast, prostate)*), and CMS incorrectly uses time data obtained from this survey to calculate reductions in service time for 10021 (*Fine needle aspiration; without imaging guidance*), which replaced 88170 when it was deleted in 2002—there is a clear difference in the descriptors for these two codes. Further, 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 manual 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 88170 in 1995; 2017 survey data show that radiologists and endocrinologists now represent less than 4 percent of total utilization of 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 rely on changes in time from a 1995 survey of a diagnostic laboratory code with PC/TC indicators as a rationale for proposing a work RVU that is significantly lower than the RUC’s recommendation.

- **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 Anatomic Pathology section of the CPT manual to the Surgery/Integumentary 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 88170 and 88171 were misplaced in the CPT manual 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 10021 and 10022. The ACS wishes to highlight that CMS has 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 we instead recommend that CMS review similar minor procedures that have a 0-day global designation when considering the appropriate valuation for the FNA biopsy codes. For example, recently reviewed 0-day global codes in the table below require similar work, do not include imaging, have 15 minutes of intra-time, and are all valued much higher than the RUC recommendation of 1.20 for code 10021. These codes suggest that a higher value could have been supported if compelling evidence was presented and accepted.

<table>
<thead>
<tr>
<th>Year Reviewed</th>
<th>CPT Code</th>
<th>Code Descriptor</th>
<th>RVW</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>36555</td>
<td>Insertion of non-tunneled centrally inserted central venous catheter; younger than 5 years of age</td>
<td>1.93</td>
</tr>
<tr>
<td>2016</td>
<td>36556</td>
<td>Insertion of non-tunneled centrally inserted central venous catheter; age 5 years or older</td>
<td>1.75</td>
</tr>
<tr>
<td>2016</td>
<td>36569</td>
<td>Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; age 5 years or older</td>
<td>1.70</td>
</tr>
<tr>
<td>2016</td>
<td>55700</td>
<td>Biopsy, prostate; needle or punch, single or multiple, any approach</td>
<td>2.50</td>
</tr>
<tr>
<td>2015</td>
<td>62320</td>
<td>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or</td>
<td>1.80</td>
</tr>
</tbody>
</table>
CPT code and 10X12 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*): CMS disagrees with the RUC-recommended work RVU of 1.63 for 10X12 and instead proposes a work RVU of 1.46 based on the recommended interval of 0.43 additional RVUs for ultrasound guidance when performed with a fine needle aspiration biopsy. This proposal is relative to CMS’ proposed value of 1.03 work RVUs for 10021.

**We do not support CMS’ proposed value for 10X12.** Code 10X12 replaced 10022, which was subjected to the same review and changes as 88170 by the CPT, RUC, and CMS in 1995, 2002 and 2003. Code 10022 was code 88171 prior to CPT 2002. Further, similar to our argument for valuing 10021, we believe that the best references when considering work should be codes with a 0-day global and not XXX global codes such as CMS-suggested reference codes 99225 (*Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity*) and 99232 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity*), both of which are non-invasive services based on "per day" of care. More relevant codes for comparison and support of the RUC-recommended work RVU of 1.63 for 10X12 would be recently reviewed 0-day global codes as shown in the table below, which require similar work, include imaging as inherent, and have 20 minutes of intra-time.

<table>
<thead>
<tr>
<th>Year Reviewed</th>
<th>CPT Code</th>
<th>Code Descriptor</th>
<th>RVW</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>19283</td>
<td>Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance</td>
<td>2.00</td>
</tr>
<tr>
<td>2015</td>
<td>47536</td>
<td>Exchange of biliary drainage catheter (eg, external, internal-external,</td>
<td>2.61</td>
</tr>
</tbody>
</table>
or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation

<table>
<thead>
<tr>
<th>Year</th>
<th>Code</th>
<th>Description</th>
<th>RVUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>50435</td>
<td>Exchange nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation</td>
<td>1.82</td>
</tr>
<tr>
<td>2015</td>
<td>64463</td>
<td>Paravertebral block (PVB) (paraspinal block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)</td>
<td>1.90</td>
</tr>
<tr>
<td>2014</td>
<td>64489</td>
<td>Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)</td>
<td>1.80</td>
</tr>
</tbody>
</table>

The ACS urges CMS to consider the new evidence provided above and accept the RUC recommendation of 1.20 work RVUs for 10021 and 1.63 work RVUs for 10X12 as the correct relative values when compared to comparable invasive procedure codes that require similar time and similar work.

Biopsy or Excision of Inguinofemoral Node(s) (CPT code 3853X)

CMS proposes to accept the RUC recommendation of 6.74 work RVUs for 3853X; however, the Agency expresses concern that this code has been assigned a 10-day global period by the RUC. CMS notes that the two CPT codes that are often reported with this code, 56630 (Vulvectomy, radical, partial) and 56633 (Vulvectomy, radical, complete), are both 90-day global codes that are typically provided in an inpatient setting. In addition, the Agency indicates that 3853X has a discharge visit and two follow up visits in the global period, which is consistent with the number of postoperative visits typically associated with 90-day global codes. Therefore, CMS proposes to assign a 90-day global indicator for 3853X rather than the 10-day global period reflected in the RUC recommendation.

Although the ACS agrees with CMS that 3853X is a major procedure and should have a 90-day global assignment, we believe that the RUC made its work RVU recommendation based on a 10-day global period. Therefore, we do not believe that the RUC-recommended work RVU of 6.74 may not be correct for this procedure and 90 days of follow-up care since 3853X was surveyed and reviewed as a 10-day global code with 10-day global reference codes. If CMS believes the code should be assigned a different global period, then the College believes that stakeholders should be given the opportunity to re-survey 3853X to determine the correct number of visits that would be typical for a 90-day global period and the corresponding correct work RVU.

Gastrostomy Tube Replacement (CPT codes 43X63 and 43X64)
CMS proposes to accept the RUC-recommended work RVU of 0.75 for 43X63 (Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract) and work RVU of 1.41 for 43X64 (Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract). The ACS appreciates that CMS recognizes that the RUC-recommended work RVUs are the correct values for 43X63 and 43X64 relative to other codes in the PFS.

The Agency also proposes to refine the equipment times for codes 43X63 and 43X64 in accordance with standard equipment time formulas. It appears that CMS may be using a different formula to calculate equipment time than that used by the RUC and other stakeholders. The Agency acknowledges use of the PE spreadsheet for indicating clinical staff labor, supplies, and equipment time, but has never proposed or finalized specific equations related to calculating equipment times. We ask that CMS provide the formulas used to calculate equipment times and to indicate which direct PE clinical labor service times are being added or removed when proposing refinements. Without this information, we cannot comment on the proposed refinements for 43X63 and 43X64.

Diagnostic Proctosigmoidoscopy – Rigid (CPT code 45300)

CMS proposes to accept the RUC-recommended work RVU of 0.80 for 45300 (Proctosigmoidoscopy, rigid; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)). The ACS appreciates that CMS recognizes that the RUC-recommended work RVU is the correct value for 45300 relative to other codes in the PFS.

CMS also proposes to refine the equipment times for code 45300 in accordance with standard equipment time formulas. We ask that CMS provide the formulas used to calculate equipment times and to indicate which direct PE clinical labor service times are being added or removed when proposing refinements. Without this information, we cannot comment on the proposed refinements for 45300.

Hemorrhoid Injection (CPT code 46500)

CMS disagrees with the RUC-recommended work RVU of 2.00 for 46500 (Injection of sclerosing solution, hemorrhoids) and instead proposes a work RVU of 1.74 based on a direct crosswalk to 68811 (Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia).
We do not support CMS’ proposed work RVU for code 46500. The RUC-recommended work RVUs were based on a comparison of work to many other injection codes that were recently valued. Even with a work RVU of 2.00 as recommended by the RUC, the intra-intensity of 46500 is well below the intensity of many other injection services, and CMS’ proposed work RVU of 1.74 results in an intra-service intensity RVW of 0.02—a value that is less than all E/M codes, including 99211. Additionally, the Agency’s proposed value does not consider that a non-reportable anoscopy will be performed at the follow-up office visit (i.e., code 68811 includes a 99211 follow-up visit, while 46500 includes a 99213 follow-up visit). The College urges CMS to accept the RUC-recommended work RVU of 2.00 for 46500.

Removal of Intraperitoneal Catheter (CPT code 49422)

CMS proposes to accept the RUC-recommended work RVU of 4.00 for 49422 (Removal of tunneled intraperitoneal catheter). The ACS appreciates that CMS recognizes that the RUC-recommended work RVU is the correct value for 49422 relative to other codes in the MPFS. We also thank CMS for accepting the RUC’s recommendation to assign this code a 000 global period.

Evaluation & Management Visits

Lifting Restrictions Related to E/M Documentation

Public Comment Solicitation on Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty

CMS seeks comment on its proposal to eliminate an instruction in the Medicare Claims Processing Manual that states, “As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems in the office, off campus-outpatient hospital, or on campus-outpatient hospital setting which could not be provided during the same encounter.” The Agency states that this policy was intended to reflect the idea that multiple visits with the same clinician, or by clinicians in the same or very similar specialties within a group practice, on the same day as another E/M service would not be medically necessary. However, CMS notes that this instruction may not make sense with respect to the current practice of medicine, as the Medicare enrollment specialty does not always coincide with all areas of medical expertise possessed by a
clinician, and clinicians often respond to this instruction by scheduling the E/M visits on two separate days, which could unnecessarily inconvenience the patient.

The ACS supports the elimination of this provision in the Medicare Claims Processing Manual such that two clinicians of the same specialty from the same group practice may each bill and be paid for an E/M office visit for the same beneficiary on the same day for any problem in the office or outpatient setting which could not be provided during the same encounter. We believe that the elimination of the instruction as currently written would only allow two clinicians to each bill for an E/M service for unrelated problems and do not believe that it is appropriate to continue to prohibit payment for E/M visits furnished by two clinicians to the same beneficiary on the same day to address different components of the same problem (e.g., a patient with an incidental finding on an abdominal computed tomography scan presents to a physician group practice to see a surgical oncologist for a new cancer diagnosis, and on the same day sees a general surgeon in the same office for the placement of a chemotherapy port; in this scenario, both physicians’ Medicare specialty designations are the same—general surgery—and both physicians are providing an E/M service for the same problem—cancer).

Documentation Changes for Office or Other Outpatient E/M Visits and Home Visits

Providing Choices in Documentation – Medical Decision-Making, Time, or Current Framework

CMS proposes to allow practitioners to choose, as an alternative to the current framework specified under the 1995 or 1997 guidelines, either MDM or time as a basis to determine the appropriate level of E/M office visit to report. CMS is proposing to retain the current CPT coding structure for E/M office visits and practitioners would report on the professional claim level of visit (1 through 5) they believe they furnished using CPT codes 99201-99215. Since CMS is proposing to create a single rate under the PFS that would be paid for services billed using the current CPT codes for level 2 through 5 E/M office visits, physicians would only be required to meet the documentation requirements currently associated with a level 2 visit for history, exam, and/or MDM (except when using time to document the service). However, CMS anticipates that physicians will continue to document their evaluation and management work that is consistent with the level of care furnished for clinical, legal, operational, or other purposes.

One of the major shortcomings of the current E/M documentation guidelines is their lack of attention to the needs of patients and how care is delivered in current
practice. We agree that the current guidelines are inefficient and create duplicate, lengthy records simply to meet billing rules for payment. Use of EHRs for documentation has allowed providers to more easily over-document by cutting and pasting information, both to increase compliance and out of concern for CMS audits. Consequently, medical records have ballooned with large volumes of data. While some of this information captures the medical decision making that is important for supporting a code level, not all of the large volume of information entered into the patient record is relevant to the specific patient encounter. Inability to identify relevant information for future encounters can then lead to medical errors, patient safety issues, and physician burnout. Therefore, we commend CMS for considering options for physicians other than documenting using the 1995 and 1997 guidelines and we provide more detailed comments on the use of MDM and time below.

Medical Decision-Making

We support CMS’ thoughtful approach to reducing administrative burden by offering clinicians the option to use MDM alone to document the level of E/M service provided. Of the various components of the current E/M documentation guidelines, MDM is key. For surgeons in particular, MDM is paramount for accounting for the medical complexity of the patient who may or may not require surgery. The elements of MDM include:

1. the number of diagnosis or management options;
2. amount and/or complexity of data to be reviewed; and
3. risk of significant complications, morbidity, and/or mortality.

Of the three elements of MDM, we consider the table of risk to be a reasonable approach to defining the tiers of problems, medical decisions, and management in terms of minimal, low, moderate, and high levels of risk. Given that we cannot support the proposed single payment rate for E/M levels 2-5, we understand that maintaining the levels of E/Ms will require continued mandatory level-based documentation and a need for CMS to continue to audit E/M claims.

We are comfortable with CMS moving forward as proposed to rely on MDM in its current form, but the table of risk will eventually require updates due to increasing complexities in care options and increased patient engagement. Additional risk tables would likely be required, but over time metadata can be used to further build the table of risk. Analytics can be used to show where a patient fits on the table of risk using claims, physical assessment data, past medical history, and laboratory data. Therefore, for clinicians who use MDM for documentation, we support the use of the CMS-developed table of risk as the primary tool for determining the E/M level of service.
**Time**

CMS also proposes to allow clinicians the choice of time to document office/outpatient E/M visits regardless of the amount of counseling and/or care coordination furnished as part of the face-to-face encounter. CMS is soliciting comment on what the total time should be for payment of the proposed single payment rate for E/M visit levels 2 through 5. Again, we cannot support using a single payment rate for E/M visit levels 2 through 5, but even if CMS were to move forward with the single payment rate policy, we do not believe using time alone would be appropriate starting January 1, 2019, given the number of unanswered questions. Currently the only data available on which to base an E/M documented by time are typical times for CPT codes, which are not measurements, but rather estimates of time.

It is also unclear how the time required for office/outpatient E/M visits would interact with the proposed new add-on codes and proposed use of the prolonged services codes. For example, CMS considered requiring documentation of the typical time for the proposed single payment for an E/M level 2 through 5 visit to be 31 minutes for a new patient (the specialty weighted average of intra-service times across the current E/M visit Medicare utilization), but also considered an alternative approach of using the typical time for each level, which would require a minimum of 10 minutes for a level 2 established patient visit. Such drastically different start times make it difficult to assess the use of the prolonged services codes. We do, however, agree with CMS’ proposal that if a clinician were to use time to document an E/M and also use the prolonged services code, then the clinician should document that the typical time for the base or “companion” visit is exceeded by the amount required to report the prolonged services code.

We agree that in some cases time can be a good indicator of the complexity of the visit; but unfortunately documentation of face-to-face time alone does not take into consideration intensity or the need to prepare the chart in advance by gathering and reviewing data, images, reports, and outside system information for more complex patient interactions. We also wonder about reporting time for non-clinical related situations that may be time consuming, for example, translational services needed because the patient does not speak English. Therefore, we cannot support the use of time alone as a method of documentation without more clarification as to the time needed for reimbursement of each E/M code given the various approaches that CMS is contemplating and the varying implications related to each approach.

*Removing Redundancy in E/M Visit Documentation*
Focus on what has changed

CMS proposes that clinicians would only be required to focus documentation for established patients on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting a defined list of requirements such as review of a specified number of systems and family/social history. CMS notes, however, that if the agency were to propose the single payment rate for E/M levels 2 through 5, the CPT code descriptors would continue to include the elements of history and exam, and the agency expects clinicians to still conduct clinically relevant and medically necessary elements of history and exam and conform to the general principles of medical record documentation in the 1995 and 1997 guidelines.

Information such as past medical history, allergies, medications, social history, and family history recorded once in a fully functioning EHR would be accessible for the next visit. Re-entering previously captured information for the sole purpose of meeting the documentation requirements is unnecessary for patient care, takes up clinicians’ time, and contributes to lengthy medical records that could even result in patient harm. We are hopeful that CMS will also continue to consider ways to implement a similar provision for new patients when relevant information is available through an interoperable EHR or other data exchange. We question why, despite making this proposal, CMS indicates that the agency still expects clinicians to conduct elements of history and exam and conform to the principles of the 1995 and 1997 documentation guidelines. If CMS is allowing clinicians the choice of documentation using the current guidelines, MDM, or time, and to not re-enter information that has not changed, we view the requirement to continue to conform to the 1995 and 1997 guidelines as contradictory. However, we do fully support CMS’ proposal to not require re-documentation of information for established patients that has already been recorded from prior visits unless there is new information to be added or mistakes to be corrected.

No Need to Re-Enter Information

CMS also proposes, for both new and established patients, to not require practitioners to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary. This is a good start, but we believe that CMS can go further in coming years to utilize information accessible through an interoperable digital health information system that serves not only to ease documentation burdens, but also to inform care through clinical decision support tools and eventually through more advanced technologies such as machine learning and artificial intelligence. We support this proposal to not require practitioners to re-enter information in the medical
record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary and appreciate CMS’ inclusion of yet another approach to reducing documentation burden in this proposed rule.

Minimizing Documentation Requirements by Simplifying Payment Amounts

CMS proposes a single set of RVUs and payment under the PFS for new patient office and outpatient E/M visit codes 99202 through 99205 with a work RVU of 1.90 and a single set of RVUs for established patient E/M visit codes 99212 through 99215 with a work RVU of 1.22. CMS believes that the burden associated with documenting the selection of the level of E/M service arises from not only the documentation guidelines, but also from the coding structure itself, and goes on to state that the current payment levels for E/M visits may have been good approximations for important distinctions in resource costs in the 1990s but are increasingly outdated in the context of changing models of care and information technologies.

Cannot support payment changes taken together

It appears that CMS’ intent in proposing this policy change is to reduce documentation burden on clinicians, while generally maintaining the current E/M payment rate for most specialties. This is a goal that we fully support and we thank CMS for devoting resources to taking on this important challenge. However, we cannot support collapse of the work RVU values into one single rate under the PFS that would be paid for services billed using the current CPT codes for level 2 through 5 E/M visits because this single rate is a calculation of several values that were resource-based, but in and of itself is not a resource-based value. There is no assurance that the underlying math used to derive this single value correctly reflects the resources used to deliver care across the wide spectrum of providers in America. Additionally, we are very concerned about the separate additional policy changes that are proposed in order to avoid significant payment cuts (and bonuses) to some specialties. These proposed policy changes related to payment are based only on a snap-shot of Medicare claims utilization data and may not be consistent with the entire patient population who receive E/M services.

We are also concerned about the number of policy changes that are included as part of the proposal for one payment rate for E/M visit levels 2 through 5. In order to implement this proposal, CMS must create three new add-on codes, make changes to the multiple procedure payment reduction (MPPR) policy, make adaptations to practice expense (PE), and create new specialty-specific E/M codes. It is not possible to fully analyze the repercussions and potential distortions to the PFS from these policies individually or taken as a whole.
during the 60-day comment period for this proposed rule. Stakeholders also have no assurance that these many modifications will continue to be appropriately updated as needed in future years. CMS is implementing these changes as part of an effort to stop "code-creep," but it is also possible that these changes will not be contained over time and may compound in the future.

There are also a number of other unknowns with respect to this policy such as how the single payment rate for levels 2 through 5 will impact physicians compensated through RVU-based payment structures. This policy could also result in some physicians avoiding more complex Medicare patients because the payment rate for those visits (even with add-on codes requiring additional documentation) would be less than the current payment rate for a level 5 visits for payers that maintain the current stratified payment scale. For all the reasons above, whereas we support the proposals for changes in documentation described above, we cannot support the payment proposals.

Timeline and implementation hurdles

Even if we supported CMS finalizing these policies, we do not see how this new approach to payment for office/outpatient E/M services could be implemented on the effective date of January 1, 2019. If the CY 2019 PFS final rule is released in November of 2018, clinicians and payers would have less than two months to understand the finalized policy. But the bigger problem lies with practice management software and EHRs because this gives them very little time to make the necessary updates, which could impact billing and reimbursement. We are also concerned about the increased burden on clinicians given that private payers will still be paying for E/Ms using the 5 levels and may not adopt CMS's changes to RVUs because the payment rate was based on Medicare utilization and not private payer utilization.

Similar to CMS implementing a status "I" (Not valid for Medicare purposes, Medicare uses another code for reporting of, and payment for, these services), private payers may choose to use different RVUs for the 10 office/outpatient EM codes and may not accept the proposed new add-on G-codes. This same problem occurred when CMS did not accept changes to selected endoscopy codes in 2015 and instead applied a status indicator "I" and created G-codes for only some of a family of codes. These were not as high volume as E/M services and were only performed by a few specialties but still created a reporting and payment headache for providers and payers. Few physicians have practices limited to Medicare patients and Medicaid and private payers may continue to use the current payment rules. This will result in confusion and increased burden and cost to attempt to create a system to manage the various requirements for documenting E/M visits.

We urge CMS to continue the dialogue with stakeholders on the most direct
ways to reduce documentation burden and to refrain from finalizing any payment policy changes related to office/outpatient E/M codes for January 1, 2019.

Issues regarding resource-based requirement

The Omnibus Budget Reconciliation Act of 1989 (OBRA) created the resource-based relative value scale (RBRVS) and requires that payment be resource-based. Although that term was not described in detail in the law, creating a payment rate based on weight averaged utilization of a code set is not resource-based; rather it is a mathematical computation based on Medicare fee-for-service coding. In addition, creating separate payment amounts for primary care and a few specific specialty care add-on codes based on the amount of funding available from the multiple procedure reduction is clearly a financial shift of RVUs and not a resource-based determination. **We do not believe that CMS’ proposed single E/M payment for levels 2 through 5 is appropriate given the requirement that valuation of codes be resource-based.**

Recognizing the Resource Costs for Different Types of E/M Visits

Accounting for E/M Resource Overlap Between Stand-Alone Visits and Global Procedures

CMS proposes to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day. CMS expressed concern about overlapping resource costs that are not accounted for when a standalone E/M visit occurs on the same day as a global procedure. Instead of using modifiers to implement this policy, it appears that it is CMS’ intent to add office/outpatient E/M codes 99201-99215 to the MPPR list by changing the payment indicator to “2” although how this is to be implemented is not clear in the rule. CMS is also proposing to allocate the anticipated 6.7 million RVUs from reduced expenditures under this MPPR policy toward the values for proposed new add-on codes for inherent complexity for certain primary care and specialty care E/M services.

We note that both the AMA/RUC and CMS have identified and reviewed many procedures and services typically performed with an E/M on the same day through a screen of potentially misvalued codes. This review resulted in removal of overlapping time, supplies, and equipment. Therefore, applying the MPPR would result in further unjustified reductions. Further, the MPPR was developed during the Harvard study to account for the overlap in pre- and post-work for multiple procedures. The components of work for procedures (i.e., evaluation, positioning, scrub/dress/wait, skin-to-skin, postop through recovery) are not the
same as the components of work for discreet E/M services. In addition, we are concerned that expansion of the MPPR policy to include E/Ms could have an unwanted impact on patient care, requiring scheduling of E/M visits and procedures on separate dates to be able to recoup resource costs.

We support the accuracy of code values and consequently have concerns about this proposal to apply a 50 percent cut across the board. Even when CMS implemented reductions to individual codes for an overlap of work, CMS only considered a few minutes of the procedure evaluation and post-service time and not 50 percent of all the time and work. Similarly, for imaging and therapy codes, CMS only considers a 25 percent overlap in only the technical component between the codes when performed together. We also have concerns about applying the expenditure reductions under this policy toward proposed new add-on-codes for inherent visit complexity for primary care and other selected specialties. Savings from the implementation of this kind of policy should be directed back toward the PFS as a whole to be redistributed in a budget neutral manner and not arbitrarily shifted to a specific group of providers. In summary, we oppose the addition of E/Ms to the MPPR list. Overlap in resources has already been accounted for during individual code review and this policy change may result in unintended consequences on patient care.

Proposed HCPCS G-code Add-ons to Recognize Additional Relative Resources for Certain Kinds of Visits

Primary care add-on code (GPC1X)

GPC1X Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)

CMS proposes to more accurately account for the type and intensity of E/M work performed in primary care-focused visits, by creating a new HCPCS Level II add-on G-code (GPC1X) that may be billed with the generic E/M code set to adjust payment beyond the typical resources accounted for in the single payment rate for E/M office visits levels 2 through 5. CMS’ rationale is that the proposed value for the single payment rate for the E/M office visits levels 2 through 5 for new and established patients does not reflect additional resources inherent to primary care visits, as evidenced by the fact that primary care visits are generally reported using level 4 E/M codes. CMS notes that the additional resources to address inherent complexity in E/M visits associated with primary care services are associated only with stand-alone E/M visits as opposed to separately identifiable visits furnished within the global period of a procedure.
We oppose the implementation of add-on code GPC1X because we believe creation of this code is an example of differential payment by specialty for the same work. We describe our concerns in more detail below.

Specialty care add-on code (GCG0X)

GCG0X Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)

CMS is also proposing to create a new HCPCS Level II add-on G-code (GCG0X) to be reported with an E/M office visit service to describe the additional resource costs for specialty care that is reported by providers for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches CMS believes are generally reported using the level 4 and level 5 E/M office visit codes rather than procedural coding. CMS does not believe that the proposed single payment rate for E/M office visits levels 2 through 5 would reflect the resource costs of those types of visits, so is proposing code GCG0X for visit complexity inherent to evaluation and management associated with care provided in these care areas: endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology or interventional pain management.

We oppose the implementation of add-on code GCG0X because we believe creation of this code is an example of differential payment by specialty for the same work. We describe our concerns in more detail below.

Add-ons not tailored to complexity

We disagree with CMS’ manner of choosing certain types of services for which GCG0X would apply. First, it is clear that CMS chose the specialties to include for add-on code GCG0X based on their reporting of level 4 and 5 visits for Medicare patients with the intent to make them whole with respect to Medicare payments. If the code were truly intended to address “visit complexity,” then the code should be more carefully tailored to complex patients, not specialists, who generally report level 4 and level 5 E/M office visits. It is possible that some of the reporting of level 4 and 5 codes was based on time and not based on intensity or complexity of the patient. For example, a recent NEJM article indicated that higher level codes could be reported if significant time was required
because of a language barrier. This type of visit may require more dedicated time to deliver the same service but does not necessarily represent a more inherent visit complexity.

By selecting only some specialties or specialty care, it is quite possible that CMS has omitted others that also report level 4 and 5 E/M office visits. But more importantly, describing a code in terms of specialty care instead of patient complexity will direct use of the code by those specialties toward some patients that are not complex while not allowing the code to be used for some patients who are in fact complex by the remainder of specialties. For example, without clear guidance as is often included in CPT introductory language and parentheticals, it is possible for any provider to report GCG0X for a patient encounter for a urinary tract infection (i.e., urology centered care) or a visit related to season allergy (i.e., allergy/immunology centered care). Patients seen by surgeons are often some of the most complex with multiple co-morbidities, yet the vast majority of surgeons will not be able to use GPC1X nor GCG0X. We oppose the implementation of add-on code GCG0X because if intended to address “visit complexity” it should be more carefully tailored to complex patients, not selected specialties.

Differential payment by specialty

We view the implementation of both GPC1X and GCG0X as raising serious legal concerns with respect to differential payment by specialty for the same work. By law, CMS is prohibited from paying physicians of different specialties differently for the same work. The OBRA states,

*The Secretary may not vary the conversion factor or the number of relative value units for a physician’s service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.*

The current RBRVS E/M office visit codes are constructed and valued to address resource use and inherent visit complexity, but the proposed add-on G-code methodology creates specialty specific payment that violates the Medicare law prohibiting specialty specific payment rates for the same code.

