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December 28, 2018

Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1693-IFC

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; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (CMS-1693-IFC)

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) final rule with comment period: *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; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act*, published in the *Federal Register* on November 23, 2018.

The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large 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

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Physician Fee Schedule (PFS) and the Quality Payment Program (QPP), and we believe that we can offer insight to the Agency's modifications to such policies. Our comments below are presented in the order in which they appear in the rule.

PROVISIONS OF THE FINAL RULE FOR PFS

Determination of Practice Expense Relative Value Units

Indirect Practice Expense per Hour Data

CMS indicates that it received comments from stakeholders recommending the implementation of a new, nationwide all-specialty practice expense per hour (PE/HR) survey. The Agency notes that stakeholders were concerned that continued utilization of the American Medical Association (AMA) Physician Practice Expense Information Survey (PPIS)—the main source of data used by CMS for the development of PE relative value units (RVUs)—may lead to an inappropriate and inaccurate distortion of PE RVUs, as the practice of medicine has significantly evolved since the last PPIS was conducted. CMS states that, while it believes the PPIS data are the best currently available for PE costs, it has contracted with the RAND Corporation to explore the feasibility of updating the information used to determine PE RVUs.

While the ACS agrees that an update to PE/HR data is warranted, we do not think that RAND is the appropriate entity to conduct such a project. **The College believes that the AMA is best suited to obtain and provide new PE/HR information through a survey such as the PPIS—which collects comprehensive, multi-specialty practice cost data from a nationally representative sample of physicians—and anticipates that the medical community would be more responsive to a survey sent by AMA than to one by RAND.**

Updates to Prices for Existing Direct PE Inputs

Market-Based Supply and Equipment Pricing Update

CMS stated in the CY 2019 PFS proposed rule that it had entered into a market research contract with StrategyGen to perform a market research study for the purposes of updating direct PE inputs for supply and equipment pricing. 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. In this final rule, the Agency indicated that it will use data collected by StrategyGen to update pricing over a 4-year period for all supplies

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and equipment items reviewed. CMS seeks assistance in identifying supply and equipment items that may require additional research into their pricing.

The ACS has deep concerns with the lack of transparency in StrategyGen's recommendations and CMS' conduct for such a major revision to DPEIs. We believe that CMS' request for stakeholder assistance in identifying supply and equipment items that may necessitate further pricing research suggests that the Agency is not confident in the accuracy of the data provided by StrategyGen, and we do not think that stakeholders can adequately provide such information until CMS clarifies the individual items (e.g., contents of various kits, packs, and trays) included in StrategyGen's study.

In our comments on the proposed rule, the College highlighted several examples of significant pricing errors or problematic recommendations made by StrategyGen that we believe should have been identified and fixed by CMS during an internal validation process. We note that the Agency acknowledged in this final rule our concerns with CMS' proposal—based on StrategyGen's recommendation—to increase the price of a disposable gown (SB026) from \$0.533 to \$3.540, and subsequently finalized a reduced price of \$0.59 for this item.

While the Agency corrected the price for SB026 per the ACS' comments, it did not revise its pricing for the evaluation and management (E/M) visit pack (SA047), which, as we described in our response to the proposed rule, is not a traditional "pack" that is wrapped and opened for single use, but instead a convenient grouping of ten individual items that are typically used during stand-alone E/M visits. Despite the College's feedback, CMS finalized StrategyGen's recommended pricing of \$7.750 for SA047 (see Table 1). As shown in Table 2, the correct price for this item, based upon the contents of the E/M visit pack, should be \$5.468, not \$7.750. Considering that SA047 is priced into the PE details for over 236 million Medicare claims, CMS' error represents over a \$500 million difference in PE costs.

Table 1: Finalized Four Year Phase-In Pricing Update for SA047

CMS Code	Description	CMS 2018 Price	StrategyGen Recommended Price	Year 1 (CY 2019) Price	Year 2 (CY 2020) Price	Year 3 (CY 2021) Price	Final (CY 2022) Price
SA047	Pack, E/M visit	\$2.984	\$7.750	\$4.176	\$5.367	\$6.559	\$7.750

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Table 2: Pricing for Individual Supply Items Included in SA047

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

Without details about the pricing for each item, we cannot assist CMS in correcting equipment and supply codes that may have been mispriced by StrategyGen. **The College asks that CMS make publicly available the specific source(s) (e.g., Amazon Business, Cardinal Health, and vendor surveys), manufacturers, and pricing details (e.g., average of available item sizes, kit/ tray/ pack contents) for each supply and equipment item to facilitate both stakeholder and RUC PE Subcommittee review.**

Determination of Malpractice Relative Value Units

In the CY 2019 PFS proposed rule, CMS solicited comment regarding the next malpractice (MP) RVU update—which must occur by CY 2020—and specifically asked for recommendations on how the Agency could improve the way that specialties in state-level raw rate filings data are crosswalked for categorization by CMS to develop specialty-level risk factors and MP RVUs. The Agency states in this final rule that it will consider the feedback received for future rulemaking, particularly for the upcoming statutorily-required update to MP RVUs.