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10 42 U.S. Code § 1395w-4(c)(6).
We have also been told in briefings that for both of these add-on codes, the descriptor is tied to services provided, not to the specialty designation of the clinician providing the service (i.e. “primary care services” and “endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology or interventional pain management-centered care”). However, the language in the proposed rule and the NPRM utilization crosswalk file related to the modeling for Table 22: Specialty Specific Impacts Including Payment Accuracy Adjustment, indicate that CMS only assumes certain specialties will report these add-on services. Specifically, CMS only included utilization for family practice, internal medicine, pediatric medicine, geriatric medicine, nurse practitioner, certified clinical nurse specialist, physician assistant to estimate utilization for GPC1X and only included utilization for codes 99204, 99205, 99214, and 99215 by allergy/immunology, otolaryngology, cardiology, interventional pain management, neurology, obstetrics/gynecology, cardiac electrophysiology, urology, certified nurse midwife, endocrinology, rheumatology, pain management, hematology, hematology/oncology, medical oncology, gynecologist/oncologist, interventional cardiology for utilization estimates for GCG0X. The utilization of other specialties, such as general surgery (e.g., trauma surgeons) or surgical oncology (e.g., breast surgeons) were not included in calculating the impact of these codes.

Moreover, in the rationale for creation of code GCG0X, CMS states,

*While some of these specialties are surgical in nature, we believe these surgical specialties are providing increased non-procedural care of high complexity in the Medicare population. The high complexity of these services is reflected in the large proportion of level 4 and level 5 visits that we believe are reported by these specialties, and the extent to which E/M visits are a high proportion of these specialties’ total allowed charges. Consequently, these are specialties for which the resource costs of the visits they typically perform are not fully captured in the proposed single payment rate for the levels 2 through level 5 office/outpatient visit codes. When billed in conjunction with standalone office/outpatient E/M visits for new and established patients, the combined valuation more accurately accounts for the intensity associated with higher level E/M visits.”* (Emphasis added).\(^1\)

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\(^1\) Centers for Medicare and Medicaid Services. Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program; Proposed Rule. Fed. Reg. 2018;83:35842.
Despite the fact that CMS has indicated in the rule and during meetings with specialty staff that these add-on codes apply to services rather than specialties, in practice they appear to be focused directly on specific specialties. If every specialist within the above mentioned CMS designated specialties is assumed to bill the add-on code (GCG0X) for every office/outpatient visit, this appears to be a code directed at these specialties. This also implies that CMS is assuming that all of the listed specialties may bill code GCG0X, for less complex visits that would not have been billed at a level 4 or level 5 E/M visit because it would apply to every office/outpatient visit.\(^\text{12}\)

When asked in a public meeting whether members of the listed specialties would be able to bill the add-on code for services not related to the areas of care in the code description, CMS officials were not able to provide a definitive answer. If the code were truly intended to target types of services and not the specialists themselves, the answer should have been a clear “no.” This illustrates how code GCG0X is directed at specialties themselves, regardless of whether all of the patients that the specialist sees are complex. Therefore, we consider CMS’ interpretation of how these codes will be utilized to clearly violate the spirit of the law, if not the letter of the law itself. This language and the multiple references to “specialties” rather than “services” further underscores the apparent intent to create a payment mechanism for physicians who belong to a certain specialty, not for any physician who provides certain services.

*Proposed HCPCS G-code to Describe Podiatric E/M Visits*

CMS states that the vast majority of podiatric visits are reported using lower level office/outpatient E/M codes, with most E/M visits billed at a level 2 or 3, reflecting the type of work done by podiatrists as part of an E/M visit and that podiatric visits are not accurately represented by the proposed payment for collapsing level 2-5 E/M codes. Therefore, CMS proposes to create two HCPCS G-codes for podiatric visits (one for new patients and one for established patients).

Similar to our opposition to specialty specific add-on codes, we are opposed to specialty-specific office/outpatient E/M codes. These proposed podiatric codes

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\(^{12}\) Despite the language of the rule, which clearly shows CMS’ intent to apply these codes to entire specialties, it is not clear that the modeling followed the rule’s description. For example, urology claims for all 10 office visit codes is 7.5 million and only level 4s and 5s is 3.25 million, but the number of claims attributed to urology for GCG0X is 5 million which doesn't match either 7.5 or 3.25. For cardiology, almost 90% of all claims data for all 10 codes is used for GCG0X. We ask that CMS be more transparent with modeling to enable stakeholders to fully understand how the agency will implement these and other policies.
are also not evidence-based and are poorly defined. It is unclear what is considered a "podiatric service" and whether podiatrists will continue to be able to report CPT codes 99201-99215 for services that are not considered "podiatric services." Also, if another specialty, such as family practice, performs a "podiatric service" (e.g., wound care) or an orthopedic surgeon evaluates a patient with a bunion for special shoe fitting, it is unclear whether they will be required to report the new podiatry G-codes. If not, this is another example of CMS paying different specialties different amounts for the same work and if so, this is will result in added documentation burden to know when these other specialties are required to document non-podiatric vs podiatric E/Ms.

We note that CMS has indicated there is precedent with the ophthalmology codes (92002, 92004, 92012, and 92014) for "ophthalmological services" and that the podiatric service codes were modeled after the ophthalmology codes. However, the ophthalmology codes were specifically developed to be reported instead of 99204/99214 and 99205/99215 to accommodate significant equipment lanes totaling over $60,000 required at such visits. Ophthalmologists may still (and do) report 99201-99215, but typically report their designated codes for the higher level of service to capture the necessary equipment resources. Therefore, we do not consider the ophthalmology codes a precedent for modeling and creating new podiatry codes, rather they are a set of higher level E/M codes that bundle typical ophthalmology diagnostic equipment. We do not support the creation of new podiatric service codes because we do not support E/M codes for a single specialty.

Proposed Adjustment to PE/HR Calculation

CMS states that establishing a single PFS rate for new and established patient E/M office visit levels 2 through 5 would have a large and unintended effect on many specialties due to the way that indirect PE is allocated based on the mixture of specialties that furnish a service. As such, CMS proposes to create a single PE/HR value for E/M visits based on the average of the PE/HR across all specialties that bill the 10 E/M office visit codes weighted by the volume of those specialties’ allowed E/M services. This new PE/HR will be applied across the 10 E/M office visit codes and all the additional E/M codes that CMS is proposing in the rule. CMS states that this is the methodology used when the agency does not know the actual utilization and specialty composition of new or revised codes. If finalized, CMS will consider revisiting the PE/HR after several years of claims data are available.

The calculation of a new "specialty" PE/HR category (Evaluation and Management) using specialty weighted average E/M volume and individual specialty PE/HR is not statistically sound. The PE/HR for specialties is based on
data collected from 2007 to 2008 for the AMA PPI survey and includes direct and indirect inputs for all services performed by each specialty. The survey data collection did not separate out, for example, E/M work from all other work. It is not statistically accurate or reasonable to apply current Medicare volume of services by specialty and develop a new specialty category, which assumes that both direct and indirect PE/HR is exactly attributable to individual codes.

The calculation of a new specialty PE/HR category results in huge shifts in the Indirect Practice Cost Index ("IPCI") for a large number of specialties, which is further proof that this methodology is not statistically sound. CMS attempted to correct for this through proposed adjustments to the PE/HR calculation, which is another artificial manipulation of the data. The result is a large unintended effect on specialties given the way indirect PE is allocated, which seems inconsistent with CMS’ intent to maintain stability in payment for specialties. It is also concerning that there is no clear process for updating the new E/M PE/HR value over time or making sure it remains accurate despite the numerous policy changes that are being proposed in tandem. **We oppose calculation of a new “specialty” PE/HR category given that the method of calculating this category is not statistically sound and we do not support calculation of an E/M PE/HR as a unique specialty.**

**Proposed HCPCS G-code for Prolonged Services**

GPRO1 *Prolonged evaluation and management or psychotherapy service(s) (beyond the typical, service time of the primary procedure) in the, office or other outpatient setting requiring, direct patient contact beyond the usual, service; 30 minutes (List separately in, addition to code for office or other, outpatient Evaluation and Management or, psychotherapy service)*

CMS states that there is currently inadequate coding to describe services where the primary resource of a service is physician time. Two prolonged services codes currently exist, but they have a “first hour” threshold. As such, CMS proposes a new prolonged services HCPCS Level II add-on G-code (GPRO1) to address time beyond the typical service time of the primary procedure (i.e., primary E/M service). Although CMS does not indicate specifically what codes this add-on code may be reported with, CMS relates this code to 99354 which states "Use 99354 in conjunction with 90837, 90847, 99201-99215, 99241-99245, 99324-99337, 99341-99350, 99483)." This list includes psychotherapy codes and E/M codes for office/outpatient visits, home visits, and a new 2018 code for care planning.

Although CMS is proposing the creation of a single payment for levels 2 through 5 for office/outpatient codes, CMS still expects providers to report the appropriate
code (99202-99205, 99212-99215) for each E/M service. It is not clear whether time in the proposed new add-on prolonged service code or current add-on prolonged service codes is additive to the "calculated" weight average time that CMS is using for developing a single payment or to the time listed in each code. Is it possible that a provider could report, for example, 99213 because the visit only meets the guidelines related to that code and also report the new add-on prolonged service code GPRO1 for 16 minutes of time after the 15 minutes of face-to-face time for 99213? During listening sessions about E/M codes and documentation requirements, we have heard complaints that some office visits take a long time (e.g., language barrier, child/parent, multiple family members, redundant questions), but do not meet reporting higher level codes. Is this new code meant simply as reimbursement for extra time for any level of code?

Without knowing how CMS will finalize the documentation requirements for using time alone to report E/M services, it is not possible to know at what point during a visit a physician may start using the prolonged services code. Given that CMS did not include much by way of explanation as to how this code could be reported with E/M codes or other add-on codes, and also was not able to include this code in the impact analysis, we do not believe this code is ready to be finalized at this time. There are too many unanswered questions to be able to assess the correct reporting and impact of code GPRO1 at this time, so we do not support finalizing this policy without more information as to how it will be implemented. We also urge CMS to work through the CPT process for codes such as these because of the impact on reporting other current CPT codes given the HCPCS G-codes do not have clear guidelines, instructions, and exclusionary advice.

Alternatives Considered

CMS considered a number of other options for simplifying coding and payment for E/M services to align with the proposed reduction in documentation requirements including using patient relationship codes to adjust payment for E/M visits to the extent that these codes are indicative of differentiated resources provided in E/M visits. CMS considered using these codes as an alternative to the proposed G-codes for visit complexity for primary care and certain other specialist services.

We do not support use of MACRA mandated patient relationship codes to adjust payments for an E/M visit as there is no evidence that the current stratification of services provided accurately reflects work for multiple clinicians caring for patients in concert or in sequence. Many aspects of the use of these patient relationship codes such as how they would be adopted and how to transition roles are confusing and create another burden of documentation.
Summary of ACS Comments on E/M Documentation and Payment

<table>
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<th>Topic</th>
<th>CMS proposal</th>
<th>ACS position</th>
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<td><strong>Proposed Timeline</strong></td>
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<tr>
<td><strong>Timeline</strong></td>
<td>CMS proposes to finalize documentation and payment policies effective January 1, 2019.</td>
<td>Delay</td>
<td>January 1, 2019 is too aggressive to implement the multiple sweeping proposed payment policy changes. We do support CMS finalizing the documentation proposals effective January 1, 2019. More advanced notice to providers, employers, MACs, private payers, and patients will be required for any significant changes to E/M reporting and payment policy.</td>
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<th>Documentation Proposals</th>
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<td><strong>Documentation alternatives</strong></td>
<td>Use of MDM alone</td>
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<tr>
<td>Use of time alone</td>
<td>Cannot support</td>
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| Removing E/M Documentation Redundancy | CMS proposes that clinicians would only be required to focus documentation for established patients on what has changed since the last visit or on pertinent items that have not changed. | Support | We support CMS’ proposal to not require re-documentation of information for established patients that has already been recorded from prior visits unless there is new information to be added or mistakes to be corrected. Re-entering previously captured information for the sole purpose of meeting documentation requirements is unnecessary for patient care, takes up clinicians’ time, and contributes to lengthy medical records that could even result in patient harm. |
| | CMS proposes, for both new and established patients, to not require practitioners to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary. | Support | We support this proposal and appreciate CMS’ inclusion of another approach to reducing documentation burden in this proposed rule. Re-entering previously captured information is unnecessary for patient care. We believe that CMS can go further in coming years to utilize information accessible through an interoperable digital health information system. |

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<tr>
<th>Payment Proposals</th>
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<td><strong>Single payment rate</strong></td>
<td>CMS proposes a single payment rate for E/M</td>
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<td>Visit levels 2 through 5.</td>
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<td>Recognizing Resource Costs for Different Types of E/M Visits</td>
<td>CMS proposes to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day.</td>
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<td>CMS proposes to create a HCPCS Level II add-on G-code (GPC1X) to account for the type and intensity of E/M work performed in primary care-focused visits.</td>
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<td>CMS proposes to create a new HCPCS Level II add-on G-code (GCG0X) to be reported with an E/M service to describe the additional resource costs for specialty care that is reported by providers for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches CMS believes are generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding.</td>
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<td></td>
<td>Podiatric</td>
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The single payment rate policy is not resource-based, but instead uses a snapshot of weighted average Medicare data to calculate a single payment rate. This policy does not consider unintended consequences for providers compensated on RVUs, the additional reporting burden if all payers choose not to follow this policy, and the mismatched payment cost sharing at one rate (i.e., same cost sharing whether the visit was for pink eye or unstable hypertension and diabetes.)

The MPPR was created to account for overlap of pre- and post-work for procedures and not for E/M services. Procedures have very different components of work. Many codes have already had reduced time, supply and equipment inputs to account for overlap.

This policy might force beneficiaries to return on separate days for services that may be reported on the same day if a schedule allows.
Teaching Physician Documentation Requirements for Evaluation and Management Services

CMS proposes to eliminate its teaching physician E/M documentation policy that currently requires a teaching physician to document the extent of their own participation in the review and direction of services furnished to each Medicare beneficiary in the medical record. CMS specifies that, except for renal dialysis services, psychiatric services, or services furnished in hospital outpatient and certain other ambulatory settings, the presence of the teaching physician during procedures and E/M services may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

The ACS supports CMS’ proposal to eliminate potentially duplicative requirements for notations that may have previously been included in the medical records by residents or other members of the medical team. We thank the Agency for its efforts to reduce burden and replication of effort for teaching physicians.

OTHER PROVISIONS OF THE PROPOSED RULE

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

AUC Consultation and Reporting
Section 218(b) of the Protecting Access to Medicare Act (PAMA) directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. There are four major components of the AUC program, each with its own implementation date: (1) establishment of AUC by November 15, 2015; (2) clinical decision support mechanisms (CDSMs) for consultation with AUC by April 1, 2016; (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017; and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017.

Given numerous delays in implementation, CMS did not require ordering professionals to consult AUC using CDSMs or furnishing professionals to report information on consultation by January 2017. CMS now proposes that on January 1, 2020, the AUC program will begin with an “educational and operations testing period”, during which time ordering professionals will be required to consult specified applicable AUC using a qualified CDSM when ordering applicable advanced diagnostic imaging (ADI) services, and furnishing professionals will be required to report consultation information using established coding methods (such as G-codes and modifiers) on Medicare claims. The Agency states that it will continue to pay claims regardless of whether they correctly include AUC consultation information.

CMS also specifies that it has established a voluntary period during which clinicians can begin reporting limited AUC consultation information on Medicare claims from July 2018 through December 2019. During this voluntary period, there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation.

The ACS continues to have concerns about physicians’ ability to meet CMS’ AUC consultation and reporting requirements. While the Agency asserts that using coding structures that are already in place will ease reporting processes, it has not specified what G-codes or modifiers would be required for reporting; further, this approach has already been rejected by the National Uniform Claim Committee (NUCC) and National Uniform Billing Committee (NUBC), which stated that the use of G-codes and modifiers would be administratively burdensome and that all options to report AUC data will be costly and operationally difficult for physicians to implement. If CMS finalizes its AUC proposals, physicians will have limited time to determine how to comply with these policies, assess available CDSMs with such policies in mind, select the CDSM most appropriate for their services and practice, integrate the CDSMs into their practices—including with their EHRs and billing systems (assuming G-codes and modifiers are finalized at the same time)—and train clinicians on their use. At the same
time, physicians will be juggling reporting requirements for the Merit-based Incentive Payment System (MIPS), which will compete with the AUC requirements with respect to physicians’ time, resources, and attention.

Given the substantial burden that we anticipate the AUC requirements will impose on clinicians, the College believes that it is important that physicians and their practices are afforded the opportunity to adjust to the program in a thoughtful and deliberate manner that would allow for interoperability (i.e., integration of CDSMs into practices’ EHRs and practice management systems). Practices should also have the opportunity to develop solutions for data exchange between the ordering and furnishing physicians in order to leverage health information technology to reduce burden. To accommodate all of the above, we believe it will be important for CMS to allow for gradual implementation of the AUC requirements, and as such, we urge CMS to finalize 2020 as a truly voluntary year, similar to the proposed voluntary reporting period between July 2018 and December 2019, rather than considering 2020 a “test period.” Under such a policy, CMS would pay claims for advanced diagnostic imaging services regardless of whether the required information about the AUC consultation is included in the claim. In addition, it is critical for CMS to test that submitted claims with the AUC information are correctly processed before the program is implemented.

As CMS moves toward full accountability under the AUC program, we also recommend that CMS carefully consider the extent to which the Agency can continue to align the goals and requirements of this program with MIPS in order to minimize burden and limit duplication of effort.

REQUESTS FOR INFORMATION

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

CMS states that facilities disclosure guidelines will be updated to specify that, effective January 1, 2019, all hospitals must make available a list of their current standard charges via the internet in a machine-readable format. CMS seeks comment on ways to improve price transparency and present cost information in a consumer-friendly format. The ACS welcomes CMS’ focus on price transparency and is encouraged by the Agency’s recognition of the complex nature of providing patients with actionable data. The information currently available to consumers on cost—particularly as it relates to out-of-pocket charges for in- and out-of-network care—is sparse and inconsistent. We encourage CMS to consider the following issues as the Agency sets policies related to the communication of hospital, provider and supplier charges.
Standard Charges. CMS requests feedback on how to define “standard charges” in various provider and supplier settings, such as average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together. Billing information at the facility, provider and supplier levels is complicated and, even if averages were calculated for the billed rates of individual or groups of services, such averages would be different from what any one insurer would reimburse a hospital, provider or supplier. The College believes that standard charge data is not relevant to patients, as this information may not be in accordance with how a patient’s health plan will pay for services or supplies. We remain concerned that patients will use information about a facility’s, provider’s, or supplier’s average charges to estimate their out-of-pocket costs and that such an estimate would not be an accurate reflection of the patient’s actual bill.

Provider Responsibilities. CMS requests feedback on whether providers should be required to inform patients about how much their out-of-pocket costs for a service would be before furnishing the service. There is no single source of accurate information on patient out-of-pocket cost or total cost of care, as the contracted price of a given service can vary greatly depending on the insurer and a patient’s individual insurance policy. The prices for the same service can also vary depending on whether the service is provided in an office, an outpatient setting, an ambulatory surgery center, or on an inpatient basis in a hospital. For that reason, a physician—who is focused on providing the best quality of care for a patient—might not know the intricacies of differing contracted rates and site of service adjustments, and is therefore unlikely to know, or possibly even be able to determine, how much a patient will have to pay out of pocket for a service. We do not believe that physicians should be expected or required to inform insured patients of their out-of-pocket costs.

Accurate and Relevant Cost Data. One potential way to fill the current gaps in information available to patients would be to provide narrow, but representative, ranges of expected costs based on the patient’s characteristics and diagnosis. For example, the ACS sees great promise in the kind of granular information that can be provided by the Episode Grouper for Medicare (EGM), which was developed for CMS by a team at Brandeis University to organize claims information into logical episodes of care. EGM consists of both a software suite and a set of clinical episode definitions that have benefited from multiple rounds of physician review over several years. While originally created to provide Medicare cost information to CMS, the technology is capable of providing remarkable insights.
to the care team, and, if built for this purpose, could be invaluable for patients trying to determine potential costs for situations that are more complex than for a single service by a single provider. For cost information to be meaningful for consumers, it would need to be put into a proper format—such as an interactive rate book where patients could see estimated ranges based on historical claims of patients with similar comorbid conditions and other factors—to give them a precise estimation of what a patient with their concurrent care issues and medical history might expect.

MIPS Overview

ACS believes that the Congressional intention for the Quality Payment Program (QPP) is to integrate and streamline the existing CMS quality programs to reduce administrative burden, improve payment accuracy, and ensure that measures are meaningful to patients, providers, and other stakeholders. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) also recognizes the importance of working closely with physician stakeholders to create a strong, clinically sound program with buy-in from providers. When MACRA was passed, it was ACS’ understanding that surgeons and other physician specialties would be evaluated based on measures related to care that they provide to their patients and would have access to Alternative Payment Models (APMs) suitable to their practices in which they could participate. We envisioned Merit-based Incentive Payment System (MIPS) as a program to measure care provided within a primarily volume-based fee-for-service framework with value-based incentivizes, but ultimately as a pathway or transition toward APMs which measures value-based care.

We are now considering policies for the third year of MIPS and are concerned that the implementation of MACRA is not aligned with the law’s intent. The current program, as well as the 2019 payment year proposals have not moved toward a low-burden program that measures value-based care with meaningful measures. The MIPS program is not able to incentivize surgical quality for the following reasons:

- The measure science used in MIPS lacks rigor, and the chance for misclassification of surgeons by the included measures is high.
- Standardized risk adjustment methodologies are critical when comparing clinical outcomes across different registries/cohorts, yet surgical MIPS measures do not account for risk factors. For example, we tested the surgical site infection (SSI) MIPS measure collected through the ACS Surgeon Specific Registry (SSR). ACS compared the unadjusted SSI measure rates to the risk-adjusted SSI rates and found that approximately 50 percent of cases were misclassified when risk adjustment was not
performed. Yet, CMS does not require the risk adjustment of the SSI measure.

- The measures and MIPS categories remain siloed, complex and do not fit into surgical workflow. They do not promote a cycle of improvement where measures are captured electronically across an episode of care, available on a patient dashboard at the point of care, then used to identify areas for improvement. The measures are sporadic, catching a moment of care without designs to generate knowledge about care and drive improvement. Thus, the reporting of measures is driven by threats to reimbursement rather than true quality improvement and the end goal of higher value health care.

- Most surgical care is not captured in the MIPS measurement system because larger practices report the CMS Web Interface program measures, which are primary-care focused. CMS is focused on simplification of measurement and on broad reaching, population health rather than specific measures aimed at quality improvement of surgical care.

- There is not an opportunity to accurately and meaningfully target the cost of an episode of care being assessed, which would provide useful and transparent information to providers and patients. Few surgeons are provided information about unwarranted variation in care using the CMS methods for measuring cost.

- CMS continues to miss the mark on digital health information for a particular patient. Instead, the agency is heavily focused on electronic health records (EHRs) which continue to lack interoperability and the EHR incentive programs fail to truly promote EHR vendors to achieve true interoperability, but rather attempt to put the task on the backs of providers who are in no technological position to make the EHR products interoperable. The clinical will is ready to build digital health information knowledge artifacts which improve care by leveraging information from across the entire digital spectrum. Yet, CMS continues to rely on siloed EHR products that cannot interoperate with other EHRs or data systems to follow the patient.

For these reasons, most surgeons will engage in the CMS program as a payment program, rather than a program that actually moves the needle on quality, with the sole aim of penalty avoidance because they don’t find any meaning in aligning with the required efforts. In a worse-case scenario, surgeons will feel compelled to participate in the MIPS program and divert their current quality efforts toward
MIPS at the expense of targeted and effective quality improvement efforts that have proven to drive improvements in care.

We understand that given the complexity of the CMS legacy programs—the Physician Quality Reporting System (PQRS), the Physician Value-Based Payment Modifier (VM), and the EHR Meaningful Use Incentive Program—and the extreme diversity and broad range of physicians in the programs, that simplification has proven to be a daunting task. Comparing these efforts and scoring physicians to the MIPS mean or median further adds to this challenge. However, we seek clarity and direction from the Agency on the goals of the QPP. In our letter, we highlight the following high-level comments that we believe will work to achieve the intent of MACRA:

1. **Clarify the Agency’s Goal for the QPP Program.** We seek clarity and direction from the Agency on the goals of the QPP. ACS believes, at a minimum, physicians should report care based on common conditions with common measures which works toward the goal to have a single source of truth (one system to aggregate data across a clinical domain).

2. **Increase Benchmarking Reliability and Validity with a Single Source of Truth.** The current CMS solutions to measurement science are inadequate for accurately informing patients and providers. We need solutions that provide consistent, reliable methods for a single source of truth (one system to aggregate data across a clinical domain), including: standardized data definitions, standardized risk adjustment/data analytics, consistency of data ascertainment methods, and common normalization methods. This goal cannot be achieved with the proposed multiple disparate data systems that have competing measures and methodologies.

3. **Incremental Increases to the MIPS Performance Threshold Are Appropriate, Not Doubling the Threshold.** The proposal to double the MIPS performance threshold from 15 to 30 greatly increases burden. Based on the level of MIPS participation required to meet a 30-point threshold, ACS finds the selection of this number arbitrary, too high of a bar, and strongly believes clinicians need a clearer explanation of how this program drives quality improvement before increasing the threshold this drastically.

4. **Maintain 2018 MIPS Category Weights for Burden Reduction and Consistency.** The MIPS program requirements are onerous and complex. Stability is critical for program success and reducing administrative burden. The current CMS proposal to change category weights from 2018 to 2019 (Quality from 50 percent to 45 percent and Cost from 10 percent to 15
percent) not only adds to the confusion and burden, but it also does not make any advancements in reliability and validity based on the proposed cost measures.

5. **Amend Quality Performance Period to 90 Days.** CMS should modify the Quality Performance Category reporting requirements to align with the 90-day reporting period in the Promoting Interoperability (PI) and Improvement Activities (IA) performance categories. The nation does not have the infrastructure to implement a 12-month Quality reporting period, and multiple existing program policies impede successful reporting over the first quarter of the performance year. A 90-day reporting period would accomplish the same goals, and also better align with PI and IA.

6. **Maintain the Use of High-Value Topped Out Measures.** ACS opposes the general removal of all measures based on topped out status but supports the transition high-value topped out measures into a composite or as part of a verification program such as the ACS Trauma Verification, Review, and Consultation (VRC) Program.

7. **Encourage Qualified Clinical Data Registry (QCDR) Reporting by Reducing Barriers and Increasing QCDR Measure Integrity.** CMS has created too many barriers for QCDRs to successfully achieve their original Congressional intent, which has subsequently resulted in compromised integrity of QCDR measures, as well as making QCDR measures less appealing and overly burdensome to report. Examples of these barriers include:
   - Impossible CMS implementation timelines to be operational;
   - Year-to-year changes to QCDR measures which prevent the development of benchmarks based on historical data;
   - Capping the possible points for QCDR measures that do not have a benchmark to 3 points instead of 10 points;
   - The current proposal to require free licensure of QCDR measures which will increase the risk of inaccurate benchmarks, result in other measure integrity issues, and dissuade QCDRs from investing in the development of better measures over time.

8. **Increase Transparency for the Cost Performance Category.** As CMS continues to refine the existing cost measures and create new measures, a full picture of cost is needed both to provide patients with actionable information to make the best treatment decisions and to create opportunities for clinicians to generate savings.
9. **Promote Widespread Interoperability Across the Digital Ecosystem.** The objective of PI should be the attainment of widespread health data system interoperability, not only between meaningful users of Certified Electronic Health Record Technology (CEHRT), but more broadly throughout the wider clinical data ecosystem. It is critical for CMS to realize that we are not going to solve interoperability problems with the current PI approach which focuses solely on EHRs and EHR functionality.

10. **Remove All-or-Nothing Requirements for PI category and do not mandate 2015 CEHRT.** The PI category remains too similar to the Meaningful Use (MU) legacy program, as PI continues to use a rigid all-or-nothing scoring approach and mandates the use of CEHRT. This approach is not meaningful for surgeons, disrupts clinical workflow, and will disproportionately create barriers for small and rural practices that have limited IT resources.

11. **Continue Creating A Clear Value-based Payment Pathway from MIPS to Advanced APMs.** CMS should make it as accessible as possible for physicians to transition from MIPS, to MIPS APMs, to Advanced APMs. MIPS APMs represent a stepping stone between MIPS and Advanced APMs while potentially creating more coordinated care, reducing administrative burden, and building knowledge necessary for physicians to move toward Advanced APMs, which is one of the clear goals of MACRA. We urge CMS to strongly consider, test and implement new models such as those recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC).

12. **Align Advanced APM Requirements and Maintain Flexibility.** ACS supports aligning healthcare standards across payers wherever possible to reduce administrative burden. This includes creating standards and requirements that are the same or at least compatible for Advanced APMs in Medicare and Other Payer Advanced APMs. This will allow payment models to be more easily implemented by physicians and health systems across payers. We also urge CMS to test and implement additional Advanced APMs that better recognize and incorporate the work and expertise of surgeons and other specialists, including models reviewed and recommended by the PTAC.

13. **Consider the ACS Episode-based Surgical Measurement Framework.** ACS seeks to work with CMS to pilot test a surgical measurement framework which moves away from fragmented, sporadic measures towards episode-based measures sets within clinical domains. We propose that this framework should include a combination of three elements:
• Standards-based facility-level verification programs,
• Patient reported experience and patient-reported outcome measures,
• Traditional quality measures including registry and claims-based measures.

ACS GENERAL COMMENTS: SEEKING A CLEAR PATH TOWARD QUALITY AND VALUE

We appreciate the challenges QPP presents as a payment program which tries to improve quality in healthcare and to reduce unnecessary costs in care. We also appreciate the challenge of reducing the burden on clinicians in order to promote participation in the payment program. At the same time, we are sensitive to the possibilities of miscalculations in quality-based, payment programs which could result in disruptions to long-standing, meaningful quality initiatives within surgical disciplines. We approach the challenges of CMS regulations with a sense of responding in the short-term in order to promote compliance with the federal rules while also taking a long-term view in suggesting CMS consider more focused pathways in hopes of directing proper support for surgical quality, care improvement, and cost savings.

However, as proposed, surgeon engagement in the program will continue to be rote and technical until the program is truly meaningful to the care that surgeons provide and the care that patients receive. The program uses metrics which are broadly applied across physicians without a real appreciation for the details involved in surgical quality and improvement despite the provision of suggestions to design the program as such. In addition, the complexities of scoring across the various aspects of the program do not foster quality. While we appreciate the efforts behind these proposals, the short-term MIPS results will continue to fail to incorporate the use of meaningful surgical measures and dilute efforts for true long-term surgical quality improvement. Given the shortcomings of the MIPS program, we wish to promote meaningful use of existing and highly regarded surgical quality programs into CMS payment programs both in the short-term and long-term goals for the QPP:

• As QPP moves forward in the short-term, CMS continues to recruit physicians into the program using multiple participation pathways and deploys broad metrics without regard for what motivates surgeons to improve, what helps patients understand quality, and what demonstrates effective cost controls. Can CMS demonstrate how adult immunization metrics as reported by surgeons in the Web Interface measure set have aided patients in surgical quality? Or can CMS provide evidence that surgical outcomes will improve by surgeons performing primary care
functions for tobacco cessation education or medication reconciliation in the General Surgery Specialty Measure Set? Is CMS' goal to recruit physicians into the program, regardless of its overall impact on the quality of care they deliver or ability to reduce the associated costs? Without a plan specific to drive surgical quality improvement, CMS appears to recruit surgeons into an inaccurate measurement system which lacks a reasonable and meaningful ability to benchmark surgical care or drive improvement. The result is that surgeons seek optimal CMS payment program scores rather than scores based on true surgical quality. Surgeons will seek to obtain a minimum score to avoid a penalty in Quality, Improvement Activities, and Promoting Interoperability. It is less likely a surgeon would seek to outperform in quality when the metrics used in measuring excellence fail to represent high quality surgical care or even provide actionable data on which to focus quality improvement efforts. Penalty avoidance, not quality care, will rule the day. Does CMS feel this meets the intent of the MACRA legislation?

- Or is the goal to be able to compare physicians within and across specialties with reliability and validity? It is difficult to imagine that Congress intended MACRA to array all physicians across a series of benchmarks and provide a tournament model of rewards and penalties of all disciplines in aggregate. For example, can CMS point to metrics which define excellence in trauma care for a surgeon with adequate benchmarks which would reliably and validly compare the surgeon’s performance to an internist’s metrics for adequate testing of a chronic condition such as diabetes? We believe the legislation was intended to measure clinicians with benchmarks within their disciplines. Then, rewards and penalties would be distributed based on performance relative to those benchmarks.

In addition, CMS currently measures some physicians with scores assigned to individuals by proxy through metrics measured within a Taxpayer Identification Number (TIN) and applied broadly across all providers under the TIN. Oftentimes these measures do not represent any of the care delivered by various specialties under that TIN. It seems this same logic of a proxy of metrics from applied measures would be more accurately applied across clinical domains, regardless of the TIN source. For example, a measurement of trauma care under a hospital TIN would be a more accurate proxy for a trauma surgeon than using a proxy of primary care measures in the Web Interface reporting option under the clinical practice’s TIN. It seems artificial for CMS to consider a TIN as a
proxy and not to consider a trauma system level measure as an adequate proxy for quality. In this example, we illustrate the limits of a payment policy as a substitute for a reliable and valid quality policy.

- **Is the longer-term goal to define value in the care physicians deliver and create payment models based on that care? Or is the goal to exclude the majority of physicians and only define value in large groups?** If value-based health care is pursued, creating a foundation based on solid measurement principles will avoid the cleanup that will be needed if CMS initially pursues less rigorous and inaccurate methods. If CMS’ general goal is to define value with reliable and valid quality and improvement, at a minimum CMS should work toward the goal of having physicians report care based on common conditions with common measures into a single source to allow for standardized data analytics. More ideally, these measures should be patient-centered and have shared accountability for all clinicians who provide for an episode of care—and fit the bill for common conditions, common measures in a single source of truth. ACS also believes the QPP program should work to better support providers and incentivize optimal care while prioritizing a reduction in regulatory burden. **If CMS is committed to the MACRA goal of creating incentives to move from MIPS to APMs, CMS should provide a roadmap that outlines how the regulations incentivize quality clinical care while designing business models that promote the successful transition from fee-for-service payment updates to new clinical and financial models of care.** To help facilitate this effort, ACS outlines a framework for short, medium, and long-term goals for QPP success in surgery.

**ACS VISION:**

**Short-Term**

For the short-term, CMS’ use of multiple means for complying with the QPP’s various aspects of quality, improvement, interoperability and cost should be meaningful to the clinical specialty. If not meaningful, the ability to participate to meet minimum thresholds and avoid penalties should be readily available with clear and simple pathways for participation. While some specialties will find adequate measure sets for surgical care, most will find sporadic metrics which are not meaningful to surgeons or patients.
Medium-Term

The medium-term goal seeks to pilot test measurement frameworks which move away from fragmented, sporadic measures and toward measures sets within clinical domains such as cancer, trauma, geriatric/frail elderly surgical care, or bariatrics. In addition, patient-reported outcomes (PROs) should expand with more pilot efforts to evaluate episode-focused and surgical-focused PROs which relate to patient experience and outcomes. We seek to work with CMS to demonstrate how to benchmark and present dashboards of surgical care and reduce the burden of surgical data aggregation through pilot testing of selective use of administrative claims-based measures for a set of identified low event rate surgical care. Complex, highly variable care would be unsuitable without risk adjusted, clinically enriched outcomes measures.

Long-Term

The long-term goal builds on the medium-term goals and is based on clinical domains of care. Each of the clinical domains can be thought of as collections of team-based episodes of care. For example, clinical domains include cancer care, trauma care, frail/geriatric care, and so forth. Within the cancer domain are episodes of care related to cancer, including prevention, screening early detection, treatment, and so forth.

Since the inception of the ACS, we have sought to build standards for clinical domains with the expectation of improving overall outcomes of surgical care. To implement these standards, we have over half-century of experience in building clinical verification programs in specific clinical domains in order to drive quality, improvement, and excellence in care. Each of the major surgical domains contain a set of standards for inclusion in a renewable, triennial verification program. We envision the long-term goals would pilot test the ability to scale these verification programs as a foundational component to building a national quality system in surgical care.

In addition to these verification programs, we propose inclusion of PROs based on an episode of care in order to assess that the team-based episode is achieving the patient’s expectations. We have begun early testing and development of enriched patient-reported outcomes (PROs) which are focused on surgical outcomes. Finally, further expansion of the pilot work in the medium-term goals with regard to the use of administrative claims measures for low event rate care, we would propose using risk adjusted, clinical outcomes for complex, high risk care using the National Surgical Quality Improvement Program (NSQIP). This long-term view would require detailed pilot and testing before large scale implementation. This model is designed to recognize the complexity of modern
medicine and that it exceeds the ability of a single physician to provide all of the care a patient needs.

CY 2019 UPDATES TO THE QUALITY PAYMENT PROGRAM

MIPS Program Details

Low-Volume Threshold

The Bipartisan Budget Act of 2018 (BBA) amended the definition of the MIPS low-volume threshold. To comply with the Act, CMS proposes to modify the definition of the low-volume threshold for the 2019 MIPS performance year so that it is based on “covered professional services” and not Medicare Part B medications and services billed separately from the PFS. CMS also proposes to extend the low-volume threshold to include an additional 3rd criteria for the 2019 MIPS performance year—to be excluded clinicians or groups would need to meet one of the following three criterion: 1) have ≤ $90,000 Part B allowed charges for covered professional services; or 2) provide care to ≤ 200 or fewer Medicare Part B-enrolled individuals; or 3) provide ≤ 200 covered professional services under the PFS (newly proposed for 2019). If a clinician or group meets any one of these criteria they are excluded from MIPS.

Low-Volume Threshold Opt-in

Additionally, CMS proposes that starting for the 2019 MIPS performance year, if clinicians or groups who meet or exceed one or two—but not all three—of the low-volume criterion they could “opt-in” to participate in the MIPS program. As a result of this proposed policy, CMS estimates that no additional clinicians will be excluded from MIPS and 42,000 additional clinicians will be eligible because they exceeded at least one, but not all of the low-volume threshold criteria and elect to opt-in. CMS explains that this proposal is in response to clinicians who would like to participate in the program but were excluded.

ACS appreciates CMS’ response to the public’s concern regarding the ability to opt-in to the MIPS program based on the new MIPS low-volume criteria. Although we don’t oppose the concept that some excluded clinicians may find value in MIPS and want to participate, we seek clarity from CMS on how this may impact the pool of MIPS clinicians. We are concerned that the additional clinicians who voluntarily opt-in are likely to be above the MIPS threshold and therefore may reduce the amount of bonus money from clinicians who are required to participate. This could adversely impact incentives to participate in MIPS because it could result in a lower return on investment for MIPS clinicians.
Group Reporting

CMS notes that that provider groups have asked to allow a portion of groups to report as a separate subgroup on measures and activities that are more applicable to them, and their MIPS score would be based on the performance of the subgroup. CMS explains that they are exploring the feasibility of this request, including allowing this functionality through a new MIPS identifier.

ACS supports flexibility which would allow for providers to report measures that they find meaningful and have been shown to drive improvements in care. We have heard from many surgeons that their institution or employer currently reports via the CMS Web Interface which does not include measures meaningful to surgical care. Therefore, we believe this concept could allow specialists who form subgroups to better utilize more meaningful measures for targeted quality improvement. As CMS considers the implementation of this policy, we encourage CMS to consider a policy that would move toward more meaningful group reporting with high statistical rigor that promotes team-based care with shared accountability. ACS advocates for CMS to allow specialists to identify subgroups across clinical domains or diseases. We strongly urge CMS when considering the concept of a subgroup within a clinical domain to use a single source of truth for establishing benchmarks and driving improvement. For example, the Society of Thoracic Surgeons’ (STS) database is a single source of truth within a domain. Without that single source, CMS complicates data benchmarking and meaningful use of the knowledge gained. These single sources not only help patients and surgeons, they help the payers in consolidating knowledge into a report from one source to aggregate data for that clinical domain. This establishes a high statistical rigor which would mean that for a given disease all data are defined one way, interpreted and aggregated consistently, normalized consistently, analyzed and reported by the same methodology for all providers who report on that clinical domain.

MIPS Performance Period

For the 2019 performance year, CMS proposes to maintain the current performance periods for the MIPS performance categories:

- Quality category: maintain a 12-month performance period (and for 2020 and future years)
- Cost category: maintain a 12-month performance period (and for 2020 and future years)
- Improvement Activities category: a minimum of a continuous 90-day period within the calendar year (and for 2020 and future years)
- Promoting Interoperability: a minimum of 90 continuous day period within the calendar year (and for 2020)

ACS appreciates that these proposals promote stability by maintaining the same performance period from the 2018 performance year. However, we strongly opposed the 12-month reporting period for the Quality component of MIPS in our comments last year, and we continue to strongly oppose this policy. **ACS urges CMS to modify the Quality performance year to align with 90-day reporting for the PI Performance Category and IA Performance Category and to reduce the burden of 12-month reporting. We simply cannot have a full year of reporting without a better cycle of implementation for measures, including automated data flows. And, once we achieve the goal of automated data, 6 months should be sufficient time for highly reliable measurement.**

Challenges in both the 2017 and 2018 performance years have demonstrated that traditional registries and QCDRs simply do not have the systems in place to support a 12-month performance period for the Quality component. CMS requires measure submissions from measure stewards, registries and QCDRs well in advance in order to meet the internal CMS timelines, but CMS does not give consideration for the timing it takes for registries, QCDRs and other vendors to update systems to reflect the upcoming year’s measures and then educate users.

Some examples include:

- **CMS publication of MIPS measures demonstrate that a January 1, 2019 start date is not feasible for providers or registries and/or vendors.** CMS publishes the MIPS measures specification the last week in December, giving registries and providers several days to build out any changes and educate clinicians. This timeline makes it impossible to launch registries by January 1st of the performance year.

- **CMS did not approve ACS QCDR measures until December 15, 2017 yet expected the SSR to be live by January 1, 2018.** As a result of the late approval and major changes and the build required for new measures, ACS was not able to launch and allow for full reporting functionality of our QCDR measures in a timely way—starting on January 1, 2018 our members could enter their cases but they could not include those cases as part of the MIPS measure until the updated measure specifications were built into the system. The likely result is that most surgeons will not choose to report QCDR measures given the burden of retrospective data entry. A 90-day reporting minimum would relieve registry participants of having to retrospectively report measures. Additionally, we had similar approval and implementation delays for the 2017 performance year and did not meet the case minimums for any of the measures. Therefore, after
all of the efforts registry users will put forth reporting our measures, they will only score a maximum of three points because we are unable to determine a benchmark.

- **Most registries require manual data entry and therefore do not have seamless data transfer from EHRs or other data sources.** Due to the lack of interoperability in the current clinical care system, 60% of all-payer data for a 12-month period is too burdensome.

**MIPS Performance Category Measures and Activities**

**Performance Category Measures and Reporting**

**Claims Submission**

CMS proposes to limit the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and to allow clinicians in small practices to report claims as a group. CMS explains that it wants to phase out claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. The agency acknowledges that while it would like to move towards the utilization of electronic reporting by all clinicians and groups, small practices continue to face additional challenges.

As discussed in our comments on topped-out measures, there are many process measures which CMS has deemed topped which could be of critical value to patient care. These measures should not be eliminated based on topped out status, but instead should be removed as they are not meaningful or do not contribute to patient safety. The proposed policy for topped out measures is fit for a payment program and not consistent with true quality programs. As such, it might seem reasonable to apply to quality measures which track sporadic, disconnected events. However, as we discuss in in the Topped Out Measures section, topped out measures which are determined to be high value and worthy of continued measurement should be included as part of a composite whereby they continue to be measured and ensure the maintenance of high quality care and patient safety.

**Quality Performance Category**

Using the authority granted in the Bipartisan Budget Act of 2018, CMS proposes to weight the Quality performance category at 45 percent of the final MIPS score for the 2019 performance year which is a 5 percent decrease from the 50 percent weight in the 2018 performance year. **ACS opposes this proposal and advocates for a continued Quality performance weight of 50 percent.** The continuation of the final score weights from 2018 to 2019 performance years will promote consistency, stability, and simplicity for the third year of MIPS. Additionally,
as discussed in the Cost performance category, we support a continued weight of 10 percent for the 2019 performance year because the new episode-based Cost measures have only undergone testing on a small scale, and are not understood by clinicians.

Quality Data Submission Criteria

As stated in the MIPS Performance Period comments above, ACS urges CMS to modify the Quality performance year to align with 90-day reporting for PI and IA performance categories and to reduce the burden of 12-month reporting. We simply cannot have a full year of reporting without a better cycle of implementation for measure, including automated data flow. And, once we achieve the goal of automated data, 6 months should be sufficient time for highly reliable measurement.

Background and Policies for the Call for Measures and Measure Selection Process

High Priority Measures Definition

CMS currently identifies a high priority measure as an outcome, appropriate use, patient safety, efficiency, or care coordination quality measure. CMS proposes to add opioid-related quality measures to the definition of a high priority measure in order to focus on the major public health concerns related to use and abuse of addictive opioids. CMS also requests feedback on what aspects of opioids should be measured.

The ACS puts the welfare of our surgical patients above all else, and we believe that surgeons, as prescribers, can play a role in optimizing pain management strategies that will decrease frequent and prolonged opioid use. Pain is an inevitable, but undesirable, consequence of surgery, and while opioid-based pain control for the postoperative patient is a therapy supported by numerous national medical specialty societies, these prescriptions carry risks, which include chronic usage, addiction, and overdose. In the midst of this public health crisis, surgeons have a major responsibility to understand and mitigate the risks associated with prescribing opioid analgesics and to participate in a broader solution. To this end, ACS agrees that opioid-related measures should be categorized as high priority. In regard to what aspects of opioids should be measured, we believe highly coordinated efforts are needed to target the complex opioid epidemic. From the surgical perspective, ACS supports measures that incentivize the use of multimodal analgesia (MMA) as part of an Enhanced Recovery After Surgery (ERAS) protocol for optimal analgesia.

ERAS prioritizes the use of non-opioid pain management techniques, recommending a multimodal analgesic approach for “optimal analgesia,” defined
as a technique that optimizes patient comfort and facilitates functional recovery with the fewest medication side effects.\textsuperscript{13} Multimodal analgesic techniques employ “the use of multiple, simultaneous mechanisms of pain control acting synergistically to improve analgesic effect and reduce the doses of any single agent.”\textsuperscript{14} Measures that incentivize these processes will aim to reduce the opioid doses required or avoid the use of opioids in totality, thereby reducing the risk for common side effects associated with opioid use that delay recovery.\textsuperscript{15} The success of ERAS lies in uniting the entire perioperative team in the spirit of improving patient care. Its efforts span across all phases of care (preoperative, intraoperative, postoperative, and post-discharge) as well as medical specialties (surgery, anesthesiology, nursing, pharmacy, and physical therapy). Special focus should be given to measures which incentivize care coordination for pain management, foster shared decision making for a patient’s pain management treatment, and PROs and PREs which measure functional recovery. Making patients part of the MMA program is extremely important in pain management, and therefore MMA should engage patients preop and should be used as tool to carry them thru their full recovery.

\textbf{CMS Web Interface Measures}

Currently, groups with 25 or more eligible MIPS clinicians can report using the CMS Web Interface Option. Although CMS is not proposing changes to the data submission criteria, or the requirement for which size group can report using this option, the agency seeks comment on expanding the Web Interface Option to groups with 16 or more eligible clinicians. CMS also seeks comment on building upon the CMS Web Interface submission type by expanding the core set of measures beyond the primary-care focus of the current core measures to include other specialty-specific measures, such as surgery.

It is our understanding that there is no indication that the current set of core measures used in the Web Interface improves surgical care. However, it is very difficult to comment on an expansion of the CMS Web Interface measure set, as well as the expansion of this option to smaller groups without knowing 1) what


type of measures CMS is considering, 2) how applicable these measures would be to specialties, and 3) how this policy would be implemented (e.g., if CMS were to add surgery-specific measures, would surgical and primary care groups alike be required to report on the same “core” set of measures). Therefore, we welcome the opportunity to discuss this with CMS in further detail.

Moving forward, we encourage CMS to consider policy that enables more meaningful participation with high statistical rigor. **ACS advocates for CMS to allow specialists to identify sub-groups across clinical domains or diseases.** We strongly urge CMS when considering the concept of a subgroup within a clinical domain to use a single source of truth for establishing benchmarks and driving improvement. For example, the STS database is a single source of truth within a domain. Without that single source, CMS complicates data benchmarking and meaningful use of the knowledge gained. These single sources not only help patients and surgeons, they help the payers in consolidating knowledge into a report from one source to aggregate data for that clinical domain. This establishes a high statistical rigor which would mean that for a given disease all data are defined one way, interpreted and aggregated consistently, normalized consistently, analyzed and reported by the same methodology for all providers who report on that clinical domain.

ACS acknowledges that this may not easily fit into how CMS has configured the CMS Web Interface reporting option. However, this will result in a more reliable benchmark for surgery and it could be a pathway to standardize measurement across sub-groups for a given clinical domain. Currently, there are 21 registries reporting on the General Surgery Specialty Measure Set which means CMS publishes the measure specifications, then companies like CE City, Fig, Epic, and ACS each aggregate their own version of the measure, some risk adjusting the data, some not, but all reporting to CMS. It is impossible to reconcile all those data into a highly reliable, single benchmark for payment with consistent and valid individual surgeon representations. **We urge CMS to carefully consider how this policy could increase measurement rigor, rather than exacerbate the lack of rigor across MIPS measurement options for specialists.**

**Specialty Sets**

In review of the General Surgery Specialty Set, ACS would like to highlight what we believe there are errors in the current proposed list of measures. In the General Surgery Specialty Measure Set in Table B.20 of the proposed rule, CMS lists the measure titled “Sentinel Lymph Node Biopsy for Invasive Breast Cancer” for inclusion in the 2019 performance year. This measure was not included in the specialty set in the 2018 final rule and is not mentioned as an addition in this proposed rule. **However, the ACS does support the inclusion of the “Sentinel**
**Lymph Node Biopsy for Invasive Breast Cancer**” in the General Surgery Specialty Set. In addition, the measure titled “Preoperative Diagnosis of Breast Cancer” is proposed for removal from the General Surgery Specialty Measure Set, but was not included in the measure set finalized in 2018 – this also seems to be an error. The ACS also supports the removal of the “Preoperative Diagnosis of Breast Cancer” measure from the General Surgery Specialty Set. We are seeking clarity to determine whether the “Sentinel Lymph Node Biopsy for Invasive Breast Cancer” measure is proposed as a new addition to the specialty set in 2019, as well as if the removal of the “Preoperative Diagnosis of Breast Cancer” measure is in fact an error.

**Topped Out Measures**

CMS previously finalized a lifecycle for topped out measures where, after a measure benchmark is identified as topped out in the published benchmarks for two years, in the third consecutive year it is identified as topped out it will be considered for removal through notice-and-comment rulemaking or the QCDR approval process and may be removed from the benchmark list in the fourth year. CMS also previously finalized a 7-point cap to be applied to measures identified as topped out in the published benchmarks for two consecutive years. Beginning in the 2019 performance year, CMS proposes to change its existing policy so that once a measure has reached an extremely topped out status, defined as a measure with an average mean performance within the 98th to 100th percentile rage, it may propose the measure for removal in the next rulemaking cycle, regardless of the point it is in the topped out measure lifecycle. CMS’ rationale for this proposal is that for measures that meet this level of performance, there is very little variation where meaningful distinctions can be made. CMS further explains that topped out measures require data collection burden without added value for clinicians but CMS would consider retaining the measure if there are compelling reasons as to why it should not be removed. CMS also proposes to exclude QCDR measures from the topped out timeline previously finalized since QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle. However, CMS notes that topped out QCDR measures might not be approved through the QCDR measure approval process.

For the same reason ACS opposed the 4-year timeline for topped out measures in our comments to the 2018 proposed rule, we also oppose CMS’ proposal for extremely topped out measures. We cannot support these policies because the general removal of all measures based on the mean performance – often calculated based on limited data that reflects only a small sliver of applicable clinicians – does not consider the importance of a measure and may have unintended consequences on patient safety. The
The CMS approach to topped out measures might have merit in a budget-neutral payment program, but misses the mark for a quality program. In fact, a highly reliable quality system attempts to identify all the critical measures and seeks topped out performance in all of them. High value process measures are crucial to a coordinated surgical team. These high-value topped out process 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. Medical and surgical care is complex and spans time, across unique patients, and disparate care systems. Tracking this information is critical for prevention—by receiving information on a possible event can help providers prevent it from occurring altogether. Many surgical measures that are deemed topped out tell an important story as part of the care continuum. For example, measuring antibiotics before surgical care was once adequate. However, we have come to realize that to track patients optimally, we need checklists of interrelated processes that are closely tied to outcomes (e.g., sepsis bundles). Additionally, surgical science has advanced around enhanced recovery protocols, commonly referred to as ERAS. ERAS is a more comprehensive patient-centered approach to optimize care which requires nutritional plans, shared IV fluid strategies, a multi-modal analgesic program, pain treatment plan, infection prevention protocols and outcome tracking. The multidisciplinary nature of successful ERAS strategies are well-documented and widely-supported throughout the medical literature. By pulling all the surgical teams together in a checklist for these processes, the goal is to achieve 100 percent performance on the processes and to achieve greater tracking of outcomes, including PROs. **CMS’ proposed policy values single measures which track sporadic, disconnected events. Instead, we encourage CMS to recognize composites of high value process measures that can demonstrate consistency and highly reliable care processes and include those as part of a composite which spans the phases of surgical care or as part of a verification program.**

**QCDRs**

CMS proposes to exclude QCDR measures from the 4-year topped out timeline that was finalized for the 2018 performance year. CMS is proposing this change since QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle like other MIPS quality measures. Under the proposal, once a QCDR measure reaches topped out status under the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.
This proposal runs counter to CMS’ intent to promote the use of QCDRs. The early removal of measures from QCDRs could reduce the incentive for surgical subspecialties to develop and strengthen new measures, and prevent them from establishing benchmarks based on historical data. Additionally, applying a scoring cap on “topped out” measures disincentives clinicians from submitting these QCDR measures, further exacerbating the ability to establish benchmarks for these measures in MIPS.

**While we generally oppose the removal of quality measures based on topped out status alone, if CMS is going to adopt a topped out measure policy, then it should at least allow for the same removal timeline for QCDR measures as CMS allows for MIPS CQMs.** As discussed later in this proposed rule, due to the year-to-year measure changes required by CMS for approval of our QCDR measures sets, there is no consistency or stability. As a result, there has been a very low number of surgeons who report on QCDR measures. Adding to these challenges is that the lack of stability in QCDR measures, preventing QCDR measures from developing benchmarks, and preventing clinicians from scoring more than 3 points on a measure.