We wish to reiterate that the current MP premium data collection and calculation processes employed by CMS and its contractor, Acumen, are



neither transparent nor precise, and that any MP RVU updates made using the most recent premium data provided by Acumen will unfairly reduce payments for physicians who regularly furnish surgical services. In our (1) CY 2019 PFS proposed rule comment letter, (2) CY 2018 PFS proposed rule comment letter, and (3) a separate, MP RVU-specific letter sent to HHS and CMS in September 2017, the ACS urged the Agency 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 accurately for each distinct specialty and premium class.^{1,2,3}

The College believes that medical specialty societies are well-positioned to survey their members at the practice level to obtain valid MP premium data, and we encourage CMS to provide a pathway (using a process similar to that enacted in the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 for PE RVUs) for such societies to gather and share MP premium information with CMS for the purposes of enhancing the Agency’s dataset.⁴ **We stand ready to work with the Agency to ensure that separate and correct surgical and non-surgical premium data for all specialties are obtained to compute resource-based MP RVUs for CY 2020.**

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

Brief Communication Technology-based Service

CMS finalized the valuation and code descriptor for Healthcare Common Procedure Coding System (HCPCS) code G2012 (*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*) as proposed for CY 2019. The Agency clarified that “audio-only real-time telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission” may be used in the provision of this service. **The ACS requests that CMS add this**

¹ American College of Surgeons. (2018). *CY 2019 MPFS Comment Letter*. Retrieved from https://www.facs.org/~media/files/advocacy/regulatory/cy_2019_mpfs_comment_letter_%20acs.ashx

² American College of Surgeons. (2017). *CY 2018 MPFS Comment Letter*. Retrieved from <https://www.facs.org/~media/files/advocacy/regulatory/cy%202018%20acs%20mpfs%20comment%20letter.ashx>

³ American College of Surgeons. (2017). *MP RVU Sign-On Letter*. Retrieved from https://www.facs.org/~media/files/advocacy/regulatory/pli_signon_letter_083018.ashx

⁴ Balanced Budget Refinement Act of 1999, P.L. 106-113 § 212



terminology to the code descriptor for G2012 to clearly indicate the specific types of communication technologies that may be utilized for such service under Medicare billing rules.

Evaluation & Management Visits

For CY 2019, CMS finalized changes intended to reduce E/M documentation burden, including policies that will (1) permit physicians to choose to only document components of an established patient's history and exam that have changed since the patient's last visit, and (2) remove the requirement that physicians re-enter a new or established patient's chief complaint and/or history that has already been documented in the medical record. The Agency did not immediately finalize its proposed modifications to the valuation of E/M codes and instead postponed these adjustments until CY 2021, at which point CMS will establish a single payment rate for E/M office/outpatient visit levels 2, 3, and 4. In addition, CMS will allow for E/M documentation via either medical decision-making or time alone instead of applying the current 1995/1997 documentation guidelines in CY 2021; alternatively, physicians may choose to continue to use the current 1995/1997 guidelines. CMS also finalized several add-on codes for primary care visits, specialty visits, and extended visit services for CY 2021.

The ACS thanks CMS for finalizing its burden reduction proposals and for offering documentation options beyond the 1995/1997 guidelines. We also appreciate that the Agency did not finalize its proposed single payment rate for E/M office/outpatient visit levels 2 through 5 for CY 2019. However, we remain concerned about the CY 2021 single payment rate and add-on codes finalized for E/M office/outpatient visit levels 2, 3, and 4. **We strongly urge CMS to consider additional proposals regarding these issues that are introduced over the next year, and ask that the Agency not move forward with the single payment rate and add-on code policies finalized for CY 2021.**

OTHER PROVISIONS OF THE FINAL RULE

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Proposals for Continuing Implementation

Identification of Outliers

Section 1834(q) of the Social Security Act requires 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: (1) establishment of AUC; (2) identification of mechanisms for consultation with

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AUC; (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals; and (4) annual identification of outlier ordering professionals.⁵ The Agency seeks comment on the fourth component of the AUC program, and specifically solicits feedback to inform its methodology for identifying outliers who would eventually be subject to prior authorization (PA) when ordering advanced diagnostic imaging services.