**Categorizing Measures by Value**

CMS seeks comment on implementing a system where measures are classified as a particular value (gold, silver or bronze) and points are awarded based on the value of the measure. **ACS opposes this policy because we believe that this concept over-simplifies the complexity of measures, including which stakeholder(s) determine a measure’s value.** Again, this approach by CMS reflects a payment program and not a quality program. All the structure and processes of care add together to deliver optimal surgical quality. This sporadic, siloed concept of measurement is extremely disruptive to building a quality of care, team-based model. The philosophical approach CMS continues to take where the primary intent is to define quality as part of a payment program is not going to prove as rewarding as the longstanding quality programs such as the US trauma quality system. In the trauma system, complex structural and process measures are topped out as standards of care which must be met in order to gain a level of trauma verification. Measuring risk adjusted outcomes for those trauma patients then rounds out the quality program and together these define Level I, II and III trauma centers. At no time are single metrics weighted as gold, silver or bronze as a single establishment for quality. And, furthermore, based on the CMS value classification, who would be the arbiter for defining the various level of value? One measure that is not as much value to a purchaser may be of great value to a surgeon or a surgical patient, and so on. We encourage CMS to
prioritize ensuring that specialties have measures in MIPS that are meaningful before attempting to assign different values to existing MIPS measures.

**Cost Performance Category**

**Weight in the Final Score**

In the CY 2018 QPP final rule, CMS established that the weight of the Cost performance category would be 10 percent of the final score for the 2020 MIPS payment year. As stated in the BBA of 2018, for the second through fifth years for which the MIPS applies to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the Cost performance category score. MACRA requires, however, that by MIPS payment year 2024, the Cost performance category should be weighted at 30 percent of the MIPS final score. In this rule, CMS proposes to increase the Cost performance category from 10 percent to 15 percent of a MIPS eligible clinician’s final score for the 2021 MIPS payment year.

We have a number of concerns regarding the existing cost measures. We agree with CMS that the cost measures are still relatively early in the development process and that clinicians do not have the level of familiarity or understanding of cost measures that they do of comparable quality measures. We understand that CMS is concerned about facilitating a smooth transition from the current 10 percent weight to the required 30 percent weight for the 2024 payment year; however, the concern about a large jump in the weighting of the MIPS Cost score closer to the 2024 payment year is outweighed by the concern about requiring clinicians to use cost measures that are still new and not adequately tested. For these reasons, we do not support increasing the Cost performance category to 15 percent of the final MIPS score.

**Cost Criteria**

**MSPB Measure – Specifications**

Although CMS did not propose any changes to the Medicare Spending per Beneficiary (MSPB) measure, we continue to have concerns with this measure. We appreciate that CMS has convened an expert workgroup to provide input on this measure over the last few months. We agree with many of the comments made by stakeholders that were considered in the discussion of this workgroup including concerns with the attribution rule that attributes each MSPB episode to the clinician billing the plurality of Part B service costs during the index admission. Stakeholders have indicated that this rule attributes episodes to specialties with relatively high expense, but with little involvement in the course
of care. It also does not appropriately account for team-based care in the hospital setting. In addition, individual clinicians are attributed a small number of MSPB episodes, leading to unreliable Cost scores.

We also restate our concerns that the 0.4 reliability threshold used for the MSPB measure is extremely low when the minimum in the literature is 0.7 for “acceptable” reliability. ACS believes that CMS should not accept the lower limit of “moderate” reliability (0.4) as we do not see the value in setting such a low bar for reliability. We strongly encourage CMS to demonstrate “good” reliability (0.8) for the MSPB measure so that MIPS clinicians have confidence in the program and can learn to improve the value of the care they deliver.

In the CY 2017 QPP final rule, CMS finalized a technical change to the MSPB measure by removing the specialty adjustment that accounted for the case-mix difference across the patient population. CMS stated that the specialty adjustment is not necessary and may not be needed, yet CMS did not provide data to support this statement. CMS initially applied the specialty adjustment to all cost measures, publicly supporting this decision with evidence and educational materials, but CMS then finalized the specialty adjustment for removal without an explanation as to why it is no longer necessary. Due to this lack of transparency, we continue to oppose this previously finalized change to the MSPB measure that removes the specialty adjustment.

We urge CMS to strengthen the measure reliability, validity, and risk adjustment methodology for the MIPS program, not lower the bar. We also note the importance of the sociodemographic status (SDS) factors and how these factors can impact outcomes for providers who care for patients of diverse backgrounds. When developing policies surrounding the MSPB measure and the Cost performance category generally, CMS should consider the increased costs in caring for these patients, and we ask that CMS adjust for those differences when calculating the Cost performance category in future years.

2017 MIPS Feedback Reports

The 2017 MIPS Feedback Reports lacked sufficient detail, especially with respect to the MSPB measure. The limited information in the 2017 MIPS feedback reports is not useful in promoting insight or effectively changing behavior as currently presented, but it is possible that this information could be useful if given sufficient additional detail.

For example, if a physician’s cost were scored and the physician was deemed “expensive” due to receiving a low decile score, there should be an explanation as to why the physician received the low score. The physician should know how the score was calculated and should receive more information about the range of
deciles and what they represent. The physician should also be able to query costs by individual patient in order to review specific charges. The physician might then notice, for example, that there were some unnecessary x-rays ordered or unnecessary consults. This information would give the physician actionable feedback that more attention to detail and better teamwork is needed. Frequently updated reports would then allow physicians to track patterns and change behavior. For these reports to work, they would have to include interpretable cost data on individual patients issued on a two to three month basis.

As currently displayed, however, most surgeons would not be able to interpret the cost feedback in the reports. This is especially true if Medicare Part A charges are added. Unfortunately, given the current level of detail in the cost feedback for the MSPB measure, most physicians will likely ignore the reports or be very frustrated. **We recommend that CMS provide more information in the MIPS feedback reports on how the Cost scores are determined and more detailed information on the costs attributed to individual patients.**

**Episode-Based Measured Proposed for the 2019 and Future Performance Periods**

CMS has developed episode-based measures intended to represent the cost to Medicare for the items and services furnished to a patient during an episode of care. CMS has worked with a measure development contractor, Acumen, to seek stakeholder feedback on episode-based cost measures through a Technical Expert Panel (TEP) and clinical subcommittees. Acumen solicited expert and clinical input for measure development, national field testing, and various stakeholder engagement activities. The subcommittees provided input on the components of episode-based cost measures including triggers and windows, item and service assignments, exclusions, attribution methodology, and risk adjustment variables. The new episode-based measures developed by the clinical subcommittee were conditionally supported by the Measure Applications Partnership (MAP) with the recommendation of obtaining National Quality Forum (NQF) endorsement. CMS proposes to add all eight Acumen-developed episode-based measures, shown in CMS Table 33 below as cost measures for the 2019 MIPS performance period and future performance periods. The national field testing for these measures occurred during a short five-week period of October 16, 2017 to November 20, 2017 when solo practitioners and clinician groups were able to access field test reports about their cost measure performance on the CMS Enterprise Portal if they were attributed at least 10 episodes for at least one of the eight measures during the measurement period of June 1, 2016 to May 31, 2017.
As CMS develops episode-based cost measures, we urge the Agency to view the issue of cost in patient-centric terms, and not only in terms of a physician payment update under MIPS. This means that cost information should be available and presented to the patient and should include all services the patient is likely to receive from all providers and facilities related to a given episode of care. Such information is more representative of the way patients experience care, and when coupled with meaningful information on quality, will provide patients with a clearer picture of the value of care they are considering. On the other hand, presenting a patient with their out-of-pocket cost for a small grouping of services as part of a narrow episode, is not enough to allow them to make informed decisions and could ultimately be misleading and do more harm than good.

Given the importance of price transparency for patients, we have concerns about Acumen’s approach to cost measure development due to the narrow focus of these measures. If CMS’ goal with the MIPS program is to keep all physician payment updates relatively similar, then these measures will likely support that goal. On the other hand, if CMS intends to create measures that can provide useful and actionable information for both patients and physicians, then more detail is needed. Expanding the types of services included in a bundle is also important in order to create opportunities for savings. If a bundle only includes services that are narrowly related to the condition or procedure, there is little to no scope for a physician to influence the work of his/her team-based care that is typically provided today. As CMS continues to refine the existing cost measures and create new measures, a full picture of cost is needed both to provide patients with actionable information to make the best treatment decisions and to create opportunities for clinicians to generate savings.

### TABLE 33: Episode-Based Measures Proposed for the 2019 MIPS Performance Period and Future Performance Periods

<table>
<thead>
<tr>
<th>Measure Topic</th>
<th>Measure Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective Outpatient Percutaneous Coronary Intervention (PCI)</td>
<td>Procedural</td>
</tr>
<tr>
<td>Knee Arthroplasty</td>
<td>Procedural</td>
</tr>
<tr>
<td>Revascularization for Lower Extremity Chronic Critical Limb Ischemia</td>
<td>Procedural</td>
</tr>
<tr>
<td>Routine Cataract Removal with Intraocular Lens (IOL) Implantation</td>
<td>Procedural</td>
</tr>
<tr>
<td>Screening/Surveillance Colonoscopy</td>
<td>Procedural</td>
</tr>
<tr>
<td>Intracranial Hemorrhage or Cerebral Infarction</td>
<td>Acute inpatient medical condition</td>
</tr>
<tr>
<td>Simple Pneumonia with Hospitalization</td>
<td>Acute inpatient medical condition</td>
</tr>
<tr>
<td>ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)</td>
<td>Acute inpatient medical condition</td>
</tr>
</tbody>
</table>
In addition to expanding the types of services included in a bundle in order to increase variation, we urge CMS to go beyond standard, average episode pricing and to consider patient specific pricing. Each patient is unique and has different aspects clinically, socioeconomically, and so forth. Using logical algorithms and analytics, it is possible to establish a patient’s individualized, risk-adjusted costs for the episode of care they received during a period of time. It is also possible to use this methodology to help individual patients understand the expected costs for the projected services they will need. When a patient undergoes a procedure, they are faced with more than the surgeon’s and anesthesiologist’s costs. Common expenses could also include preoperative imaging and labs, hospital or facility costs, postoperative testing, skilled nursing, rehabilitation and home health. Underlying co-morbidities for individual patients can also add to the costs of managing an episode of care. By using an episode based pricing tool, patients can come to understand the total cost for the condition or procedure. Their out-of-pocket costs can also be calculated once the total cost of care is exposed. Episode-based pricing tools are therefore able to provide insights that are meaningful to both the payers and the patients. This tool, known as an episode grouper, was originally developed under a contract with CMS for Medicare but additional work is ongoing with the intent of making it more widely available.

There has been limited education on how these episode-based cost measures will be used for individual clinicians or groups and the impact that these measures will have on the Cost component. Given that the data clinicians received on the MSPB measure was poorly attributed and difficult to understand, these new measures add another data field unlikely to help clinicians improve the value of care delivered. We have heard from our members that many were unable to understand how they could improve care based on the value-based payment modifier model without assistance from financial analysts to sift through the data received. We are concerned that use of these episodes could add additional unvalidated data to be analyzed.

Although CMS and Acumen conducted national fielding testing for these measures, the testing period, at only a little over one month, was too brief. We do not believe that many stakeholders understood what the field tests were for and we do not consider this amount of time adequate for specialty societies to notify their members about the development of cost measures for MIPS and the importance of field testing. We also note that accessing the reports proved challenging for our members who tried to view them. This presented an additional barrier to the success of the field testing. We appreciate CMS’ efforts to engage stakeholders through National Provider Calls, but we consider the field testing period to be too rushed and therefore inadequate for assuring that these episode-based cost measures are ready for implementation in the MIPS cost performance category.
We are also concerned that these measures do not demonstrate a link of cost to quality. The fact that CMS has proposed to remove a number of quality measures from the Quality performance category could make the linkage of cost to quality for the 2019 performance period even more attenuated. We also strongly urge CMS to align these measures with quality measures for a more comprehensive value measurement.

Finally, it is unclear what percentage of physicians will be captured by these 8 new cost measures. It is not fair to hold only some physicians accountable under new cost measures if there are not episodes available to all. For the above reasons, although we generally support the development and eventual use of episode-based cost measures and we consider them to be an improvement over the MSPB measure, we do not believe the current 8 measures are ready to be used in the MIPS Cost performance category at this time.

Reliability

In the CY 2018 QPP final rule, CMS finalized a reliability threshold of 0.4 for measures in the Cost performance category. In this rule, CMS stated that the reliability of the proposed eight episode-based cost measures meets the reliability threshold of 0.4 for the majority of clinicians and groups at a case minimum of 10 episodes for procedure episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures.

As stated above for the MSPB measure, the 0.4 reliability threshold is extremely low when the minimum in the literature accepted is 0.7 for “acceptable” reliability. Our comments on reliability for the MSPB measure also apply to the use of the 0.4 reliability threshold for the episode-based cost measures. ACS believes that CMS should not accept the lower limit of “moderate” reliability (0.4) as we do not see the value in setting such a low bar for reliability. Again, we strongly encourage CMS to demonstrate “good” reliability (0.8) for all measures in the Cost performance category so that MIPS clinicians have confidence in the program and can learn to improve the value of the care they deliver.

Attribution

For acute inpatient medical condition episode groups, CMS proposes to attribute episodes to each MIPS eligible clinician who bills inpatient E&M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization. This attribution methodology is intended to emphasize team-based care and expand the measures’
coverage of clinicians, patients, and cost. For procedural episode groups, on the other hand, CMS proposes to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

We do not support the attribution methodology for the procedural episode groups because we believe that attribution should be shared instead of concentrated on only the MIPS eligible clinician who renders a trigger service. ACS favors attributing financial responsibility for an episode of care to all individuals in the care team based upon their particular role in providing care for the specific patient. For example, the ACS has proposed an APM that would use an algorithm to identify all clinicians who participate in an episode of care for a patient and infer their specific role based on claims. In the ACS model, a specific share of the financial responsibility would be shared across all providers with the same relationship or role in caring for that patient for that episode. We divide the care team into several categories based on their role including Primary, Principal, Episodic, Supporting and Ancillary providers. ACS believes that this method of attribution would be minimally burdensome since it is accomplished automatically through claims, and would have the added benefit of creating incentives for care coordination.

Improvement Activities Performance Category

Background

The ACS would like to thank CMS for providing stability in the IA category of MIPS and for its continued openness to considering additions to its list of approved activities. For the 2019 performance year, CMS proposes six new IAs and modifications to five existing IAs. The ACS believes that the proposed new activity, Comprehensive Eye Exams and the proposed modification to the Participation in MOC Part IV activity are applicable to surgery and we support these proposals.

As discussed throughout the letter, the ACS believes in a continuous cycle of quality improvement for surgical care. Within the improvement cycle, surgical quality is measured across the five phases of care: preoperative, perioperative, intraoperative, postoperative, and discharge. Quality performance in the described phases of care is captured digitally and available at each point of care—this process will also allow for the identification of failure points in each phase. These failure points captured by quality measures inform Improvement Activities for a continuous cycle of improvement. We seek to work with CMS to achieve this continuous cycle of quality improvement for surgical care in MIPS.

Subcategories
Last year, we commented that the Surgical Risk Calculator and Enhanced Recovery After Surgery (ERAS) protocols should be separated and included as individual IAs. Both activities are currently included as a single action that can be completed for credit in the “Use of Patient Safety Tools” activity in the Patient Safety and Practice Assessment subcategory. The ACS would like to reiterate our comments from last year, because we strongly believe that these activities are distinctly different, justifying separation into individual activities and reclassification of the current subcategory:

- **Surgical Risk Calculator:** We believe the Surgical Risk Calculator is more appropriately classified in the Beneficiary Engagement Category, rather than the Patient Safety and Practice Assessment subcategory. The Surgical Risk Calculator is not only a tool that is used in the decision for surgery, but it is also used to facilitate the informed consent discussion and enables patient-centered decision making.

- **Continuous Quality Improvement of ERAS for Patients:** The ACS agrees that the ERAS protocols are appropriately categorized as a Patient Safety Tool. However, we believe that ERAS should be its own individual high-value activity. ERAS is an innovative approach to delivering standardized and evidence-based care across the entire surgical episode and has demonstrated significant improvements in surgical outcomes.

**Improvement Activities Inventory**

For the 2019 performance year, ACS submitted five new IAs, four of which were not included in the proposed rule because CMS stated that each is duplicative of an existing IA. In addition to the four activities that were not included in the proposed rule, we submitted the activity, “Continuous Quality Improvement of Enhanced Recovery After Surgery for Patients.” While this activity was not included as a new separate improvement activity due to similarities to an existing improvement activity, the Agency noted that the actions of the submitted activity can be undertaken to fulfill the requirements of the “Use of Patient Safety Tools” activity (IA_PSPA_8). In regards to the other four measures listed below that were not included in the 2019 proposed rule, CMS did not clarify which IAs in the current IA inventory list our submitted measures are duplicative of or fall under. The ACS requests clarity from CMS regarding the below IAs. We ask that CMS state, in writing, the existing activities of which our submissions
were duplicative to help us guide our members to available activities they can report.

- Cancer Patients Presented at a Multidisciplinary Tumor Board
- Improvement of Cancer Care Coordination
- Improving Patient Education with Evidence-based Surgical Risk Assessment Tools
- Performing Process Improvement in Trauma Care

The ACS applauds CMS’ inclusion of new IAs, which will be applicable to surgeons. ACS supports the inclusion and modifications of the following IAs:

- Comprehensive Eye Exams
- Participation in MOC Part IV

Criteria for Nominating New Improvement Activities

Proposed Removal of One Criteria

In the CY 2017 QPP final rule, CMS implemented a policy that awarded bonus points to the Promoting Interoperability performance score of MIPS eligible clinicians who use CEHRT to complete certain eligible activities in the Improvement Activities category. In the CY 2019 QPP proposed rule, CMS proposed a new approach to scoring the PI performance category, which would require the removal of the availability for a bonus score for attesting to the completion of one or more specified improvement activities using CEHRT. To align the criteria for which improvement activities can be included in the program and the proposed PI scoring methodology, CMS proposes the removal of the criterion titled, “Activities that may be considered for an advancing care information bonus” beginning with the 2019 performance year and future years.

The ACS does not support the removal of this bonus score and believes that CMS should maintain the availability of bonus points for attestation of improvement activities using CEHRT, as well as non-CEHRT digital services which represent interoperability. Upgrading and utilizing CEHRT requires a large investment for many surgeons; we believe that maintaining this bonus score will ultimately provide stability in this category, reward surgeons who have made the investment to upgrade and utilize the 2015 edition CEHRT, and encourage physicians to gravitate toward improvement activities involving the use of CEHRT further promoting the goal of interoperability. Maintaining the bonus points in the PI category will also reduce reporting burdens for clinicians because
less reporting will be required to meet the performance threshold in the PI category.

**Weighting of Improvement Activities**

The ACS thanks CMS for providing transparency and clarification in the criteria previously used to assign high and medium weights to improvement activities. In past years, activities were proposed to be high-weighted based on the extent to which they align with activities that support the patient-centered medical home, or if the activities required performance of multiple actions, participation in a MIPS eligible clinician’s state Medicaid program, or identified as a public health priority. CMS has also given high weighting to certain improvement activities based on the intensity of the activity. In this proposed rule, CMS provides clarification on the determinations used to allow high-weighting based on the intensity of the activity by saying, “an activity that requires significant investment of time and resources should be high-weighted.”

**With the designations CMS outlines for a high-weighted activity, we ask CMS to reconsider its decision to ascribe a medium weighting to the use of the ERAS protocols.** ERAS involves care coordination with the patient and all the care providers across the timeline of a clinical episode. ERAS exemplifies the criteria for a high-weighted activity because of the intensity of the activity and the time required for successful completion. We also believe that ERAS directly addresses areas with the greatest impact on beneficiary care, safety, health, and well-being. In addition to the previously mentioned criteria, an essential element of ERAS is the incorporation of multimodal analgesia to replace or reduce the use of opioids in post-operative pain management, thus aligning the protocols with CMS’ high priority initiatives surrounding opioid prescribing.16

ERAS protocols have generated enthusiasm in the surgical community and have demonstrated significant improvements in surgical care. ERAS is an innovative approach to delivering standardized and evidence-based care and has been shown to reduce surgical complications, improve patient satisfaction, and decrease length of stay (LOS) and associated hospital costs without increasing readmission rates.17,18,19 ERAS also prioritizes the use of non-opioid pain management

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techniques by recommending a multimodal analgesic approach. Multimodal analgesic techniques employ “the use of multiple, simultaneous mechanisms of pain control acting synergistically to improve analgesic effect and reduce the doses of any single agent.”\(^5\) Implementing these processes aim to significantly reduce the opioid doses required or avoid the use of opioids in totality, thereby reducing the risk for common side effects associated with opioid use that delay recovery.\(^20\) The success of ERAS lies in uniting the entire perioperative team in the spirit of improving patient care. Its efforts span across all phases of care (preoperative, intraoperative, postoperative, and post-discharge) as well as medical specialties (surgery, anesthesiology, nursing, pharmacy and physical therapy). The ACS, in collaboration with The Agency for Healthcare Research and Quality (AHRQ) and Johns Hopkins Armstrong Institute for Patient Safety and Quality, has developed the Improving Surgical Care and Recovery (ISCR) program to implement evidence-based enhanced recovery protocols in multiple surgical specialties across the U.S.

Within ISCR, individual elements of care or process measures are measured and targeted for quality improvement. ISCR incorporates patient-reported experience and patient-reported outcomes as a component of the overall care paradigm. This model thus lends itself to the episode-based quality measure framework. Most care, including surgical care, involves episodes of care with discrete patient goals. The past decade of ERAS research and the ACS ISCR program have identified key process measures that are associated with better patient outcomes, which include both traditional outcomes measures, such as mortality and morbidity, but also patient-reported outcomes. These process measures are best recognized in the phases of care across the episode of patient care. Linking these high value process measures with both traditional outcomes and patient-reported outcomes represent the next level of measurement science. Assessing these process measures collectively, instead of single outcome measures, will provide a more accurate representation of the quality of healthcare delivery and is an opportunity to build measures in a modern framework for a given episode. ERAS has the potential to transform surgical care delivery across the nation. It focuses on improving each incremental step in the healthcare delivery pathway, not just the end result.

**Request for Comments**


In this proposed rule, CMS requires clinicians to use 2015 edition CEHRT to be eligible for a performance score in the PI category. With this in mind, CMS has requested comments on ways to incentivize the use of CEHRT in the Improvement Activities category. CMS specifically seeks feedback on whether to apply high-weighting for any improvement activity employing CEHRT. ACS has the following recommendations:

- **Offering more high weighted activities applicable to surgical practice** will help surgeons to succeed in this category and reduce the number of activities they would be required to report to meet the total score requirement for IA, therefore reducing overall burden.

- **While the ACS does not believe that the use of 2015 CEHRT should be mandated, we do believe that physicians who have invested in the technology should receive incentives for utilization across additional performance categories.**

**Timeframe for the Annual Call for Activities**

For 2019, CMS proposes an extension to the Annual Call for Activities timeframes previously finalized in the CY 2018 QPP final rule. In this proposed rule, CMS is proposing to delay the year for which nominations of prospective and modified improvement activities would apply and expand the submission timeframe/due date for nominations for the CY 2019 performance period and future years. If adopted, this would increase the possible time from submission of an IA to possible implementation from one year to two years, and extend the submission timeframe/due date, allowing an additional four months for activity submission.

The ACS does not support the extension of the timeframes for the Annual Call for Activities. We believe extending the timeframe from submission to implementation is a barrier to previously stated goals in aligning improvement activities with the quality improvement cycle. With this in mind, we would like CMS to consider maintaining the previously adopted one year submission to implementation timeframe to allow for yearly modifications and additions of improvement activities based on data generated in quality measurement.

In addition, we would like to thank CMS for considering those submitting improvement activities by proposing to extend the Annual Call for Activities timeframe by four months, but we believe the benefit of being able to modify or add measures each year outweighs the need for additional submission.
Improvement activities do not require the same reliability and validity testing necessary for successful quality measures, presenting a less burdensome submission process. That said, the ACS would like the opportunity to submit improvement activities each year that are informed by the quality improvement cycle.

**Promoting Interoperability (PI)** (previously known as the Advancing Care Information Performance Category)

As we transition toward episode-based care with shared accountability, the need for digital information to flow between all members of a team and relevant systems will grow more complex, yet is critical to successful patient care. Therefore, a national model for accelerating interoperability across EHRs, mobile devices, registries and patient clouds which support this transition is critical to the future of our healthcare system. CMS states in the proposed rule that they are beginning a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. The ACS supports this increased focus, however the current digital environment cannot deliver the information needed by the surgical team to provide even basic care, and the current PI program perpetuates the continued development of one-off inoperable and siloed EHR products. The PI objectives and measures do not reflect true interoperability or support bidirectional health information exchange across multiple systems and platforms. In fact, the current PI measures detract from progress toward a learning healthcare system and simply add to reporting burden for surgeons. It is critical for CMS to realize that we are not going to solve interoperability problems with the current PI approach which focuses solely on EHRs and EHR functionality.

CMS and Office of the National Coordinator for Health IT (ONC) must work together to address the significant shortcomings of the PI performance category, starting with a more robust set of objectives and measures that capture actual functions of interoperability across multiple disparate providers, patients and systems. To this end, we have the following recommendations:

1. **CMS should collaborate with the ONC to aid specialty medicine and other stakeholders in the process of creating clinical conceptual models as a necessary first step toward building the technical logic models and applied terminologies and value sets needed for interoperability.** This is the process of translating clinical content in its context to enable the level of interoperability needed by the clinical team to provide the best care. Clinical knowledge can then be digitally exchanged when the computable logic models are translated into semantic interoperability. Furthermore, as clinical logic models turn into computable logic models, these should be open source for all
to use and held in a public-private partnership repository. From these repositories, individuals can create APIs for exchangeable knowledge.

2. **To enable digital health information interoperability across EHRs, mobile devices, registries and patient clouds, the government should take a stronger leadership role in public-private partnerships to foster working relationships between clinical experts and technology experts.** This should include establishing a framework, processes, overall governance, priorities, policies, support for resources needed to convene clinical content and context expertise alongside technology and standards expertise. The physician community, in collaboration with other stakeholders, would have a go-to home from which to select specific clinical domains to create interoperable solutions, and those domains would lead to open source interoperable digital standards.

3. **EHR certification standards should be created to require EHRs to be compliant with the described open source digital standards that meet criteria for clinical interoperability.** This would greatly aid in data liquidity, which would eliminate data blocking, and enable patient cloud environments.

In the past year, the ONC released a draft version of the Technical Exchange Framework and Common Agreement (TEFCA) and US Core Data for Interoperability (USCDI) for public comment. These documents include some of our above recommendations, but do not go far enough to include the entire digital ecosystem, still focusing on interoperability through EHRs.

As the new name of the Promoting Interoperability suggests, CMS is beginning a new phase of EHR measurement that has an increased focus on interoperability. In the opinion of the ACS, the PI category should focus on interoperability beyond just EHRs in order to leverage digital health information from any source, be it EHR or smart phones. During this new phase, EHRs should have to improve not only their read functionality, but their write functionality as well. Data exchange starts with read functionality and must eventually have write functionality to accomplish fully functioning interoperability. **We recommend CMS adopt PI measures of functional interoperability that focus on read and write functionality in order to accomplish greater interoperability among EHRs and other health information technology (HIT).** Furthermore, the government should act as an enabler through creating this as a standard which an EHR must have.

To illustrate our commitment to interoperability, the ACS is working with Healthcare Services Platform Consortium (HSPC) and Clinical Information Interoperability Council (CiIC) to advance the logic models needed. HSPC and
CiiC represent non-profit organizations which bring the clinical expertise and the informatics engineers into an implementable common strategy for building use cases for interoperability. ACS examples include building a common set of cancer standards for staging, for stage-specific treatment, and so forth. We also are working to build the surgical risk calculator as an automated digitally interoperable tool. These efforts are predicated on HL7 standards such as using Fast Healthcare Interoperability Resources (FHIR).

We recognize an overhaul of the current program is not possible in a short timeframe, however, we need fundamental reforms in the PI program to support a national model for accelerating interoperable solutions, which starts with the objectives and measures on which they are scored in the current PI performance category. The measures currently in the PI category focus on disparate, standalone functions of EHRs. For MIPS to truly become a quality improvement program that harnesses the functions of HIT to advance the practice of medicine, CMS needs to connect the PI measures to quality performance measures which then inform improvement activities for a full cycle of improvement. As detailed later in this letter, as one alternative, PI measures can be integrated into evidence-based verification programs to help track clinical quality through the use of digital services that can identify failure points and be used for corrective actions. This integration into a verification program would mean the measures for PI are part of the clinician’s workflow, reducing burden and increasing its meaningfulness. **Clinicians should be focused on clinical decisions at the point of care, not thinking about documenting for purposes of payment.** CMS should recognize what is meaningful to surgeons, including their ability to engage with patients, care team members, using clinical data registries and other data sources to improve surgical outcomes — starting with the decision for surgery and throughout the episode of care.

A detailed description of how ACS envisions the pathway to true interoperability can be found later in this letter in our comments to the “Request For Information On Promoting Interoperability And Electronic Healthcare Information Exchange Through Possible Revisions To The CMS Patient Health And Safety Requirements For Hospitals And Other Medicare- and Medicaid-Participating Providers And Suppliers.”

We look forward to working with CMS on ways to improve the use of digital health information that will support care across systems and providers.

**Certification Requirements Beginning in 2019**

As previously finalized, beginning with the 2019 performance period, MIPS eligible clinicians (ECs) must use 2015 Edition CEHRT to participate in the PI
performance category. Unlike year 1 and 2 of the MIPS program, clinicians will no longer be able to use 2014 Edition CEHRT or a combination of 2014 and 2015 Edition CEHRT to participate in the PI category. CMS asserts that 2015 Edition CEHRT provides more functionality, such as application programming interfaces (APIs), enhanced certification criteria, and standards that advance the interoperable exchange of health information.

While the ACS recognizes these additional functionalities in 2015 Edition CEHRT move in the right direction for achieving interoperability, we do not believe 2015 Edition CEHRT should be mandated for many reasons. First, the PI category is narrowly scoped to exchanging information between EHRs. As stated earlier, the goal should be the bidirectional exchange of information across the entire data ecosystem. Second, the initial and continued costs to upgrade and maintain CEHRT for MIPS are a barrier for many clinicians, disproportionally effecting small and rural practices. Third, there is no proof that 2015 Edition CEHRT helps to improve surgical care. Even with the addition of an API function it is still not useful to surgeons at this state because there are not well developed apps in the marketplace to leverage the API functionality within surgical care. For these reasons, ACS does not see the utility in narrowly mandating 2015 Edition CEHRT and requests the continued use of 2014 Edition CEHRT to meet the PI program requirements. Additionally, we strongly believe other non-CEHRT digital services which represent interoperability be permitted to meet the PI category requirements.

Narrow Scope

The ACS believes a complete overhaul of the PI category is necessary to make adoption and use of health information technologies and digital health information meaningful for surgeons. The current PI program perpetuates the continued development of one-off inoperable and siloed EHR products. The PI objectives and measures do not reflect true interoperability or support bidirectional health information exchange across multiple systems and platforms. In fact, the current PI measures detract from progress toward a learning healthcare system of continuous quality improvement and simply add to reporting burden for surgeons. It is critical for CMS to realize that we are not going to solve interoperability problems with the current PI approach, which focuses solely on EHRs.

Resource Barriers

CMS cited ONC in the CY 2019 IPPS rule, “That at least 66 percent of ECs and 90 percent of eligible hospitals and critical access hospitals (CAHs) have 2015 Edition available based on previous EHR Incentive Programs attestation data.”
The wording in this statement suggests 66% of ECs do not necessarily have 2015 Edition CEHRT, but that many of these ECs will need to upgrade their system. Additionally, this statement also suggests 1/3 of ECs would not be able to update to the 2015 Edition CEHRT without buying a new EHR. We seek clarity on these estimates.

We encourage CMS to approach this transition with flexibility in mind, as there is wide variation across the nation in healthcare organization’s capacity and resources to update their IT infrastructure, especially for small and rural practices. A recent GAO study reported that there are many challenges for small and rural practices, including selecting an EHR system that is best suited to meet their reporting needs, maintaining an EHR system, and that obtaining support from vendors may be magnified for small and rural practices. One stakeholder interviewed by GAO even stated a new EHR system can cost $400,000. The study also reported vendors routinely charge fees for services, such as adding certain measures into an EHR system or upgrading to new certification standards. In many cases, practices did not see a return on their investment

Even for the practices that already have 2015 Edition CEHRT, there are maintenance costs every year associated with changes to comply with new regulations. At the provider level, one analysis found that for an average five-physician practice, there was $85,500 in maintenance expenses during the first year. These constant changes are not just costly for clinicians, but require EHR vendors to divert their energy to compliance issues, rather than innovating their products.

We hope that CMS will keep this information in mind and not hold hospitals and eligible clinicians to the same standard in their ability to adopt and update their EHR and IT systems, since many small and rural physician groups struggle to justify using limited resources to adopt and update.

Utility for Surgical Care

The current measures in the PI category focus on the functions of 2015 Edition CEHRT, not it’s utility. The measures also do not enhance a quality improvement


cycle since they are not connected to clinical quality measures or other performance improvement categories. For the PI category to be meaningful for surgeons it needs to be integrated into a measurement system that is part of a quality improvement cycle.

While the additional functionalities of 2015 Edition CEHRT move in the right direction, the API function is not yet useful for surgeons since there are not relevant applications for surgical specialties. Only once the 2015 Edition CEHRT is completely ready to meet the specific needs of surgeons will it be beneficial for surgeons to devote their limited resources towards it.

For these reasons, we do not believe 2015 Edition CEHRT should be required. Instead of creating a system of mandated requirements, the ACS encourages a system that offers incentives, such as bonus points, for the uptake of HIT that advances the interoperable exchange of health information including, but not limited to, EHRs. We believe a regulatory system that provides rewards is superior to a system that mandates requirements because this will provide more autonomy for clinicians to make business decisions that reflect their needs, while moving in the future direction CMS envisions.

While this performance category continues to require refinements, we thank CMS for maintaining the automatic exemptions for special status clinicians and the PI hardship exception. We encourage CMS to explore adding more special status clinicians to the list of criteria for automatic exemptions, such as adding clinicians in small practices to this list so that they do not have to apply for an exemption. We also thank CMS for acknowledging the large role EHR vendors play in the ability of clinicians to participate in the PI category by adding new exclusions to previously existing PI measures.

Scoring Methodology

Scoring Methodology for 2017 and 2018 Performance Periods

During the 2017 and 2018 performance year of MIPS, the PI category scoring methodology consisted of three categories of measures: base, performance, and bonus. In this proposed rule, CMS shared that they received hundreds of questions requesting clarification of various aspects of the scoring methodology, as many clinicians found it overly complex and not intuitive.

The ACS has received many calls from our members asking for clarity on the PI scoring methodology, as well. We agree the current scoring methodology is overly complex and should be changed to be more intuitive. The ACS thanks CMS for acknowledging the confusion created by the PI category, and addressing
the need for change by proposing new scoring methodologies that streamline the
program and reduce burden. The following section fully details ACS’ thoughts on
how to build a meaningful scoring methodology for the PI category in MIPS.

Proposed Scoring Methodology Beginning with the MIPS Performance Period in
2019

CMS proposes two possible alternatives to the current PI scoring methodology:
The “proposed” scoring methodology and an “alternative” scoring methodology.
Both scoring methodologies would move away from the hybrid pay-to-report/pay-
for-performance methodology used in 2017 and 2018, to a purely pay-for-
performance scoring methodology beginning in CY 2019. CMS seeks comment
on which scoring methodology to adopt.

Proposed and Alternative Methodology

The primary methodology CMS proposes is as follows and is detailed in Table
36:

- Include a combination of new measures, as well as the existing PI
performance category measures, broken into a smaller set of four objectives
and scored based on performance. The smaller set of objectives would include
e-Prescribing, Health Information Exchange, Provider to Patient Exchange,
and Public Health and Clinical Data Exchange.
- MIPS eligible clinicians would be required to report certain measures from
each of the four objectives, with performance-based scoring occurring at the
individual measure-level.
- Each measure would be scored based on the MIPS eligible clinician’s
performance for that measure, based on the submission of a numerator and
denominator, except for the measures associated with the Public Health and
Clinical Data Exchange objective, which require “yes or no” submissions.
- Each measure would contribute to the MIPS eligible clinician’s total PI
performance category score. The scores for each of the individual measures
would be added together to calculate the PI performance category score of up
to 100 possible points for each MIPS eligible clinician.
- The MIPS eligible clinician would need to report on all of the required
measures across all objectives in order to earn any score at all for the PI
category. Failure to report any required measure or reporting a “no” response
on a “yes or no” response measure unless an exclusion applies, would result in
a performance category score of zero.
- The Security Risk Analysis (SRA) measure would remain part of the
requirements for the PI category, but would no longer be scored as a measure
and would not contribute to the MIPS eligible clinician’s PI score. To earn
any score in the PI category, CMS proposes that a MIPS eligible clinician would have to report that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the performance period occurs.

Table 36: Proposed Scoring Methodology for the MIPS Performance Period in 2019

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Measures</th>
<th>Maximum Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>e-Prescribing</td>
<td>e-Prescribing</td>
<td>10 points</td>
</tr>
<tr>
<td></td>
<td><strong>Bonus</strong>: Query of Prescription Drug Monitoring Program (PDMP)</td>
<td>5 points bonus</td>
</tr>
<tr>
<td></td>
<td><strong>Bonus</strong>: Verify Opioid Treatment Agreement</td>
<td>5 points bonus</td>
</tr>
<tr>
<td>Health Information Exchange</td>
<td>Support Electronic Referral Loops by Sending Health Information</td>
<td>20 points</td>
</tr>
<tr>
<td></td>
<td>Support Electronic Referral Loops by Receiving and Incorporating Health Information</td>
<td>20 points</td>
</tr>
<tr>
<td>Provider to Patient Exchange</td>
<td>Provide Patients Electronic Access to Their Health Information</td>
<td>40 points</td>
</tr>
<tr>
<td>Public Health and Clinical Data Exchange</td>
<td>Choose two of the following:</td>
<td>10 points</td>
</tr>
<tr>
<td></td>
<td>Immunization Registry Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Electronic Case Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Public Health Registry Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Data Registry Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Syndromic Surveillance Reporting</td>
<td></td>
</tr>
</tbody>
</table>

The “alternative” scoring methodology approach would be scored at the objective level, instead of the individual measure level, and MIPS eligible clinicians would be required to report on only one measure from each objective to earn a score for that objective. Under this alternative, instead of six required measures, the MIPS eligible clinician total PI performance category score would be based on only four measures, one measure from each objective. Each objective would be weighted similarly to how the objectives are weighted in its proposed methodology, and bonus points would be awarded for reporting any additional measures beyond the required four.

The changes to the proposed scoring methodology and measure set are a huge improvement and do a lot to streamline the requirements of the PI performance category. However, the “proposed” methodology continues the rigid, all-or-nothing approach of the current scoring methodology and does not provide clinicians with the flexibility that CMS envisions. The PI category remains too similar to the Meaningful Use legacy program, as many of these changes are superficial and do not go far enough to improve the performance category. The PI
category continues to not be integrated in a clinical workflow of a surgeon and remains siloed from other MIPS categories.

For 2018, MIPS clinicians must meet all of the base measures in order to be eligible for a score in the PI category. Under the “proposed” methodology, clinicians would still need to report on all of the required measures (i.e., at least a 1 in the numerator) across all objectives in order to earn any score at all for the PI category. Failure to report any required measure or claim exclusion would result in a PI score of zero. Thus, this proposal does not give clinicians full flexibility to pick and choose which measures is most relevant to their practice. **For these reasons, ACS supports a PI program that does not have an “all-or-nothing” approach.** We strongly believe that these scoring methodologies run contrary to past commitments by CMS to move away from an “all-or-nothing” reporting. ACS urges CMS to remove this requirement in order to receive a PI category score by allowing clinicians to gain category points on the measures they do report. **Between the primary proposal and the “alternative” scoring methodology, we support the “alternative” methodology because it is less rigid and provides clinicians with more flexibility to report measures which are part of their workflow.** Additionally, to further reduce burden, ACS recommends that CMS only require that clinicians attest to satisfying each measure for at least 1 patient instead of using a performance rate. Under this policy, each “yes” would be worth that measure’s potential points. A yes/no attestation-based approach would reduce operational burden, as well as help facilitate EHR development to be more responsive to real-world patient and physician needs, rather than designed simply to measure, track, and report.

In the short-term, to make the PI category more streamlined and approachable, **ACS requests that CMS only require clinicians to earn 50 performance category points to fully satisfy the PI category and receive 25 points toward the final MIPS composite score.** Clinicians should be able to pick and choose which PI measures to report, based on which are most relevant to their practice. They should not be **required** to report on any single measure in order to satisfy the minimum requirements of the category. If they can achieve 50 points by performing well on three measures, then that should suffice. The 50 point minimum aligns with the number of points hospitals must earn to be considered a “meaningful user” and avoid a penalty under the Hospital Promoting Interoperability Program, as finalized through the recent 2019 IPPS final rule. It would be inappropriate to hold clinicians to a higher standard since they often have fewer resources than hospitals. If CMS were to adopt a lower MIPS Performance Threshold (e.g. 20 points), along with a 50 PI category point minimum, clinicians can then fully meet the MIPS Performance Threshold by only participating in the PI category.
As a longer-term alternative, instead of having a rigid, all-or-nothing PI category based on the functionality of CEHRT, the goal of PI should function to capture data in the clinician’s workflow to identify areas for improvement as part of a clinician’s continuous quality improvement activities. We strongly suggest CMS consider a new approach for the PI program, which would create an incentive-based, tiered scoring methodology which rewards the bi-directional sharing of information and functionality across the digital ecosystem. The tiers can be divided into four general categories, starting with EHR interoperability, with data streams moving bi-directionally across EHRs, mobile devices, registries and clouds where the data can be used to support Clinical Decision Support (CDS), and eventually result in artificial intelligence or computer adaptive learning:

1. EHR ↔ EHR
2. EHR ↔ EHR ↔ mobile device
3. EHR ↔ EHR ↔ mobile device ↔ registries/clouds with Clinical Decision Support guidelines
4. EHR ↔ EHR ↔ mobile device ↔ registries/clouds with Clinical Decision Support guidelines ↔ machine learning / artificial intelligence

Promoting Interoperability/Advancing Care Information Objectives and Measures Specifications for the 2018 Performance Period

Measure Proposal Summary Overview

In this proposed rule, CMS seeks to reduce the number of objectives and measures in the PI performance category. CMS proposes to:

- Remove 4 measures: Patient-Specific Education; Secure Messaging; View, Download, or Transmit; and Patient-Generated Health Data
- Combine Request/Accept Summary of Care and Clinical Information Reconciliation measures into a single measure; Support Electronic Referral Loops by Receiving and Incorporating Health Information.
- Add 2 new measures: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement (OTA)

CMS states their intent for these proposed changes is to ensure the measures better focus on the effective use of health IT and reduce administrative burden. ACS recognizes CMS’ efforts to reduce burden and improve the PI performance category, but as stated earlier, believes the PI category requires a complete overhaul. In the short-term, we agree that these changes will reduce burden. ACS supports the removal of Patient-Specific Education, Secure Messaging, and View,
Download, or Transmit measures, as these measures are reliant upon patient action, which are outside a clinician’s control.

As discussed above, the ACS believes the PI category should be promoting bidirectional exchange of information across the entire digital ecosystem as part of the clinical workflow and identify areas for clinical quality improvement. With the proliferation and ubiquity of smart devices, we believe CMS should continue to encourage the use of patient-generated healthcare data, and believe the Patient-Generated Health Data measure should be modified to better capture the measure’s intent.

Additionally, CMS needs to recognize the many changes made from year-to-year in the PI performance category, including changing the names of objectives and measures, which add to clinician confusion and frustration with MIPS. We ask CMS to keep this in mind in future rulemaking as the program needs more stability and consistency to gain greater acceptance and adoption amongst the surgeon community.

**Security Risk Analysis Measure**

In previous years, the SRA measure was required under the Protect Patient Health Information Objective. The SRA requires clinicians to attest “yes” to conducting or reviewing a security risk analysis, implementing security updates as necessary, and correcting identified security deficiencies. In this proposed rule, CMS plans to eliminate the Protect Patient Health Information Objective and make the SRA a standalone, unscored measure that must be performed during the performance year in order to be eligible to earn any score for the PI category. CMS is seeking comment on whether the SRA measure should remain part of the program as an attestation with no score, or whether points should be associated with this measure.

If the SRA measure is kept as part of the PI category, the ACS believes clinicians should receive credit for the work done and resources spent. Clinicians recognize the importance of keeping their patient’s electronic public health information (e-PHI) secure, but have difficulty properly conducting an SRA because they are not cybersecurity experts, often requiring them to hire outside consultants to complete the SRA. Therefore, the technological, encryption, and other cybersecurity components of the SRA should be shifted toward the health IT vendor and

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not a burden placed on clinicians. Vendors create the products and have better technical know-how than their customers. Clinicians would still attest to conducting an analysis of the human, natural, and environmental threats to their information systems that contain e-PHI. However, we have moved beyond the days where sending medical records via fax to the wrong recipient was a major risk. Today, hackers and ransomware threaten our systems and require much more technical mitigation that only a health IT vendor has the expertise to address.

Ideally, CMS would provide the standards that products would have to meet to pass the SRA to the IT vendors, and then the vendors attest to their customers that their product conforms to the CMS standard. For example, this can be similar to what is done in the automobile industry in regard to certifying catalytic converters. The vehicle owner is required to maintain their catalytic converter and may have a rough idea of its purpose, but they would not be able to evaluate if a catalytic converter is working properly—nor is it necessary to know the ins-and-outs of a catalytic converter to operate a vehicle. Rather, the automobile manufacturer tests and meets the requirements of the Environmental Protection Agency (EPA) certification process in order to be market-ready for customers to use, and when the vehicle needs maintenance it is brought to an automobile mechanic. CMS should consider adopting a similar process for CEHRT and HIT so technical experts are the ones ensuring not only the foundational security of the products they produce, but that the products are being implemented correctly in the field, that security updates are being deployed properly and when necessary, and that deficiencies are correctly identified and addressed. The ACS welcomes the opportunity to work with CMS on how they could implement this alternative.

Promoting Interoperability Performance Category Measure Proposals for MIPS Eligible Clinicians

Measure Proposals for the e-Prescribing Objective

The ACS puts the welfare of our surgical patients above all else, and we believe that surgeons, as prescribers, can play a role in optimizing pain management strategies that will decrease frequent and prolonged opioid use. Pain is an inevitable, but undesirable, consequence of surgery, and while opioid-based pain control for the postoperative patient is a therapy supported by numerous national medical specialty societies, these prescriptions carry risks, which include chronic usage, addiction, and overdose. In the midst of this public health crisis, surgeons have a major responsibility to understand and mitigate the risks associated with prescribing opioid analgesics and to participate in a broader solution.

As CMS engages in efforts to reduce the number of individuals who improperly or unnecessarily receive opioid analgesic prescriptions, it is critical that
physicians be involved in such activities. The ACS, with its 100 year history in establishing standards for the national improvement of surgical care, is committed to the implementation of a multimodal plan focused on policy, physician education, and patient/caregiver education to address opioid abuse.

The ACS seeks to assure that surgical patients continue to have adequate pain control and receive the proper postoperative care needed to restore their overall health and avoid prescription opioid-related complications. We believe that surgeons have a responsibility to minimize their patients’ postoperative pain while addressing the societal imperative to avoid overprescribing, and in 2017 developed the following five principles to guide our efforts in preventing opioid abuse and addiction in surgical patients:

![](acs-guiding-principles-to-prevent-opioid-abuse-and-addiction.png)

CMS has identified two new measures which align with broader HHS efforts to combat the opioid epidemic and increase the use of Prescription Drug Monitoring Programs (PDMPs) to reduce inappropriate prescriptions, improve patient outcomes, and promote more informed prescribing practices. CMS proposes to
add two new measures to the e-Prescribing objective that are based on electronic prescribing for controlled substances (EPCS): “Query of PDMP” and “Verify Opioid Treatment Agreement.” For both measures, CMS proposes to define opioids as Schedule II controlled substances. Initially, these measures would be optional to report, but available for bonus points, given they may not be fully developed by their health IT vendor or not fully implemented in time for data capture and reporting in 2019. These measures will then be required to report in the 2020 performance year.

Proposed Measure: Query of Prescription Drug Monitoring Program (PDMP)

Under the e-Prescribing Objective, CMS is proposing a new measure, Query of PDMP, which will measure the use of data from CEHRT to conduct a query of a PDMP for Schedule II opioid prescriptions. The ACS supports the intent of this measure as we believe the use of PDMPs is a strong tool in the fight against the opioid epidemic, but we do not support the measure as written and believe the measure should remain optional for the 2020 performance year.

PDMPs, which are statewide databases that collect information on the distribution of controlled substance prescriptions, can be used to track opioid prescriptions in some manner in all states except for Missouri. While the ACS has promoted the use of PDMPs to inform clinical decision-making and facilitate intervention at the point of care, we remain concerned that PDMP data are not standardized and are poorly integrated into existing workflows. Further, each state with an established PDMP has its own set of laws governing what type of drug use data are available, what type of prescriber can access the PDMP, and how the data are shared. Currently, PDMPs largely operate as outdated repositories that do not provide physicians with the real-time, actionable information needed to determine a patients’ pattern of prescription drug purchase or prior therapies (such as methadone or buprenorphine prescriptions) used to treat opioid use disorders. In addition, PDMPs do not effectively share data across states, enabling patients who live near state borders to duplicate opioid prescription purchases in each state without the prescribing physician’s knowledge. As a result of these inefficiencies, checking PDMPs is cumbersome, time-consuming, and may yield incomplete information.

The country’s opioid crisis highlights the need for digital solutions that break down data silos and provide prescribers with comprehensive, patient-specific information. Prescription history databases, whether established at the state or national level, must interact and share information to be effective and important clinical tools that will allow surgeons to better identify patients at high risk for opioid prescription abuse and tailor their prescribing behavior accordingly. An ongoing push toward standardized databases with the ability to share information
across state borders is essential to ensuring physicians receive accurate information, and the ACS strongly believes that there must be interoperability in the data contained in PDMPs with electronic health records (EHRs) and secure, mobile digital health information and e-prescribing systems available to physicians using such devices as smartphones to streamline accessibility and promote patient safety. Integration of PDMPs into the clinical workflow could greatly improve feasibility of checking patterns of patient opioid prescription purchases and thereby increase utilization. We encourage CMS to explore opportunities to build upon the existing PDMP foundation and leverage health information technologies to support the functionality of PDMP data within EHRs or other secure mobile digital health information and e-prescribing systems, opportunities to initiate or expand interstate data sharing, ways to facilitate secure prescriber-pharmacy communication, and how to establish benchmarks to assess PDMP use.

To combat this widespread issue, CMS and ONC should work towards making one national standard for PDMPs and reward clinicians who use the national standard. As CMS and ONC work to implement national standards for PDMPs and to ensure that they are used more consistently and universally across the nation, the agencies should also work with vendors to amend the EHR certification process and other secure, mobile digital health information systems so that it includes rules about PDMP queries and data exchange. Until these issues are addressed, CMS should not mandate this measure for 2019 and beyond.

Proposed Measure: Verify Opioid Treatment Agreement

CMS proposes to introduce another measure to the e-Prescribing Objective, Verify Opioid Treatment Agreement (OTA). This measure is defined as, “For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS EC using CEHRT during the EHR reporting period, if the total duration of the patient’s Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look back period, the EC seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient’s electronic health record using CEHRT.”

The ACS agrees that there needs to be better exchange of information of a patient’s treatment plan at the point of care. In the battle against the opioid epidemic, ACS stresses the need for patient engagement and education on the risks associated with opioids. While many providers find the use of OTAs to be
beneficial, there are mixed findings for the value and appropriateness of OTAs in the literature24. As such, we appreciate that the measure verifies if an OTA exists, rather than mandating the creation of an OTA. Surgeons should have the autonomy to determine the most useful tools for treating surgical patients.

**Feasibility of Reporting the Verify Opioid Treatment Agreement**

CMS raises many feasibility issues regarding an EC’s ability to meet the Verifying Opioid Treatment Agreement measure, especially the varied opinions of OTA utility amongst clinicians, differing prescribing practices, and lack of standardization across States. This measure is dependent on the documentation done by other providers, which is not standardized. To improve the clinician’s ability to successfully meet this measure the OTA needs to be easily searchable in EHRs and displayed in a universal format. The ACS agrees with CMS that there are many feasibility issues with this measure that must be resolved before it is a required measure. As was finalized in the CY 2019 IPPS final rule, we urge CMS to maintain this measure as voluntary in the 2019 and 2020 performance years.

**Characteristics That Should Be Included in an Opioid Treatment Agreement**

The ACS believes that the OTA should be one part of a comprehensive treatment plan. This approach would have a patient’s opioid treatment agreement nested (in a standard format) into their general treatment plan, so the OTA is displayed as just one aspect of the totality of care. This approach will promote an OTA’s utility because it will be easier for the provider to use the OTA in the context of how they will communicate with patients to foster shared decision making at the point of care. Overall, the ACS believes this measure needs further refinement and would benefit from a formal measure development review process where many of CMS’ feasibility concerns can be evaluated.

**Proposed Removal of the Patient-Generated Health Data Measure**

CMS proposes to remove the Patient-Generated Health Data (PGHD) measure beginning in the 2019 performance year. CMS explained the measure did not accomplish its intended goal since it is not fully health IT based and CMS did not

specify the manner in which health care providers would incorporate the data received.

While the PGHD measure did not accomplish its goal, the ACS sees value in the intent of the measure. The ONC has been working on improving this measure, and even recently published a whitepaper that details a future policy framework for PGHD. ACS supports ONC’s efforts to improve this measure as PGHD creates a pathway for advancing care coordination, improving the patient-provider relationship, and fostering innovation. PGHD also aligns to the MyHealthEData Initiative by putting patients at the center of care by generating their own data and controlling its distribution. The activity in the private sector is also making this measure increasingly more feasible as technology companies create health applications that capture biometric data, as well as house traditional health information. For example, Apple’s recent efforts with their HealthKit application use FHIR resources to access an individual patient’s health information on different platforms and store the information on a patient’s personal smart device. That patient may use Apple compliant applications to provide representations of their personal health to them on their mobile phone.

As stated earlier, ACS believes the PI performance category should not be confined to EHRs, but the entire digital ecosystem and part of the clinical workflow. The PGHD measure is truly innovative and can take advantage of integrating data from the proliferation of smart devices, like smartphones, smart watches, and remote monitoring devices to improve patient-centered care. We advise CMS to closely follow ONCs work in this area, as they may be able to identify how to modify this measure to better capture its intended goal. Once the measure specification issues are resolved, CMS should once again propose the PGHD measure for inclusion in the PI category in future rulemaking.

Proposed Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures

In 2018, the Public Health and Clinical Data Registry Reporting objective was not required as part of the base score, but was eligible to gain points in the performance and bonus score. CMS is proposing to change the name of the objective from Public Health and Clinical Data Registry Reporting to Public Health and Clinical Data Exchange. CMS also proposes that a MIPS clinicians would be required to submit 2 of the 5 measures associated with the objective: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting. Additionally, since these measures were not required in 2018, CMS proposes to add exclusion criteria for each of the Public Health and Clinical Data
Exchange measures beginning with the performance period in 2019.

**ACS strongly believes this objective should be a bonus, and not required for successful participation.** The path for participation and exclusion is convoluted and will require an onerous amount of effort on the part of the clinician. For surgeons to be able to confidently meet the requirements of this objective there needs to be a clear path and proper resources. We ask that CMS create user-friendly resources clinicians can use to search for registries that qualify for measures under this objective. As of right now, the CMS resource page directs people to AHRQ’s Registry of Patient Registries, but this resource does not indicate if a registry qualifies for reporting under the Public Health and Clinical Data Exchange objective. We also would like to reiterate our comments from last year that CMS should provide clearer guidance on the requirements (including documentation requirements) associated with each of the stages of “Active Engagement,” since many clinicians and registry vendors still do not fully understand what distinguishes one stage from another, as well as what it actually means for a registry to “Declare Readiness,” since the guidance in this space has been vague.

**Until there is a clear, established path nationally for clinicians and registry vendors to meaningfully participate with this measure, the ACS opposes this as a requirement to report.** Clinicians that are not part of a hospital or large system will go through an onerous process to determine eligibly, apply for exclusions, and establish new workflows or solutions to meet this objective. **Instead, we believe the Public Health and Clinical Data Exchange objective should be voluntary and eligible for bonus points in performance year 2019.**

ACS does see a clear path for how registries can promote interoperability in the MIPS program. Registries are a key component to many of the ACS quality improvement programs, because they are powerful tool for quality improvement. Registry reporting is required as part of ACS verification programs in cancer, trauma and bariatrics in order to identify failure points, drive improvement, and track disease longitudinally. The electronic capture of clinical data across these registries informs improvement activities for a cycle of improvement that is a natural part of the clinical workflow, while promoting interoperability. For further discussion on how ACS believes registries can be used in MIPS via verification programs in the future, see section of this letter titled *Future Approaches to Scoring the Quality Performance Category.*

**Many of the measures in the Public Health and Clinical Data Exchange objective are not applicable to surgical care.** Not only are many of the measures not applicable to surgical care, they are also not in the surgical workflow, making the measures a burden that takes away from patient care. This
objective requires clinicians to take on the onerous task of identifying their eligibility, claiming exclusions to multiple measures if they do not meet the requirement to report more than one of the measures, and establish new processes/workflows to meet the measures applicable to them. Individual clinicians and small practices do not have the same capacity as hospitals and should not be held to the same requirements under the hospital Promoting Interoperability program. Hospitals likely participate in registries that meet this measure already and have large administrative staff dedicated to compliance, whereas individual clinicians and small practices have a lean staff and likely do not currently participate in the registries that meet the measures in this objective.

**CMS should consider expanding the options under this objective so there are more relevant alternatives for surgeons.** One possible addition is including participation in PDMPs as an option to participate in this objective, as this is widely applicable across surgical specialties and surgeons would know for sure if they can currently meet this measure. Additionally, the wider use of PDMPs is a goal of HHS’s opioid epidemic efforts and this provides another policy lever to incentivize their uptake in a non-mandatory way. CMS should also consider expanding the objective to include risk-adjusted, outcome-based clinical data registries, like NSQIP, as it is strong data resource for public health research and quality improvement.

The ACS thanks CMS for adding exclusion criteria to the measures in this objective, as many of these measures are not applicable to surgeons and would make them unable to successfully participate in the PI category. However, as noted earlier, we do not believe that clinicians should be burdened by having to file exclusions for irrelevant measures.

**Request for Comment – Potential New Measures Health Information Exchange Across the Care Continuum**

CMS solicits feedback on two new potential measures for inclusion in the Health Information Exchange objective: “Support Electronic Referral Loops by Sending Health Information Across the Continuum” and “Support Electronic Referral Loops by Receiving Health Information Across the Care Continuum.” The first measure is described as, “for at least one transition of care or referral to a provider of care other than a MIPS EC, the MIPS EC creates a summary of care record using CEHRT; and electronically exchanges the summary of care record.” The other measure, Support Electronic Referral Loops by Receiving Health Information Across the Care Continuum is described as, “for at least one electronic summary of care record received by MIPS EC from a transition of care or referral from a provider of care other than MIPS EC, the EC conducts clinical information reconciliation for medications, mediation allergies, and problem list.”
CMS seeks comment on whether these two measures should be combined into one so that a clinician engaged in exchanging health information across the care continuum may include any such exchange in a single measure. CMS also seeks comment on whether additional settings of care should be considered for inclusion in the denominators, and if a provider should be allowed to limit the denominators to a specific type of care setting based on their organizational needs, clinical improvement goals, or participation in an alternative payment model.

**Combining the Two New Potential Measures**

While the ACS supports the intention of these measures, the measures are not entirely parallel to one another. The measure regarding “sending health information” requires the full summary of care record; the “receiving information” measure requires just medication, medication allergies, and current problems list. Exchanging information with send and receive functionality is a major step in the right direction. The exchange of information should be in a standardized, machine readable format so that the information is enabled into the clinical workflow and not merely exchanged and filed in folders in the digital health information database. In addition, if the information exchanged is machine readable in standard formats, the full summary, medications, allergies and problem lists could be bi-directionally shared, without being inconsistent with what information could be sent and what could be received. In this way, combining the send/receive measures into one would provide optimal data exchange and the information could be leveraged and fit for whatever purpose is needed to better deliver care.

**Limiting the Potential New Measures to Transitions of Care and Referrals Specific to Long-Term and Post-Acute Care, Skilled Nursing Care, and Behavioral Health Care Setting:**

“Support Electronic Referral Loops by Sending Health Information Across the Continuum” and “Support Electronic Referral Loops by Receiving Health Information Across the Care Continuum.”

CMS solicits comment on whether the denominator of the potential new measures should be limited to transitions of care and referrals to long-term and post-acute care, skilled nursing care and behavioral health care settings. **We believe this measure should not be limited to these points of care and should be available to all of the settings clinicians interact with** in order to encourage the exchange of health information to all of the providers that care for a patient across the care continuum.
While we support the broadening of the denominator to ensure coordination with all types of settings, the ACS also supports allowing providers to limit the denominators to a specific type of care setting based on their organizational/clinical needs, as appropriate. This way, no setting is excluded, but providers will not be burdened with having to demonstrate this functionality in settings where they do not have adequate control over HIT choices and management.

**Incentivizing Write Functionality Within EHRs**

“Support Electronic Referral Loops by Sending Health Information Across the Continuum” and “Support Electronic Referral Loops by Receiving Health Information Across the Care Continuum” measures bring a larger issue to light that affects the measures’ ability to be implemented in a meaningful way for patients and providers. EHRs currently allow end users to use “receive” functions, like reading their allergy or medication list, but there is a lack of willingness of HIT vendors to allow users to use “write” functionalities within their EHR. Write functionalities within the EHR allow end users to more easily add, display, and share information to other end users. **CMS should seek policy levers to incentivize EHR vendors to integrate “write” functionalities in their products.**

The ACS welcomes the opportunity to work with CMS on exploring how this could be implemented.

**APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs**

CMS proposes to change the order in which the requirements in the third APM criterion are listed to state that the APM bases payment incentives on performance on quality measures and cost/utilization, and further to modify regulations to specify that a MIPS APM must be designed in such a way that participating APM Entities are incented to reduce costs of care or utilization of services, or both.

ACS agrees that this change helps to clarify CMS’ intent and appears to be consistent with the intent of the MACRA statute. ACS also welcomes the flexibility granted by CMS’ clarification that the first performance year for an APM is the first year in which quality reporting is required for the full performance period, even if the APM begins after that date.

**MIPS APM Criteria**
The ACS sees potential benefits in MIPS APMs both as an important step on the pathway toward value-based payment in Advanced APMs as well as a means of reducing administrative burdens through streamlined reporting in MIPS. For those practices who are risk averse and with viable options available, MIPS APMs will provide a logical first entry into this type of payment model. The MIPS APM Scoring Standard should reduce reporting burden on individual practices to allow them to focus on improving care. For these benefits to be realized, it is important that the regulations implementing this reporting option be understandable and to the extent possible should be identical to, or compatible with those implementing Advanced APMs and Other-Payer APMs. However, as noted in other sections, ACS continues to have concerns that the current quality and cost measurement framework throughout the QPP is frequently not reflective of the work of surgeons and may not provide accurate information on the quality of care they provide or actionable insights for improvement.

Calculating MIPS APM Performance Scores

Quality Performance Category

CMS is proposing that in order to reduce burden on solo practitioners, it will modify the exception for participants in MSSP Accountable Care Organizations (ACOs) that do not report quality measures such that beginning in 2019, solo practitioners would be allowed to report on any available MIPS measures, including individual measures, in the event that their ACO fails to complete reporting for all Web Interface measures.

CMS is also proposing that, beginning with the 2019 performance period, the complete reporting requirement for Web Interface reporters be modified to specify that if an APM Entity (in this case, an ACO) fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, they will score the CAHPS for ACOs survey and apply it towards the APM Entity’s Quality performance category score.

ACS believes that these common-sense proposals will allow for the fair assessment of APM participants in the unlikely case that the ACO in which they participate does not submit the required information. Furthermore, allowing solo practitioners to submit data on available MIPS measures will help to reduce burdens on these individuals while allowing them the opportunity to report and have their performance scored in the event the ACO does not meet its reporting obligations.

Promoting Interoperability Performance Category
CMS proposes that beginning in the 2019 MIPS performance period to allow MIPS eligible clinicians who participate in the Medicare Shared Savings Program (MSSP) to report on the PI performance category at either the individual or group level like all other MIPS eligible clinicians under the APM scoring standard.

While ACS has significant concerns about the direction of the PI performance category in general, we believe that providing additional options for MIPS eligible clinicians to participate in a way that is reflective of the way in which clinicians are organized for care delivery is a positive step.

**MIPS Final Score Methodology**

**Quality Measure Benchmarks**

As discussed throughout this letter, the current measure results misinform patients and result in multiple disparate data systems on measures that lack meaning for surgery. As we previously discussed, accurate measurement requires more than common definitions or common data elements found in measure specifications. This was demonstrated when ACS harmonized the ACS NSQIP SSI measure with the Centers for Disease Control and Prevention CDC National Healthcare Safety Network (NHSN) SSI measure when measuring in the same facilities. After harmonization, 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 rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP.25

**Therefore, the MIPS measurement systems need rigor in common data aggregation, common data analytics, and reporting. We strongly urge CMS to use a single source of truth for establishing benchmarks and driving improvement within a clinical domain.** Without that single source, CMS complicates data benchmarking and meaningful use of the knowledge gained. These single sources not only help patients and surgeons, they help the payers in consolidating knowledge into a report from one source to aggregate data for that clinical domain. This establishes a high statistical rigor which would mean that for a given disease all data are defined one way, interpreted and aggregated consistently, normalized consistently, analyzed, and reported by the same methodology for all providers who report on that clinical domain.

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The STS National Database is an example of consistency across measurement because one data system exists for a small number of operations, allowing for a single method for data aggregation, analytics, and reporting. If STS had multiple vendors collecting and analyzing data, results would not be as useful even after large expansive efforts. Currently, there are 5 registries reporting on the General Surgery Specialty Measure Set, and 21 reporting on the ACS Surgical Site Infection (SSI) measure. This means CMS publishes the measure specifications, then companies like CE City, Fig, Epic, and ACS aggregate their own version of the measure, some risk adjusting the data, some not, each reporting to CMS. It is impossible to reconcile all those data into a single benchmark for payment.

As discussed later in this proposed rule, CMS should work with QCDRs to establish consistency in registry measures in order to allow for the establishment of QCDR benchmarks. Due to the year-to-year measure changes required by CMS for approval of our QCDR measures sets, there is no consistency or stability. As a result, there have been a very low number of surgeons who report on QCDR measures. Adding to these challenges is that the lack of stability in QCDR measures from year to year prevents QCDR measures from developing benchmarks—resulting in many QCDR measures scored at 3 points. This disincentives clinicians to report QCDR measures, does not enable a quality target for improvement, and contributes to the overall complexity of the MIPS program.

Assigning Points Based on Achievement

*Floor for Scored Quality Measures*

For the 2019 MIPS performance period, CMS proposes to continue to apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. **ACS appreciates the stability in the 3-point floor and believes that this will reduce confusion across clinicians and will help to reduce burden.**

*Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks*

For the 2019 performance year, CMS does not propose any changes for measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data completeness criteria for the CY 2019 MIPS performance period. CMS also proposes to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend regulation text accordingly. Measures submitted by small practices would continue to receive 3 points for all future CY MIPS performance periods, although CMS may revisit this policy through future rulemaking. ACS
appreciates the consistency and stability carried over from the 2018 performance year, but urges CMS not finalize policy which assigns zero points for measures that do not meet the data completeness starting in the 2020 performance year. Due to the complexity and associated burden, we believe it is important to recognize clinicians who put in effort to report, versus those who report no data.

**Small Practice Bonus**

In the CY 2018 QPP final rule, CMS finalized the addition of a small practice bonus of 5 points to the final score for the 2018 MIPS performance period for MIPS eligible clinicians, groups, APM Entities, and virtual groups that meet the definition of a small practice and submit data on at least one performance category. However, for the 2018 performance year, CMS proposes to change the small practice bonus. Instead of applying 5 points to the MIPS Final Score, the agency proposes to add 3 bonus points to Quality component of the MIPS score. CMS explains that they propose this change because small practices are less likely to submit quality performance data, less likely to report as a group and use the CMS Web interface, and more likely to have lower performance rates in the Quality performance category than other practices.

However, despite CMS’ rationale that small practices have very low performance in the Quality category, the overall impact of the proposed 3-point bonus will be of less value to their MIPS Final Score and therefore deflate small practice bonus. In the example CMS provides, the agency notes that for many clinicians in small practices, the Quality performance category weight may be up to 85 percent of the final score (this would be the case if a small practice applies for and meets the PI hardship application and does not meet the case volume minimum for Cost). With a weight of 85 percent, a small practice bonus of 3 points added to the quality performance category will result in 4.25 bonus points added to the final score for clinicians in small practices. CMS explains that they think this is appropriate because it is similar to the impact of the small practice bonus CMS finalized for the 2018 MIPS, which provided an additional 5 points to the Final Score.

ACS does not support this proposal. This would unfairly disadvantage small practices that could be assessed under the Cost performance category, or that choose to report under the PI performance category rather than seeking an exception. This proposal also overly relies on reweighting of those categories to reach almost-comparable levels of bonus points that are available for MIPS performance in 2018. And, it is also our understanding that CMS does not have data to suggest small practices performed better in MIPS than expected so it is unclear why the agency would deflate this bonus. Furthermore, changing this unnecessarily adds confusion and instability to the overall MIPS program. Lastly, as discussed in the *Flexibility for Weighting Performance Categories* section, we
strongly support shifting the PI weight to IA instead of quality in cases where clinicians qualify for an exemption since the quality category lacks reliability, validity and meaning for surgery—if this policy were implemented, the small practice bonus would be even more deflated. For these reasons, ACS does not support a 3-point bonus added to the MIPS quality component and urges CMS to continue to offer a 5-point bonus to the MIPS Final Score.

Future Approaches to Scoring the Quality Performance Category

Defining Surgical Value: ACS Alternative Proposal for Measurement in MIPs

In the proposed rule, CMS notes that it is considering alternative mechanisms to reduce MIPS reporting burdens and make the program more meaningful to clinicians. One of the concepts CMS has been exploring is linking performance categories—Quality, Improvement Activities and Promoting Interoperability—to reduce burden and create a more cohesive and closely linked MIPS program. CMS discusses that one possibility is to establish several sets of new multi-category measures that would cut across the different performance categories and allow clinicians to report once for credit in all three performance categories. CMS seeks comment on this reporting model, as well as measure and activity suggestions to enhance the link between the three performance categories.

ACS greatly appreciates CMS soliciting feedback on how to reduce burden and to make the MIPS program more meaningful. We strongly believe CMS’ current measures put patients at risk by distracting surgeons and delivery systems from meaningful measures in order to perform within CMS’ sporadic measures which were designed for a payment program and do not represent a true quality improvement program. In addition, surgeons are placed at risk of being misclassified based on the CMS MIPS metrics which lack validity and reliability. We seek to ensure that surgeons are not misclassified and that accurate representations of surgical care are used to determine payment rewards and penalties. We need data that is more reliable and valid, covering a broader cohort of surgical patients. ACS strongly supports the concept of linking performance across categories, and we are eager to deliver solutions to these challenges to assist CMS in developing a true quality improvement program. We welcome a meeting with CMS to discuss a framework we are developing which could be used to measure surgical care in the QPP program.

To frame our conceptual framework for linking performance categories, first it is critical to establish the meaning of value during this transition of fee-for-service into the next payment model CMS wishes to promote. We believe patients must have reliable and understandable knowledge about quality and cost for individuals (patients, payers, surgeons and other clinicians) to pass judgment on the value of
care in the QPP. Once patients have access to that information in a format they can understand, they can apply judgement to the value equation \( V = \frac{Q}{C} \). Below we consider how to define surgical quality and cost in the QPP program, as well as how the described program could be scored.

**Defining Surgical Quality.** With more than 50 million operations performed in the US annually, there exists a tremendous need to improve the quality of surgical care and define surgical value from the perspective of the patient. The ACS has been at the forefront of surgical quality measurement and improvement for more than 100 years. Our experience at the ACS is that the power in creating a culture of quality, safety, and improvement comes from a trusted set of evidence-based standards applied in a verification program, built upon high-quality, reliable data by employing the four ACS Principles for Continuous Quality Improvement: 1) tracking standards individualized to the patient and based on research, 2) using the right infrastructure including quality processes, checklists, equipment and staffing/specialists 3) rigorous attention to highly reliable data, including post-discharge tracking and 4) verification of overall program implementation at the point of care with an external peer-review process which creates public assurances.

As illustrated in Figure 1 below, we offer an alternative solution to the current QPP program which could act as a paradigm for all surgical quality measurement by ensuring surgeons have meaningful measures that are relevant to their patients and their practice, drive improvement towards better patient outcomes, and minimize the burden of data collection. We believe that this framework defines healthcare value in a patient-centric way based on episodes of care with intent to represent accountability across a clinical domain. **This proposed framework will need to be tested and validated.**
Figure 1. Conceptual Framework for Measuring Surgical Quality in MIPS \textsuperscript{26, 27, 28, 29}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{Conceptual Overall MIPS Score}
\end{figure}

\begin{itemize}
\item \textbf{Examples of Verification Programs:}
  \begin{itemize}
  \item Commission on Cancer (CoC) Accreditation Program\textsuperscript{26}
  \item Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)\textsuperscript{27}
  \item National Accreditation for Breast Centers (NAPBC)\textsuperscript{28}
  \item Trauma Verification, Review, and Consultation (VR&C) Program\textsuperscript{29}
  \item Enhanced Recovery After Surgery (ERAS) Standards
  \end{itemize}
\item \textbf{Examples from PRO Composite Measure:}
  \begin{itemize}
  \item Surgeon Communication before surgery
  \item Surgical Goals of Care
  \item Satisfaction with Information
  \item Postoperative Care Coordination
  \end{itemize}
\item \textbf{Clinical Data (Low event operations):}
  \begin{itemize}
  \item Surgical Site Infection (SSI)
  \item Readmission rates
  \item Etc.
  \end{itemize}
\item \textbf{Clinical Data (operations with rare events or limited scope):}
  \begin{itemize}
  \item SSI
  \item Readmission rates
  \item Etc.
  \end{itemize}
\item \textbf{Hybrid of both Claims & Clinical Data}
\end{itemize}

MIPS score encompasses activities that would meet requirements for Improvement Activities & Promoting Interoperability performance categories.


As illustrated above, the MIPS score could be based on the three components of how ACS defines quality:

1. **Patient-reported Outcomes (PROs).** The majority of surgical procedures are elective with the goal of improving a patient’s quality of life and/or function.\(^{30,31,32}\) Therefore, for most procedures, the outcome reported by the patient and for which the patient is the best source of success of the procedure. Additionally, most elective procedures have very few serious clinical events, which highlights the fact that PROs can be used to distinguish variability across clinicians and groups.

ACS is working with clinical experts from the Brandeis University, Brigham and Women’s Hospital, and University of Rochester Medical Center to deploy our quality measurement prototype for improving measures in patient reported outcomes for surgical care. We believe this framework could generate comprehensive assessments of surgical quality encapsulating both surgeons’ and patients’ perspectives across episodes of surgical care.

2. **Participation in a Standards-based Verification Program.** Our experience at the ACS is that the power in creating a culture of quality, safety and improvement comes from a trusted set of evidence-based standards applied in a verification program, built upon high-quality, reliable data. It is well documented in the literature that conformance to evidence-based standards yields better outcomes.

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\(^{29}\) Committee on Trauma, American College of Surgeons. “Resources for Optimal Care of the Injured Patient.” https://www.facs.org/~media/files/quality%20programs/trauma/vrc%20resources/resources%20for%20optimal%20care.ashx


The PI and IA requirements for MIPS could be included as standards within a verification program. For general surgery, we envision three levels of verification — Level 1, 2, and 3 which would be comparable to the process used for the ACS Trauma verification program. In this example, we could identify key processes that track failure points in surgical care across an episode of care, with the use of ERAS protocols tailored to a specific case.

3. Clinical Outcome Measures. Depending on the type of episode, this component of the score could measure accuracy of clinical outcome measures developed using claims data only, registry data only, and hybrid claims-registry data. We hypothesize that for certain operations where adverse outcomes are rare or are limited in scope, it may be possible to utilize claims data alone to validly and reliably evaluate performance; whereas, for other operations where adverse outcomes are common or can vary widely in scope, it may be necessary to utilize registry data or at least a combination of claims and registry data. For general surgery, we could determine (1) which clinical outcome measures can be accurately implemented using claims data alone to minimize burden while ensuring appropriate validity and reliability for performance assessment, and (2) which clinical outcomes measures must utilize registry data, albeit more burdensome but justifiably so.

This model relies on validation of successes by measuring outcomes using clinical data analytics which partially depend on bi-directional automated interoperability for data exchanges to and from registries. Our proposal simultaneously is integrated into surgical workflows while reducing burden by measuring compliance with standards through triennial surveys, rather than measures linked to CPT or DRG codes. Such surveys exist in thousands of delivery systems today with demonstrated success in trauma, cancer, and bariatric surgery.

Defining Surgical Cost. Critical to determining value in the QPP program is how to define the cost of care. In terms of the value statement, the cost refers to the payer and patient’s combined total cost of care (TCOC) for all the services included within the predefined episode. These costs differ from the operational costs of delivering the service. It is also important to define the costs from a patient’s out-of-pocket perspective which will vary by their insurance. Some patients have annual insurance plans with high cost deductibles, significant co-pays and lower premiums. Others have low deductibles and co-pays with high premiums. Once deductibles are met, the overall patient co-pays remain as the major driver for patients and the perceived value of their care. The payer continues to cover the remaining costs of care, thus awakening the moral hazard
of health insurance. Therefore, the patient’s definition of value may not be the same as the payers.

Currently, episodes of care can be defined for various conditions or procedures. These episodes are defined by aggregating all the relevant clinical services for a clinical window of time. The services can be all-inclusive for physicians, labs, imaging, office, inpatient, rehab, skilled nursing facility (SNF), home health, etc. Once the services are defined, logical algorithms based on those services are applied to claims database to define these costs for an episode of care for a given condition or procedure. Using this method, it is possible to establish a patient’s individualized, risk-adjusted costs for the episode of care they received during a period of time, as illustrated in Figure 2.

Given the importance of price transparency for patients, this methodology can be used to help individual patients understand the expected costs for the projected services they will need. When a patient undergoes a procedure, they are faced with more than the surgeon and anesthesiologist’s costs. They have preoperative imaging and labs, hospital or facility costs, postoperative testing, skilled nursing, rehabilitation and home health, just to delineate a few common expenses. Underlying co-morbidities for individual patients add to the costs of managing an episode of care, too. By using an episode-based pricing tool, patients can come to understand the total cost for the condition or procedure. Their out-of-pocket costs are also calculable once the total cost of care is exposed. Episode-based pricing tools are therefore able to provide insights that are meaningful to both the payers and the patients.
In this conceptual framework, scoring acts as a proxy for an individual’s judgment and helps to provide the individual with a sense of how best to combine the Quality and Cost into a value proposition. CMS could score Quality and Cost using methodology to create representation of the overall value, such as a five-star rating system.

When using scoring systems, rules and logic are used to define how best to array the variances in quality. If all the quality measures show limited variation, with clusters of clinicians all performing equally, then few clinicians will be cast as
outliers to the good or to the bad. If the quality measures display great variation, then the scoring system must define cut-points to separate the levels of service. These cut points may reflect a certain variance from standard deviations or breakup responses into deciles, quintiles or quartiles. The point is that no scoring system is perfect; these are merely tools to aid in forming a value statement.

Episodic Care Model Example

To illustrate this framework, we consider an episodic care model for cancer. The care model relies on the key roles each clinician provides at the right time. This includes primary care, which forms the home (or hub) of activity and as acts as the interface between clinical teams. Clinical teams provide care across the care spectrum (preventive and screening services, simplistic acute clinical conditions, complex acute care, chronic care, rehab, and end of life). For episodes of care within a clinical domain, such as a colectomy episode in a cancer domain, the ACS quality measurement system assesses that the key structural elements for surgical cancer care conform to industry standards using a verification or certification program; measures the PROs related to the expectations of care; and, uses administrative claims and clinical risk-adjusted (NSQIP) outcomes associated with colectomy for validating the quality of care. It is critical that all the providers who contribute to care must be supported in the digital health infrastructure to allow data to flow between providers who treat a given patient. When patients’ goals are met, providers are rewarded. This vision is illustrated in Figure 3 which provides a cancer care model example.
We seek testing of an ACS alternative proposal for measurement in MIPS because we believe it defines healthcare value in a patient-centric way by providing reliable and understandable knowledge about surgical quality and cost for individuals (patients, payers, surgeons and other clinicians). We also hypothesize that it will ensure that surgeons have valid, reliable and meaningful measures built on evidence-based QI practices that are well documented in the literature to drive improvement in care. And, and the episode-based design of the framework can represent accountability across clinical domains while fitting into workflow. We advocate for the testing of this framework for its incorporation into the MIPS program.
QCDR Measure Benchmarks Based Off Historical Measure Data

For the first two MIPS program years, MIPS eligible clinicians and groups who report on QCDR measures that do not have an available benchmark based on the baseline or performance period but meet data completeness are assigned a score of 3 measure achievement points. CMS has shared, and ACS has heard from members, that MIPS eligible clinicians are hesitant to report QCDR measures without established benchmarks due to a risk of being limited to a 3-point score for that QCDR measure. To encourage reporting of QCDR measures, CMS seeks comment on an approach to develop QCDR measure benchmarks based off historical measure data.

We thank CMS for taking steps to encourage reporting of QCDR measures. ACS agrees that there is too much uncertainty a clinician faces when selecting QCDR measures without established benchmarks since they can only achieve up to 3 points. Clinicians want to know a target to work towards and be sure that their effort is recognized in MIPS. Keeping this policy of capped points for measures without benchmarks disincentivizes their reporting. This creates a reverberating cycle that does not incentivize reporting, which then leads to a lack of reported cases necessary to establish a valid and reliable benchmark.

ACS supports the intent to use historical data to create benchmarks when the measures have been unchanged and have sufficient volume. However, the ACS is limited in our ability to provide historical data for many of our QCDRs because the MIPS program has required year-to-year modifications, consolidations, or removal of our measures. Therefore, these frequent changes may result in irrelevant historical data. QCDR measures need more stability to encourage reporting and have sufficient volume to supply valid historical data.

The ACS registries would also face feasibility issues in supplying this data in the form and manner CMS would require. First, there are the challenges mentioned above with the year-to-year changes in the measures. Additionally, for QCDR measures that have been in use for many years, it would be challenging to determine which of the registry users are MIPS eligible retrospectively.

ACS urges CMS to delay adoption of this proposal pending additional information and discussion with QCDRs. It is imperative that CMS give QCDRs the ability to provide data collected across its registry participants, including participants that are not reporting the measure to CMS for purposes of MIPS, for CMS to create benchmarks of QCDR measures. Additionally, if CMS establishes benchmarks for QCDR measures, they must be done prior to the submission window in order to give practices a sense of how they are performing compared to their peers.
In the opinion of the ACS, the right way to encourage the use of QCDRs is to give the measures more meaning and value. **First, QCDR measures without benchmarks should not have capped scores. Second, reporting through QCDRs should qualify for bonus points.** Having bonus points, especially for measures without established benchmarks in MIPS, will encourage their reporting. Most importantly, the goal should be to establish a single source of truth (one system to aggregate data across a clinical domain) for a measure. This would make it more trusted and meaningful for clinicians, as they would only be compared to those in their clinical domain. Surgeons want to be compared to peers that provide similar services in a measurement system that is highly rigorous, consistent, and reliable.

The ACS is a great example of an organization that has a trusted and rigorous approach to continuous quality improvement driven by 4 principles. We encourage CMS to consider a similar framework for measuring quality with QCDRs:

1. Establishing **standards** that are backed by research and individualized by patient.
2. Having the right **infrastructure**, including the right staffing, equipment, and checklists.
3. Use **rigorous data** from medical charts and post-discharge tracking that is backed by research and continuously updated.
4. Is **verified** through external review and ensure public assurance.

Using this framework for quality measurement and improvement has made the ACS a trusted source in the surgical domain because there is single entity implementing the measure set through consistent methodologies.

We look forward to continuing to work with CMS on this issue.

**Facility-Based Measures Scoring Option for the 2021 MIPS Payment Year for the Quality and Cost Performance Categories**

**Facility-Based Measurement Applicability**

**Facility-Based Measurement by Individual Clinicians**

In the CY 2018 QPP final rule, CMS finalized that a MIPS EC is eligible for facility-based measurement if he or she furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes for inpatient hospital (POS code 21) or emergency room (POS code 23) based on
claims for a period prior to the performance period. However, CMS received comments that on-campus outpatient hospital POS code (POS code 22) for observation services should be included as part of the criteria because they are similar to and often take place in the same physical location as inpatient services. Therefore, CMS is proposing to modify its determination of a facility-based individual in four ways:

1. CMS proposes to add on-campus outpatient hospital (as identified by POS code 22) to the settings that determine whether a clinician is facility-based.
2. CMS proposes that a clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room.
3. CMS proposes that, if it is unable to identify a facility with a Hospital Value-Based Purchasing (HVBP) score to attribute a clinician’s performance, that clinician is not eligible for facility-based measurement.
4. CMS proposes to align the time period for determining eligibility for facility-based measurement with changes to the dates used to determine MIPS eligibility and special status.

CMS explains that that these proposals will likely further expand the opportunity for individual facility-based measurement and eliminate issues associated with the provision of observation services while still restricting eligibility to those who work in an inpatient setting. As a general theme of our comments to this proposed rule, because of the lack of meaningful, valid and reliable measures for surgeons in the MIPS program, we support reporting options that require minimal burden to the practicing surgeon. We generally support this proposal and acknowledge that measures in the HVBP program can be more relevant to surgical care when compared to the CMS Web Interface measures, which is often what surgeons are held accountable for as result of current group practice reporting incentives under MIPS. We do not want clinicians and CEOs to be compelled to divert resources they use for meaningful quality efforts and use those resources for MIPS data collection and reporting in fear of receiving a penalty.

At the same time, ACS believes that facility-level reporting can drive significant improvements in health care quality and therefore that CMS should expand facility-based measurement under MIPS to incorporate facility-level measures far beyond the HVBP measure set. Specifically, for the longer-term, we can conceptualize a MIPS program that allows for facility-based measurement that considers a facility’s performance under a standards-based accreditation or verification program. Such performance would consider all applicable MIPS clinicians and groups – not just those who meet CMS’ criteria for hospital-based or facility-based status. Accreditation and verification programs would assess facilities and provide a score based on the extent to which they meet verification...
or accreditation standards that define procedural quality. We are eager to work with CMS to validate this framework.

A possible option for surgery would use the *ACS Optimal Resources for Surgical Quality and Safety*, also known as the “Red Book,” to identify the key steps across all the phases of surgery for optimal care. This could be standardized to form a verification program for all general surgery procedures. Moreover, the standards could be further tailored to address specific clinical domain, for example through adoption of standards from the following evidence-based programs:

- The ACS Trauma Verification, Review, and Consultation Program
- Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), and
- The ACS Cancer Accreditation Programs

It is well demonstrated in the literature that standards-based verification or accreditation programs – which establish the standards of care for optimal, safe care delivery in a culture of quality and safety, and conformance to standards – yields better outcomes. 33, 34, 35, 36, 37, 38, 39, 40

Another possibility to consider is testing the incorporation of facility-level measures such as those included in the ACS NSQIP into the existing MIPS quality scoring methodology, allowing for meaningful measurement and comparison across MIPS eligible clinicians. ACS NSQIP is a nationally validated, risk-adjusted, outcome-based registry with a demonstrated ability to drive improvement with a targeted approach. The use of such registry measures would incorporate valid and reliable facility-based measures that are targeted enough to reflect the performance of clinicians, while also varied enough to apply across a wide range of specialties and sites of service, thereby driving quality improvement among participating clinicians. ACS welcomes the opportunity to work with CMS on how the methodologies used to determine a facility’s performance can translate into a valid and reliable measure for facility-based measurement in the MIPS program.

With respect to CMS’ proposal to use HVBP Program performance under the Cost performance category, we believe that future policy should consider episode-based risk-adjusted measures that align with measures used for facility-based quality reporting in the Quality performance category, even if they are not currently included in the HVBP. Relying on the MSPB measure to assess resource use falls extremely short of meaningfully measuring cost and provides no actionable information to incentivize and achieving value in surgical care. As discussed in the Cost section, the CMS Episode Group for Medicare (EGM) can be used to establish a patient’s individualized, risk-adjusted costs for the care they received during a period of time.

In regard to the CMS proposals to modify its determination of a facility-based individual, ACS supports criteria that reduces reporting burden on clinicians. The HVBP measures, as a whole, are more targeted towards the care that certain surgical specialists provide compared to the measures available via the CMS Web Interface reporting, which does not capture surgical care.

*Facility-Based Measurement by Group*

In the 2018 QPP final rule, CMS established that a facility-based group is a group

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in which 75 percent or more of its eligible clinician NPIs billing under the group’s TIN meet the requirements to be facility-based as an individual. CMS does not make any changes to the determination of a facility-based group.

**No Election of Facility-Based Measurement**

CMS proposes a modified policy which would automatically apply facility-based measurement to MIPS clinicians and groups who meet the facility-based measurement criteria and to use the facility-based score to determine the MIPS Quality and Cost performance category scores, unless CMS receives another submission of quality data for or on behalf of that clinician or group and the combined Quality and Cost performance category score for the other submission results in a higher combined quality and cost performance score for MIPS. If the other submission has a higher combined Quality and Cost performance score, then CMS would not apply the facility-based performance scores for either the Quality or Cost performance categories.

ACS generally supports the proposal, which eliminates election requirements to be assessed under facility-based measurement because it will help to reduce burdens related to participation in the MIPS program. We note, however, that facility-based clinicians and groups will be at a competitive advantage if CMS finalizes the policy to take the better of their facility-based score or their otherwise submitted and calculated MIPS score for the quality and cost performance categories. Additionally, we seek clarity from CMS on how this proposal to apply the “higher of” score may put smaller practices at an even greater disadvantage under MIPS relative to their counterparts in larger practices. During a CMS meeting at the AMA on August 9, 2018, ACS asked CMS if they had modeled the impact of facility-based measurement on the whole pool of MIPS providers, including the impact on small practices. CMS explained that they did not specifically model the impact.

Although we support the implementation of facility-based measurement, without any CMS analysis of the impact, we are concerned that it could contribute to an uneven playing field – particularly when the impacts of CMS’ proposal to allow clinicians to opt-in to MIPS (which will likely add more high performers to the MIPS pool of clinicians) and the deflated small practice bonus are also taken into account. Therefore, we encourage CMS to closely monitor the impact of this policy if implemented.

**Expansion of Facility-Based Measurement to Use in Other Settings**

Although CMS has only implemented facility-based measurement in the inpatient setting, the agency notes that they are considering expanding this concept into other facilities and programs. Because the majority of surgical procedures are in
the ambulatory setting, ACS supports facility-based measurement at this level with complementary episode-based risk-adjusted cost measures based on the CMS EGM methodology. ACS welcomes the opportunity to consider the implementation of measuring surgical quality and cost in the ASC setting.

**Calculating the Final Score**

**Accounting for Risk Factors**

*Complex Patient Bonus for the 2021 MIPS Payment Year*

For the 2019 performance period, CMS proposes to maintain the same 5-point bonus for clinicians who serve complex patients, which is what the bonus was for the 2018 performance year. CMS asserts that their overall goal for was two-fold: (1) to protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing clinicians who care for complex patients at a potential disadvantage while they review the completed studies and research to address underlying issues and minimize unintended consequences.

In the proposed rule, CMS explains that the agency continues to explore options for adjustment of individual quality measures, as well as additional approaches to account for patient risk factors through adjustments to the performance category scores or the final score. The agency will continue to follow the NQF socioeconomic status (SES) trial to allow for examination of social risk factors in outcome measures. The agency also plans to continue working with the Assistant Secretary for Planning and Evaluation (ASPE), the public, and other key stakeholders to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries.

ACS appreciates that accounting for social risk factors in the MIPS program is a complex task and requires a lot of resources to identify the correct course of action. **ACS recommends the Secretary encourage CMS to work with other HHS agencies to prioritize research efforts to examine the broader social determinants of health.**

**Final Score Performance Category Weights**

For the 2019 MIPS performance period (2021 MIPS payment year), CMS proposes that the Cost performance category would make up 15 percent and the Quality performance category would make up 45 percent of a MIPS eligible clinician’s final score. As detailed in the table below, Quality would decrease 5% from the 2018 performance year from 50% in 2018 performance year to 45% for the 2019 performance year, and Cost would increase 5% from 10% in the 2018 performance year to 15% for the 2019 performance year.
<table>
<thead>
<tr>
<th>Performance Category</th>
<th>Transition Year (previously finalized)</th>
<th>2018 MIPS Performance Period (previously finalized)</th>
<th>2020 MIPS Performance Period (proposed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>60%</td>
<td>50%</td>
<td>45%</td>
</tr>
<tr>
<td>Cost</td>
<td>0%</td>
<td>10%</td>
<td>15%</td>
</tr>
<tr>
<td>Improvement Activities</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>Promoting Interoperability</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
</tr>
</tbody>
</table>

As discussed in the Quality and Cost performance category sections of this letter, ACS opposes this proposal and advocates for a continued quality performance weight of 50 percent. The continuation of the final score weights from 2018 to 2019 performance years will promote consistency, stability, and simplicity for the third year of MIPS. Additionally, as discussed in the Cost performance category, we support a continued weight of 10 percent for the 2019 performance year because the new episode-based cost measures have only undergone testing on a small scale and are not understood by clinicians.

**Flexibility for Weighting Performance Categories**

For the 2019 performance year, CMS proposes to apply similar reweighting policies as finalized for the 2018 MIPS performance period. In general, CMS proposes to redistribute the weight of a performance category or categories to the Quality performance category. CMS explains that the agency believes redistributing weight to the Quality performance category is appropriate because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs. CMS proposes to continue to redistribute the weight of the Quality performance category to IA and PI for cases when the Quality performance category is weighted at zero percent. However, for the 2019 MIPS performance period, with its proposal to weight Cost at 15 percent, CMS proposes
to reweight the PI performance category to 45 percent and the IA performance category to 40 percent.

**ACS does not support CMS’ proposal to generally redistribute weight of a performance category to Quality.** Instead, if clinicians are exempt from PI, we support PI redistribution to the IA category because we strongly believe MIPS quality measures are unreliable and should not have such a large impact on the Final Score. In the event that clinicians are also exempt from the cost category, we also would support redistribution from cost to the IA category if statutorily possible. Redistribution to IA will reduce burden and allow for simplicity. We continue to hear feedback from our members that the requirements to meet the Quality performance category are confusing, onerous and leading to physician burnout.

**Establishing the Performance Threshold**

CMS proposes a performance threshold of 30 points for the 2019 MIPS performance period. CMS’ rationale for this change is that a performance threshold of 30 points would be a modest increase over the 15 point 2018 performance year threshold. CMS also explains they believe a 30-point threshold will provide a gradual transition to the performance threshold for the 2022 MIPS performance (2020 performance year), which CMS currently estimates would be between 63.50 and 68.98 points. CMS notes that the final scores for MIPS eligible clinicians for 2017 were not yet available to include in the development of this proposal, and therefore this estimate is based on data from claims, MIPS eligibility data, 2015 PQRS data, 2014 PQRS Experience Report, 2014 VM data, National Plan and Provider Enumeration System Data, APM participation lists, and initial analyses for QP determination to model the estimated MIPS eligible clinicians, final scores, and the economic impact of MIPS final score.

ACS strongly opposes a doubling of the MIPS threshold from performance year 2018 to performance year 2019. Based on what is required to meet a 30-point threshold, ACS finds this extremely confusing, too high of a bar, and strongly believes clinicians need a clearer target. For example, if a clinician reported 6 quality measures and scored the minimum amount of points (i.e., met the data completeness threshold, but the measure doesn’t have a benchmark which is what they would earn using the ACS Surgeon Specific Registry QCDR due to lack of benchmarks), they would earn 3 points for each of the 6 measures, which translates into 13.5 MIPS points (18/60 x 45%). If they also fully satisfied the IA category, they would earn 15 more MIPS points for a total of 28.5 points. They would then still need 1.5 points to avoid a penalty, which would require reporting something for each PI measure, as currently proposed for 2019. **We cannot overstate how confusing and burdensome this is for a program that has little meaning or value to surgeons.** We consistently hear that our members are
struggling with the onerous nature of the MIPS requirements. Furthermore, we are concerned that CMS determined these thresholds based off of outdated, largely inapplicable data, which is another reason why the threshold should not be raised so dramatically. **To this end, we strongly oppose a 30-point threshold and support a lower threshold of 20.** A 20-point threshold would allow clinicians who report on 6 quality measures and receive at least 3 points per measure AND report one high weighted IA or 2 medium weighted IAs to avoid the penalty. If CMS finalizes the proposal to require 2015 CEHRT for 2019, we do not think PI should be required to avoid the penalty due to the high cost and administrative burden of upgrading CEHRT. As stated in our comments in PI section, we strongly believe 2015 CEHRT should not be mandated.

As noted in our earlier comments regarding the PI category, the ACS also requests that CMS only require clinicians to earn 50 points to receive full credit in the PI category, which would translate into 25 points toward the final MIPS composite score. The 50-point minimum aligns with the number of points that hospitals must earn to be considered a “meaningful user” and avoid a penalty under the Hospital PI Program, as finalized through the recent 2019 Inpatient Prospective IPPS final rule. It would be inappropriate to hold clinicians to a higher standard since they often have fewer resources than hospitals. **If CMS were to adopt a lower MIPS Performance Threshold (e.g., 20 points), along with a 50-point minimum to receive full credit in the PI Category, clinicians fully satisfying the PI category could avoid a penalty, which aligns with policies adopted for the Hospital PI Program.**

**Qualified Clinical Data Registries (QCDRs)**

**Proposed Update to the Definition of a QCDR**

Beginning with the 2022 MIPS payment year, CMS proposes to modify the definition of a QCDR to state that the approved entity must have clinical expertise in medicine and quality measure development. As proposed, a QCDR would be defined as, “an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.” Under this proposal, entities may also meet this definition by partnering with an external organization with expertise in medicine and quality measure development.

The ACS has raised our concerns in past comments that many QCDRs have a predominantly technical background with limited understanding of clinical quality measurement or the process for developing clinical quality measures. These vendor-led registries do not have quality improvement as their primary purpose and do not have clinical expertise or in-depth experience in quality measurement.
Instead, they are created for commercial purposes. We agree with CMS that approval of commercial QCDRs does not fulfill the original intent of QCDRs to fill critical gaps in the traditional quality measure sets and to ensure that clinicians/specialists have access to more meaningful and relevant measures. We thank CMS for recognizing this issue and for taking steps to refine the definition to better satisfy the intent of QCDRs.

While this modification to the definition of QCDRs is a step in the right direction, the ACS does not think this proposed definition, as written, goes far enough. The definition of QCDRs needs to be better suited for defining quality measurement with the high methodological rigor of a registry. We believe there should be one source of truth for a specific clinical domain. This means the registry must meet standards for data which include rigor in explicitly defining data elements used in the measurement, a single source of data aggregation to secure data integrity, a sole source for data normalization, approved and consistent statistical standards for analytics, and reporting requirements as defined by CMS.

Commercial QCDRs are at a greater risk of inaccurately implementing measures due to their lack of operational experience with measurement science. This is exacerbated by the current lack of accountability for how commercial QCDRs report on the same measures and no standardization for how they use data. For clinical quality measures to be used for cross-cutting comparisons and creating benchmarks, measures require more than what is detailed in measure specifications. CMS’ benchmarking efforts would be well served if their submitted measures met standards which included the measure specifications, aggregation rigor, normalization applications and submission to CMS. All standards within a clinical domain may be assembled via these standards and submitted to one source for verification before submission to CMS as a set of metrics suitable for benchmarking. Without any one step in the measurement process, the result will include serious errors and untrusted measurement. Due to this high risk of inconsistent implementation of measures, allowing multiple QCDRs to report on the same measure will further complicate the validity of benchmarks and can misclassify clinicians.

The STS National Database is an example of a single source of truth. There is consistency and validity across measurement because one data system exists for a small number of operations, allowing for a single method for data aggregation, analytics, and reporting. If STS had multiple vendors collecting, normalizing, and analyzing data under differing rules and logic, results would not be valid for comparative analysis. CMS should extrapolate this model to all QCDRs, where one measure is supported by one entity that represents a single clinical domain or subspecialty.
Medical societies, with clinician-led QCDRs, are well positioned to take on this role as being a trusted source of truth since they have expertise in their clinical domain and have a commitment to quality improvement. The ACS supports multiple nationally validated, risk-adjusted, outcome-based registries and verification programs for specific surgical settings, with a long track record of advancing the quality of surgical care. For example, we support a registry for trauma surgery, the Trauma Quality Improvement Program (TQIP), which is used by trauma centers to become accredited as a Level 1, 2, or 3 trauma center. TQIP has highly rigorous standards for the collection, aggregation, and reporting of clinical measures, as it is all implemented through the ACS.

By designating trusted entities in their field to serve as a single source of truth, many of the issues associated with the MIPS quality measurement, such as duplicative measures, meaningfulness of measures, and benchmarking can be resolved.

Self-Nomination Process

Self-Nomination Period

Currently, the self-nomination period for QCDRs is from September 1 until November 1 of the year prior to the applicable performance year. For the 2020 performance year, CMS proposes to revise the self-nomination to begin on July 1 through September 1 of the calendar year prior to the applicable performance period.

In the proposed rule, CMS expressed the operational issues they are facing to process, review, and approve QCDR measure submissions to meet deadlines due to the proliferation of measure applications. **ACS does not think this proposal to move the nomination process to an earlier start time will alleviate CMS’ operational issues and that this proposed policy will create extra burden and constraints for QCDRs.**

For example, the Metabolic and Bariatric Surgery Quality Improvement Program (MBASQIP) has a highly rigorous process for the capture, aggregation, and analysis of measures, that requires a 90-day collection run out period before data can be used for analysis. In regards to creating or modifying measures, it would be beneficial to review at least 6 months of data from the year prior to submission to evaluate the measures. For example, a procedure done on June 30, 2019 would lock on 09/29/2019, so we would have a month (till 11/1/2019 if current deadline remained) to review 6 months of data. This means we will have a very limited
snapshot of the user experience in the current year to make adjustments to improve the measure for the next year.

Additionally, CMS releases approved measure specifications in December, and expects QCDRs to be able to report the measures on January 1 of that performance year. This is not operationally feasible, as it can take several months to build and test systems. This is exacerbated if multiple measures require modifications each year. This is overly burdensome and hinders the consistency of measure data in terms of comparability of results over time.

While multiple fixes are necessary, including a 90-day minimum performance period for the Quality Category, one critical way to maximize stability and predictability, while minimizing redundancy would be to offer multi-year approval of QCDR measures. We believe QCDRs should be allowed to make minor modifications to measures under this multi-year approval process based on updated guidelines, evidence or measure methodologies. If QCDR measures were approved for two to three years, the earlier self-nomination deadline would not be as problematic for registry vendors and would streamline CMS’ process. CMS should reconsider this past proposal. We believe the concerns with multi-year measure approval stated by CMS (checking measures for topped out status, reflecting current clinical guidelines, and considered a standard of care), can be addressed through minor modifications by the QCDR.

**QCDR Measure Requirements**

CMS proposes to consolidate their previously finalized standards and criteria used for selecting and approving QCDR measures. Specifically, CMS proposes to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year. These additional criteria include:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.
ACS does not support this proposal and believes the QCDR measure approval process should remain separate from the standards used for the Call for Quality Measures process. It is not appropriate to align criteria for QCDR measures with those of MIPS quality measures. QCDR measures are meant to innovate clinical quality measurement by filling critical gaps in the traditional quality measure sets and targeting the needs of different specialties. Further aligning QCDR measures to the rest of MIPS quality measures fails to recognize this unique role of QCDRs. We urge CMS to maintain the current QCDR measure review and approval process.

QCDRs Seeking Permission From Another QCDR To Use An Existing, Approved QCDR Measure

CMS proposes that, as a condition of a QCDR measure’s approval for purposes of MIPS, QCDR measure owners be required to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS, beginning with the 2021 MIPS payment year. Our understanding is that, should this proposal be adopted, once a QCDR measure is approved for reporting in MIPS, it would be generally available for other QCDRs to report on for purposes of MIPS without a fee for use and without a direct license with the measure owner. The ACS strongly opposes this proposal because it undermines QCDR measure development and ownership.

CMS’ proposal is inconsistent with CMS’s decision just last year requiring that QCDRs seeking to use the QCDR measures of another QCDR must first obtain permission from that measure owner. The ACS, as part of the Physician Clinical Registry Coalition (PCRC), previously submitted comments on the CY 2018 QPP proposed rule supporting CMS’s proposal that QCDR vendors must seek permission from the owner of a QCDR measure before using that measure during the performance period, and that such permission should be obtained at the time of self-nomination. CMS also clarified that the “borrowing” QCDR must use the exact measure specification provided by the QCDR measure owner. CMS is now backtracking on this prior rule which protected the intellectual property rights of measure owners. This is yet another way CMS is not recognizing the unique difference between QCDR measures and other MIPS quality measures.

We urge CMS to instead allow QCDRs to enforce their ownership rights in the QCDR measures they develop, and require third parties to enter into licensing agreements with measure owners before they can properly use QCDR measures. We would like to work with CMS to create safeguards to protect the proper implementation of these measures and enforce the intellectual property rights of developers of QCDR measures, while also ensuring that the
measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

While we very strongly oppose this policy and do not believe it should be finalized, if it is, we at least request that CMS clarify “without modification” to include risk adjustment as well as the same standard methodology used by the measure developer.

Measures must be consistently aggregated, normalized, analyzed and represented with great rigor to provide value. Without any one step in the measurement process, the result will include serious errors and untrusted measurement. The ACS illustrated these points when we harmonized the ACS NSQIP SSI measure with the CDC NHSN SSI measure based on information available using the harmonized measure specifications in the same facilities. After harmonization of measure specifications (i.e. common data elements), 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 rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP41.

Harmonizing quality measure specifications across registries alone does not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation. Multiple QCDRs reporting on the same measure will further complicate benchmarking issues and misclassify care provided by clinicians.

We also question CMS’ ability to co-aggregate data from multiple sources on the back end. We have noticed in the past that CMS did not properly risk-adjust surgical measures, instead using raw, unadjusted data when risk-adjusted data was submitted. In this sense it does not yield proper results as detailed in the measure specification and leads to incomparable results for valid benchmarking. These improper processes increase the risk that surgeons may be misclassified in the quality of care they provide in the MIPS program. For these reasons, the ACS advocates for a single source of truth from one QCDR, where there is a single source of data aggregation to secure data integrity, a sole source for data normalization, approved and consistent statistical standards for analytics, and uniform reporting. We welcome the opportunity to meet with CMS on this solution.

Public Reporting on Physician Compare

Overview

The ACS recognizes the importance of making meaningful, objective, and scientifically valid information on the quality of surgical care publicly available. It is vital, however, that when presenting information to the public, it accurately represents the quality of care delivered by providers in a manner that meaningfully improves the public’s ability to make informed decisions about their care.

In the CY 2018 QPP final rule, CMS finalized it would not publicly report first year quality or cost measures. As such, any measure in its first year of use in the Quality or Cost performance category will not be publicly reported for at least one year. In the 2019 QPP proposed rule, CMS seeks to extend this policy further to two years. This means CMS will not publicly report first year quality or cost measures on Physician Compare for the first two years a measure is in use. CMS also proposes to eliminate the indicator of “high” performance and to maintain only an indicator for “successful” performance in the PI performance category beginning with year two of the QPP.

The current state of quality measurement has multiple methodologies for reporting disparate measures, with each potentially using its own risk adjustment methodology. This makes it extremely difficult to make meaningful comparisons among clinicians providing similar care. This difficulty extends to public reporting and therefore limits the utility of the data being provided to the patients and the public at-large. The ACS questions CMS’ ability to accurately and fairly represent the quality of care provided by individual surgeons based upon limited data submissions, which are aggregated and benchmarked with flawed methodology. Additionally, because there has been a large shift towards surgeons leaving smaller practices and becoming employees of hospitals or larger institutions, most of them are not measured on metrics meaningful to surgical care. This is because those hospitals and larger institutions use the CMS Web Interface to report MIPS for their clinicians, which only captures primary care metrics.

We discuss our comments to these proposals for each MIPS category below.

Quality

ACS supports CMS’ proposal to extend the policy to not publicly report first year measures for the first two years that a measure is in use in the Quality performance category. We agree this will help encourage clinicians and groups
to report new measures, get feedback on those measures, and learn from the early years of reporting measures before measures are made public. Additionally, extending the time period for when first year measures will be publicly posted will allow CMS to continue to develop measurement science in MIPS so that the measures are less likely to misclassify care.

However, there are many issues with publicly reporting quality measure data from MIPS due to the nature of MIPS’ flawed measurement system, and the current proposals aimed at increasing flexibility. The current MIPS Quality performance category policies and proposed policies will further exacerbate the inability to meaningfully compare providers that practice in the same clinical domain by allowing for multiple disparate data systems with competing measures and methodologies. Instead of comparing physicians in the same clinical domain on the same measures collected, analyzed, and reported in a uniform manner, the current system lumps every provider from every collection and submitter type. This lack of a single source of truth for clinical domains hinders the relevance of these measures for beneficiaries to meaningfully compare providers that deliver similar services. Creating this certainty in comparability across clinical domains on Physician Compare is a longer term goal CMS should work toward. We encourage CMS to keep this in consideration when evaluating the reliability and validity of measures and its suitability for public reporting, keeping in mind that the goal of such reporting is to allow patients to make informed decisions about their care.

Cost

In the 2018 QPP proposed rule, CMS explained that they received feedback that cost data can be difficult for patients to understand and interpret. ACS agreed with this explanation and encouraged CMS to proceed cautiously in making this information available on Physician Compare. We reiterate that CMS should proceed with caution when posting cost measures on Physician Compare due to the changes to the Cost category proposed in this rule, especially the introduction of new episodic cost measures. Surgeons need time to better understand these measures, especially in regard to how patients will be attributed to them before they are publicly reported.

CMS previously finalized first year cost measures would not be reported for the first year a measure is in use in the Cost performance category. ACS supports CMS’ proposal to not publicly report first year measures for the first 2 years a measure is in use in the Cost performance category. ACS also recommends that CMS separately consider extending the amount of years before publicly reporting the newly proposed episode-based cost measures until the Agency gains more experience collecting and analyzing these new measures in MIPS.
Promoting Interoperability

As noted previously, ACS asserts that the objective of PI should be the attainment of semantic health data interoperability across the wider clinical data ecosystem, not exclusively between users of 2015 Edition CEHRT. Any information publicly reported should be reflective of these goals.

We appreciate CMS’ efforts to integrate feedback from user testing to improve upon Physician Compare’s utility for the public. CMS found through user testing that including two different indicators (“high” and “successful”) was overly complex for users’ needs. To remediate this issue, CMS proposes to remove the “high” performance indicator and only maintain the “successful” performance indicator on Physician Compare. Until such time that CMS fundamentally revamps this performance category, ACS supports CMS’ proposal to remove the indicator of “high” performance and to only maintain an indicator of “successful” performance in the PI category.

If a performance-based scoring methodology, as proposed in this rule, is finalized, its elimination of a base score requires the definition for “successful” to be updated. **ACS seeks clarity on how the “successful” performance indicator will be defined if the PI scoring methodology no longer includes a base score.** We also request that CMS include on Physician Profile pages either an indicator of whether a clinician or group was exempt from PI or a disclaimer explaining why certain clinicians are exempt from complying with this category.

**Achievable Benchmark of Care (ABC)**

**Historical Data-Based Benchmarks**

CMS currently uses the Achievable Benchmark of Care™ (ABC) and equal ranges methodology to determine a benchmark and 5-star rating for the Quality, Cost, IA, and PI measures, as feasible and appropriate, by measure and collection type for each year of the QPP based on the most recent data available each year. This policy is intended to ensure that a benchmark could be calculated despite potential year-to-year measure changes. This also means benchmarks for publicly reported measures are not known to clinicians and groups prior to the performance period.

In the 2019 proposed rule, CMS seeks comment on modifying this policy to determine benchmarks for the Quality, Cost, IA, and PI performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the QPP. Specifically, benchmarks would be based...
on performance data from the 12-month calendar year that is 2 years prior to the applicable performance period, if such data is available. The measures for which CMS can create benchmarks based on historical data would then be published prior to the start of the performance period. CMS suggests this modification because they believe by the third year of MIPS there will be enough year-to-year stability in the measures in MIPS to create reliable benchmarks.

In theory, the ACS supports the use of historical data to create benchmarks, if the measure specifications have not changed and there is sufficient volume for a high level of validity and reliability. Providing predictable benchmarks to clinicians prior to the performance period will allow them to compare themselves to their peers and give them a quality target as they develop strategies to improve their performance.

However, given the lack of stability in the first few years of MIPS, we do not believe CMS will have enough program stability from year-to-year to create reliable and valid benchmarks. MIPS has evolved every year in terms of reporting requirements, scoring, special statuses, and measures. These constant changes and moving targets have influenced which clinicians participate, which measures are reported, which collection types are used, and how many cases are reported. If this policy were adopted, the benchmarks established for 2019 will be based on data from 2017. In the initial year of MIPS (2017), to avoid a penalty and receive a neutral adjustment, eligible clinicians only needed to achieve a final score of 3 points. One way many clinicians achieved a final score of 3, was to report data on 1 patient for 1 measure. If a large number of individuals and groups reported data on only 1 patient, the high amount of low volume reporters for a measure could skew benchmarks to be artificially higher due to a high concentration of scores at the top of the distribution—even with the controls in the ABC methodology.

We encourage CMS to proceed cautiously when using historical data to create benchmarks for public reporting as it risks misclassifying clinicians and misinforming the public. The MIPS program still needs more stability throughout the entire program from year-to-year in order to establish historical benchmarks that appropriately reflect the policies in place for the current performance year.

QCDR Measure Benchmarks

CMS is proposing to extend the use of the ABC methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as feasible and appropriate. CMS proposes to use current performance period data in year two of the QPP (2018 data available for public reporting in late 2019) and to use historical benchmark data when possible.
as detailed above, beginning with year three of the QPP (2019 data available for public reporting in late 2020).

As detailed above in our comments on the Quality performance category, we believe there will be many challenges and issues in establishing historical benchmarks for QCDR measures. We believe these issues will extend to public reporting as well and urge CMS not to finalize this proposal to create 5-star benchmarks using historical data for QCDR measures. Furthermore, the ACS believes that instead of displaying QCDR measures on Physician Compare, the QCDR measures should continue to be publicly reported on the QCDR vendor’s website. QCDR measure stewards are extremely knowledgeable about the measures they developed and can communicate how to interpret their measures in a way that is meaningful for the public. Furthermore, most QCDRs likely have their own valid and reliable benchmarking methodology based on many years of experience and knowledge in their clinical domain. The ABC benchmarking methodology may not be universally appropriate to convey the measure data in the way it was meant to be interpreted. Additionally, the ABC methodology is different from what both CMS and QCDRs use to benchmark data in MIPS for purposes of scoring and payment which will create confusion for providers. This may lead to a clinician being misclassified and misleading the public. For example, during a presentation on MIPS measure benchmarks in 2017, CMS was seeking feedback on how to apply the decile benchmarking to one of ACS QCDR measures in the MBSAQIP registry titled, MBSAQIP1: Risk Standardized Rate of Patients who Experienced a Postoperative Complication within 30 days. However, when ACS reviewed the information presented, we discovered that CMS used raw, unadjusted data for the benchmark yet the measure specifications require risk adjustment. ACS submitted both raw and risk adjusted data on this measure, as a requirement of CMS. To us this demonstrated that CMS may not have the resources to appropriately aggregate, risk adjust, and report QCDR measures.

As mentioned in our QCDR comments, having a single source of truth for a clinical domain ensures high rigor and consistency in the implementation and reporting of clinical quality measures. A single source of truth also provides a more meaningful comparison as the clinicians in the registry all practice in the same clinical domain, which aligns to the way the public seeks to make healthcare decisions. ACS quality programs have over 100 years of experience where we have worked to ensure our registries are a trusted source of quality measurement. When surgeons report to a nationally validated, risk-adjusted, outcomes-based registry, such as ACS NSQIP, they can be confident that the data has been collected, aggregated, and analyzed in a consistent method that yields a true representation of their care and provides an equitable comparison to peers in their field. The benchmarking methodologies used by ACS registries are easily
interpretable and have a proven to help surgeons and hospitals to engage in continuous quality improvement. We welcome the opportunity to work with CMS to leverage our expertise to help determine the most appropriate and useful way to publicly report QCDR measures.

**Overview of the APM Incentive**

**Advanced APMs**

**Overview**

ACS sees great potential in APMs to improve surgical care by transitioning to a model that incentivizes team-based, patient-focused, quality care. Unfortunately, there appears to be reluctance to move forward with truly innovative models. The health care community has rallied to meet Congress’ challenge to develop new physician-focused models. As of the end of August, the PTAC had received 27 proposals for new models. Fifteen of these models had been reviewed by the PTAC with recommendations sent to the Secretary of HHS. Ten of these were recommended favorably for testing or implementation, including the ACS-Brandeis Advanced-APM (A-APM) which was the first submitted to the PTAC. However, no action has been taken to test or implement any of these models.

Instead of testing new models developed by physicians, we continue to see variations on existing CMS models such as the Bundled Payments for Care Improvement (BPCI) Advanced or the ACO Track 1+. While we welcome these additional opportunities for Advanced APM participation, we feel strongly that models developed by the physician community should be tested and incorporated into the QPP.

MACRA payment policies and the establishment of PTAC clearly incentivize the development of, and participation in, APMs. ACS and others have recognized the value of creating such models and have expended significant time, effort and resources in doing so. Our experience with the PTAC was a positive one and has helped greatly in refining the ACS-Brandeis A-APM, and our thinking on Advanced APMs, as well as informing our positions on quality and cost measurement in team-based health care. However, the disconnect between the PTAC recommendation process and the testing of new models by CMS poses a significant barrier to innovation. While we believe there is great merit in the move toward Advanced APMs and plan to continue work on developing core concepts of the ACS-Brandeis A-APM, it is unfortunate that the input from the broader health care community has not led to the implementation of physician-built APMs by CMS.
Use of CEHRT

*Increasing the CEHRT use criterion for Advanced APMs*

CMS proposes to increase the percent of physicians in an APM Entity using CEHRT to communicate and document clinical care with patients and other professionals from 50% to 75% beginning in 2019.

ACS remains concerned that increasing the requirements of this criterion to 75% of eligible clinicians using CEHRT functions in 2019 could be too rapid for some APMs and could continue to be an impediment to designing models for small or rural practices. The ability of physicians to communicate clinical care with patients and other health care professionals is based on a level of interoperability that is not currently available to all clinicians using CEHRT. In addition, when CMS assesses APM models for adherence to this criterion, we urge CMS to ensure that clinicians who would have had their MIPS ACI/ PI component otherwise weighted to zero (e.g. individual hospital-based clinicians) be excluded from the base denominator of clinicians under consideration in the model.

ACS sees implementation of MACRA and other recent legislation as an opportunity to modernize the way we think about and incentivize the use of HIT. HIT could have a significant impact on value-based payment models and the overall quality and efficiency of care if it were implemented in such a way as to create a truly interoperable patient digital health information environment where data could flow freely to where it is most needed to inform care decisions.

Patients do not commonly exist in a single EHR. CMS seems to acknowledge this fact in stating that they “have prioritized interoperability which we consider to be health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable law; and does not constitute information blocking as also defined by the 21st Century Cures Act.” This is important as patients commonly see several different clinicians for outpatient care, visit an ambulatory care center, are admitted to skilled nursing facilities, seek care at home or require hospitalization. It is important to move the focus from EHRs to considering the use of all of a patient’s individual digital health information across all of these settings and incorporating available information from other sources as available, to improve his or her care.
APMs could play an important role in using digital health information to improve care if these models are allowed to flourish and innovate. Flexibility in the use of HIT, to the extent possible under statute, will be an important element of improved care.

MIPS Comparable Quality Measures

General Quality Measures: Evidence-Based, Reliable, and Valid

CMS has proposed that beginning on January 1, 2020 at least one of the quality measures upon which an Advanced APM bases payment, including QCDR measures, must be finalized on the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid.

ACS concurs that quality measures should be evidence-based, reliable and valid and the mere fact that a measure is submitted in response to the MIPS Call for Quality Measures is not enough to substantiate this. However, ACS is concerned that in general, the current quality measurement system used by CMS in the QPP fails to accurately incentivize the value created by robust continuous quality improvement cycles. The measures used are untrusted, lack actionable information for improvement and therefore, become burdensome.

ACS would also ask that CMS outline its process and expected timeline for determining if measures are evidence-based, reliable, and valid if they are not currently included in MIPS or endorsed by a consensus-based entity.

Outcome Measures: Evidence-Based, Reliable, and Valid

CMS proposes to explicitly require that an outcome measure must be evidence-based, reliable, and valid (unless, as specified in the current regulation, there is no available or applicable outcome measure) effective January 1, 2020, and would specifically require that at least one outcome measure for which measure results are included as a factor when determining payment to participants under the terms of the APM for purposes of paragraph (b)(1) must also be a MIPS comparable quality measure.

In addition to the concerns noted above, ACS is concerned with this requirement since there is little variation in outcomes for many surgical procedures as judged by existing outcome measures. This is due to decades of continuous quality improvement efforts and can be exacerbated by the small sample size of the number of procedures provided by a physician over a single payment period. Therefore, outcome measures alone are not sufficient to verify that the
highest quality care is made available to patients. For that reason, we offer an alternative solution to the current QPP program which could act as a paradigm for all surgical quality measurement by ensuring surgeons have meaningful measures that are relevant to their patients and their practice, drive improvement towards better patient outcomes, and minimize the burden of data collection. We believe that this framework defines healthcare value in a patient-centric way based on episodes of care with intent to represent accountability across a clinical domain. This proposed framework will need to be tested and validated. We propose that this framework should include a combination of three elements:

- Standards-based facility-level verification programs,
- Patient reported experience and outcomes measures, and
- Traditional quality measures including registry and claims-based measures.

ACS proposes that combining these three elements could provide a much clearer picture of the quality of care provided to the patient, including not just the surgeon, but the entire care team. **This conceptual framework will need to be tested and validated.**

**Bearing Financial Risk for Monetary Loss**

**Generally Applicable Nominal Amount Standard**

CMS proposes to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for Qualifying APM Participant (QP) Performance Periods 2021 through 2024. **ACS agrees that the generally applicable revenue-based nominal amount standard should remain at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities through 2024.** ACS supports continuing the current level of risk for stability as more Advanced APMs are developed and more physicians choose to participate. We ask that the current level of risk be continued at least until such time that additional data are available to suggest a different approach. Given that there is still a lack of available Advanced APM participation options for surgeons and until such options become available, CMS should not be overly restrictive in setting the risk standard unless there is concrete available evidence that another threshold is more appropriate.

If CMS does consider increasing this amount in the future, this decision should be based upon behavioral economic analyses of Advanced APMs, including the levels of risk that they are able to take on and the impact of risk on participation.
Additionally, as CMS has not yet tested or implemented physician-focused APM models, such as those recommended by the PTAC, if risk levels are increased in the future, any new models implemented after such time should benefit from a phase in to those hire risk levels over a sufficient period of time.

**Qualifying APM Participant (QP) and Partial QP Determinations**

CMS proposes that for each of the three QP determinations, it will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations will be completed approximately 3 months after the end of that determination time period.

**The ACS is in strong agreement with this proposed change to reduce from 90 days to 60 days the claims run-out for QP determinations** and welcomes any changes that allow CMS to complete its analysis earlier and provide determinations in a timelier manner.

CMS also proposes that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment.

**ACS agrees that excluding Partial QP eligible clinicians from MIPS reporting requirements and payment adjustments unless an affirmative election is made should be the default.** ACS believes that while some QP eligible clinicians may choose to voluntarily report data in hopes of receiving a positive MIPS adjustment, making this the default in the absence of an explicit election would likely result in applying MIPS performance assessments to clinicians who were not aware that they had any reporting responsibilities given their Partial QP status.

**All-Payer Combination Option**

**Other Payer Advanced APM Criteria**

ACS strongly agrees with the CMS goal to align the Advanced APM criteria under the Medicare Option and the Other Payer Advanced APM criteria under the All-Payer Combination Option in order to simplify the QPP and encourage participation in Other Payer Advanced APMs. As envisioned by the MACRA legislation which created the QPP, there should be a pathway for physicians to increase their participation in value-based payment from MIPS, to MIPS APMs and ultimately becoming QPs in Advanced APMs if they so choose. Maintaining
identical, or at least compatible requirements for APMs in MIPS, Advanced APMs and Other Payer Advanced APMs will greatly aid in this journey for physicians and will also benefit efforts aimed at burden reduction. However, as noted in other sections of this letter and clarified below, ACS believes improvements can be made to these criteria, particularly in the areas of CEHRT Use and Quality Measurement.

Use of CEHRT

*Increasing the CEHRT Use Criterion for Other Payer Advanced APMs*

CMS proposes to change the current CEHRT use criterion for Other Payer Advanced APMs so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity to use CEHRT.

As noted above, ACS remains concerned that increasing the requirements of this criterion to 75% of eligible clinicians using CEHRT functions in 2019 could be too rapid for some APMs and could continue to be an impediment to designing models for small or rural practices. The ability of physicians to communicate clinical care with patients and other health care professionals is based on a level of interoperability that is not currently available to all clinicians using CEHRT. In addition, when CMS assesses APM models for adherence to this criterion, we urge CMS to ensure that clinicians who would have had their MIPS ACI/ PI component otherwise weighted to zero (e.g. individual hospital-based clinicians) be excluded from the base denominator of clinicians under consideration in the model.

*Evidence of CEHRT Use*

CMS proposes that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of eligible clinicians in 2019, and 75 percent of the eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement.

ACS recognizes the important role that digital health information can play in improving care. We also appreciate CMS flexibility in providing multiple manners in which to demonstrate that CEHRT utilization is either required by the APM or that the participants in the APM have adopted CEHRT to the required degree, such as through documenting the CEHRT adoption rate of a private payer’s network. However, as noted elsewhere in this letter we believe the focus
should be on the use of patient digital health information, not on the use of the EHR specifically.

MIPS Comparable Quality Measures

General Quality Measures: Evidence-Based, Reliable, and Valid

CMS proposes, effective as of January 1, 2020, that at least one of the quality measures used in a payment arrangement with an APM Entity must be finalized on the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid.

ACS appreciates the desire to keep requirements consistent across APM programs and concurs that quality measures should be evidence-based, reliable and valid. However, ACS is concerned that in general, the current quality measurement system used in many payment programs may fail to accurately incentivize the value created by robust continuous quality improvement cycles. The measures used are untrusted by providers, lack actionable information for improvement and therefore, become burdensome.

ACS would also ask that CMS outline its process and expected timeline for determining if measures are evidence-based, reliable, and valid if they are not currently included in MIPS or endorsed by a consensus-based entity.

Outcome Measures: Evidence-Based, Reliable, and Valid

CMS proposes effective January 1, 2020 to explicitly require that, unless there is no applicable outcome measure on the MIPS quality measure list, at least one outcome measure that applies in the payment arrangement must be evidence-based, reliable, and valid.

In addition to the concerns noted above, ACS is concerned with this requirement since there is little variation in outcomes for many surgical procedures as judged by existing outcome measures. This is due to decades of continuous quality improvement efforts, and can be exacerbated by the small sample size of the number of procedures provided by a physician over a single payment period. Therefore, outcome measures alone are not sufficient to verify that the highest quality care is made available to patients. For that reason, we offer an alternative solution to the current QPP program which could act as a paradigm for all surgical quality measurement by ensuring surgeons have meaningful measures that are relevant to their patients and their practice, drive improvement towards better patient outcomes, and minimize the burden of data collection. We believe that this framework defines healthcare value in a patient-centric way based on
episodes of care with intent to represent accountability across a clinical domain. This proposed framework will need to be tested and validated. We propose that this framework should include a combination of three elements:

- Standards-based facility-level verification programs,
- Patient reported experience and outcomes measures, and
- Traditional quality measures including registry and claims-based measures.

ACS proposes that combining these three elements could provide a much clearer picture of the quality of care provided to the patient, including not just the surgeon, but the entire care team. **This conceptual framework will need to be tested and validated.**

**Financial Risk for Monetary Losses**

**Generally Applicable Nominal Amount Standard**

CMS proposes to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2019 through 2024.

**ACS agrees that the generally applicable revenue-based nominal amount standard should remain at 8 percent of the total combined revenues from the payer of all providers and suppliers in participating APM Entities through 2024.** ACS supports continuing the current level of risk for stability as more Advanced APMs are developed and more physicians choose to participate. As noted we also support maintaining compatible regulations across Advanced APMs and Other Payer APMs wherever possible. We ask that the current level of risk be continued at least until such time that additional data are available to suggest a different approach. Given that there is still a lack of available Advanced APM participation options for surgeons and until such options become available, CMS should not be overly restrictive in setting the risk standard unless there is concrete available evidence that another threshold is more appropriate.

If CMS does consider increasing this amount in the future, this decision should be based upon behavioral economic analyses of Advanced APMs, including the levels of risk that they are able to take on and the impact of risk on participation. Additionally, as CMS has not yet tested or implemented physician-focused APM models, such as those recommended by the PTAC, if risk levels are increased in
the future, any new models implemented after such time should benefit from a phase in to those hire risk levels over a sufficient period of time.

**Determination of Other Payer Advanced APMs**

**Multi-Year Other Payer Advanced APM Determinations**

CMS has proposed a multi-year determination process for Other Payer Advanced APMs in which the requester would need to submit information only on any changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement up to 5 years. For multi-year payment arrangements, CMS proposed to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria and, thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement.

ACS supports this proposal and agrees that it will reduce administrative burdens which could otherwise create unintended barriers to payers and others requesting an Advanced APM determination.

**Calculation of All-Payer Combination Option Threshold Scores and QP Determinations**

**QP Determinations Under the All-Payer Combination Option**

CMS proposes to allow requests for QP determinations at the TIN level (in addition to the APM Entity level and the individual level) in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity.

CMS further states that they will make QP assessments at all requested levels and determine QP status on the basis of the most advantageous applicable assessment. ACS appreciates this additional flexibility in making QP determinations. This flexibility may be necessary for small practices and individuals unable to achieve the threshold through participation in a single entity due to lack of availability or other factors.

**Request For Information On Promoting Interoperability And Electronic Healthcare Information Exchange Through Possible Revisions To The CMS**
Patient Health And Safety Requirements For Hospitals And Other Medicare And Medicaid Participating Providers And Suppliers

CMS seeks feedback from stakeholders on how the Agency could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (i.e., the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs)) to further advance electronic exchange of information that supports safe and effective transitions of care between hospitals and community providers. This Request for Information (RFI) describes a number of examples of potential revisions to current CMS CoPs, specifically related to electronic transfer of information to assist discharge. The RFI also poses several questions related to possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information.

Revisions to the CMS Patient Health and Safety Requirements

We appreciate CMS’ attention to the importance of electronic healthcare data exchange and eventually interoperability that would serve to inform care. We do not believe that use of the CMS CoPs/CfCs/RfPs is an appropriate way to advance interoperability at this time. Instead, CMS and ONC should focus on a more direct strategy to incentivize increased interoperability. Exchange of electronic patient data and interoperability will advance in stages as clinicians and facilities become more sophisticated and as technology improves. We also encourage HHS to translate the Office of the National Coordinator for Health IT (ONC) Interoperability Roadmap into an operational plan to provide clinicians with the tools they need to access interoperable digital health data. Prior to this, CMS could implement rewards and penalties to encourage the use of interoperability. But at this time, hospitals and providers should not be faced with exclusion from the Medicare and Medicaid programs due to failure to comply with CoPs/CfCs/RfPs intended to further advance electronic exchange of information.

Discharge Use Cases

One way to begin to expand interoperability is to examine specific use cases. If CMS intends to start with transitions of care or discharge as initial use cases, we urge the Agency to take into consideration the longitudinal needs of the patient and not to simply focus on electronic transmission of EHRs related to the admission at issue. For example, if an elderly patient with heart disease who had been living independently was admitted to a hospital for a broken hip and subsequently required SNF care, the data that are transmitted upon transfer to the
SNF should not just be limited to information related to treatment of the ankle; rather, it should include information related to the treatment of all the conditions and diseases that the patient is being treated for in addition to historical information about the patient’s care prior to the admission so that the patient’s clinicians understand the needs of the patient prior to the broken hip. In addition, relevant data should not be limited to information recorded in EHRs but should also include pertinent information collected through other means such as clinical registries, public health registries, cancer databases, labs, other healthcare facilities, and apps.

To further develop this use case, the ideal data for interoperable knowledge exchange related to a discharge should be in the form of a core set of post-discharge knowledge artifacts applicable to the majority of surgical patients. Such information would include: (1) the work that the surgeon did; (2) why the surgeon provided this care to the patient; (3) events that occurred during the hospitalization; (4) the status of the patient upon discharge (whether the patient is ambulatory, whether the patient in pain, what the patient’s baseline medications are, etc.); and (5) subsequent care needed (e.g., rehab, chemotherapy, or radiation). This information can be communicated to anyone who would need to understand the care that the patient received while in the hospital. In addition to the core set of surgical knowledge artifacts, additional procedure- and condition-specific knowledge artifacts should be defined as well. This information should be built using exchangeable standards and should comprise a library of artifacts that can be utilized in multiple use cases. Data that are transferred should not be limited to just EHRs; rather, relevant data from the wider clinical data ecosystem collected through a range of technologies should be incorporated. Finally, data should be shared in a way that is usable for the recipient, be it an EHR vendor, another type of vendor that is running an app, or the patient. It is not enough that data be transferred in a way that only EHRs can accept.

**Interoperability**

We would also like to take this opportunity to speak to the important topic of interoperability more generally. The ACS supports efforts to move toward a standards-based interoperable digital health information system that serves not only to ease documentation burdens, but also to inform care through clinical decision support tools and eventually through more advanced technologies such as machine learning and artificial intelligence.

The complexity of modern medicine has exceeded the ability of a single physician to provide all the care that a patient requires because there are limits to the
amount of information one can process. The clinical care model is growing increasingly complex and the need for digital information to flow between all members of a team is critical to successful patient care and prevention of medical error. Such data must be captured or documented digitally, but also must be synthesized and represented back to the provider in a convenient and usable format. Without access to interoperable and usable digital health information, providers spend hours documenting and searching for information, which is extremely burdensome. In addition, without interoperability, providers lose the opportunity to truly leverage health care data available in the entire clinical data ecosystem to enhance algorithms of care and treatment plans, analyze outcomes of therapy, and track resources.

The ultimate goal is to achieve an interoperable digital health information system. This would assimilate data from not only EHRs but also other patient data sources such as registries, performance measurement, smart devices, medical devices, research data systems, pharmacy data, and more. An essential point to stress is that data liquidity extends beyond a patient’s consolidated medical record and patient data should become available for a range of applications or services, thereby enabling a knowledge representation wherever needed. A digital health information system requires creation of HL7 digital standards for patient information to smoothly interoperate and be represented in a clinical workflow within and between EHRs and all the locations where patient data reside.

**Need for both clinical and technical standards**

One way to describe our view of interoperability in more granular terms is to start with use cases, which are libraries of ideas that involve all aspects of care. Use cases are designed by clinicians, government agencies, and others and are placed into the cloud to improve workflow and to achieve optimal patient care. Examples of use case ideas include clinical decision support, making guidelines or evidence available, automating registry exchanges, building outputs for performance measurement, and communicating across care delivery teams. This RFI appears to indicate that CMS considers the discharge use case as a potential starting point.

Although clinical and technical standards needed for interoperability are developed separately, the clinical experts must join with the technology experts to provide the context and contextual profiles needed for use cases and eventually to build apps. Development of clinical logic models requires understanding the details of clinical care and mapping them to specific computable terminologies. We believe that the clinical experts are best positioned to develop and maintain
such clinical logic models. On the technical side, standards for how to define data, the value sets for the data, and the data models needed should be developed by technical experts such as those with expertise in HL7, FHIR, and open application program interfaces (APIs).

Once developed, use cases can be combined into a patient specific longitudinal care use case repository with help from clinical delivery systems, government agencies, specialty societies, payers and purchasers, and patient advocates. The objective is to develop a library of use cases that can be held in a use case repository. The use case repository would serve as one of the foundational elements for building the digital components of a learning health system. The digital infrastructure of a learning health system lacks full development of its architecture, but such a use case repository would serve as a first step toward building the infrastructure for standards-based interoperability.

**ACS Recommendations**

We believe that all related government agencies should work together to promote interoperability. Multiple government agencies have already shown interest in this area and can contribute to important effort of improving interoperability. The National Institutes of Health (NIH) is doing work in research interoperability, the Centers for Disease Control and Prevention (CDC) in clinical guidelines conformance, the Agency for Healthcare Research and Quality (AHRQ) in quality, and CMS in regard to clinical value. Given this activity, it would be helpful if clinical logic models and care mappings that we described above could be developed in the National Library of Medicine (NLM) as an open repository. It would also be helpful to have computable logic models as open source. Examples are those suggested, created, and shared through the Healthcare Services Platform Consortium (HSPC). Having a dedicated entity governing updates, availability, and version control of logic models would further promote trust and communication among stakeholders, and progress consensus-based standards for interoperability.

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 Vinita Ollapally, Regulatory Affairs Manager, at vollapally@facs.org, or Jill Sage, Quality Affairs Manager, at jsage@facs.org.
Sincerely,

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