While the College recognizes that CMS is directed by statute to develop a mechanism for the annual identification of outlier ordering professionals, and to apply PA for imaging services ordered by such outliers, we continue to believe that PA is an inefficient and onerous requirement for providers. The extensive PA processes currently imposed by private payors—including Medicare Advantage organizations—already place an extraordinary administrative burden on physicians and their practices, and we believe that such payors routinely and increasingly use PA to deter physicians from ordering or furnishing medically necessary treatment for patients, rather than as a legitimate mechanism for identifying overutilization.

The ACS remains concerned that the introduction of such processes into the Medicare program will inappropriately delay patient care and unduly restrain providers who adhere to clinical standards and evidence-based medicine. **We therefore urge CMS to limit the scope of AUC PA requirements to those providers whose performance (after adjusting for patient population) suggests a pattern of overutilization within the eight priority clinical areas finalized by the Agency in the CY 2017 PFS.**⁶ In addition, while we appreciate CMS' clarification in this final rule that the AUC PA exception for emergency medical conditions is applicable in situations where such a condition is *suspected*, even if it is determined later that the patient's condition was *not* in fact emergent, the College believes that the Agency should not apply these requirements in the emergency department (ED) at all. **Specifically, we urge CMS to exempt ordering professionals that are identified as outliers within the Agency's priority clinical areas from AUC PA when rendering services in an ED.**

As CMS continues to proceed with implementation of the Protecting Access to Medicare Act (PAMA) AUC program requirements, and in the absence of subsequent legislation that makes changes to the AUC program, **we also ask that the Agency incorporate three major elements in its execution of AUC PA to ensure scientific rigor and offer regulatory relief to patients and providers:** (1) base PA logic on current evidence from appropriate clinical experts and publish such logic as an open standard with a public comment period; (2)

⁵ Recognizing Appropriate Use Criteria for Certain Imaging Services, 42 U.S.C. § 1395m(q)

⁶ Appropriate Use Criteria for Advanced Diagnostic Imaging Services, 42 C.F.R. § 414.94(e)(5)

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facilitate the development and utilization of clinical decision support tools using Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) for the purposes of digitizing and automating PA within electronic health records (EHRs); and (3) encourage all health plans to use the same open standards and electronic services for PA in order to avoid both the imposition of different PA logic from each payor, as well as confusion related to compliance with multiple plans' PA requirements in the clinical setting.

CY 2019 Updates to the Quality Payment Program

MIPS ACS Overview

Considering the Congressional intent of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the ACS envisioned the Merit-based Incentive Payment System (MIPS) as a program to initially measure care within a primarily volume-based, fee-for-service framework with value-based incentivizes, but ultimately as a pathway or transition toward alternative payment models (APMs) to measure value-based care. However, the QPP is a payment program, not the patient-centric quality program as intended by law, and does not measure quality aligned with the care delivered by coordinated care teams in clinical models. Instead, the QPP is designed around administrative claims transactions using unrelated quality measures as a proxy for quality and measurement of “success.” As such, QPP measure reporting options are designed around a clinician's tax ID or Medicare provider identifier, and do not consider a patient's individual care journey across time for their condition. This results in a fragmented measurement system with metrics that are disconnected from the patient's clinical experience.

CMS has missed the opportunity to define and measure value and instead has retrofitted the siloed legacy programs used prior to MACRA (e.g., the Physician Quality Reporting System (PQRS), Value Modifier (VM), and Meaningful Use) to create the current MIPS program. Such legacy programs were created through the lens of fee-for-service transactions where quality measures were based on billable services. The measures that came from these programs are not valid, reliable, or meaningful to surgical care and are therefore burdensome. They continue to create distractions for surgeons who are told by their hospital employers or C-suite that performance on MIPS is important for the hospital's bottom line. As a result, most surgeons are ranked based on measures in the Web Interface, which evaluates compliance with immunizations, blood pressure control, diabetes control and tobacco cessation. These measures do not inform surgical patients about episodes of surgical care (i.e., the patient's experience), and they do not provide information needed by surgeons to improve care, including critical patient safety indicators. It has become clear that the QPP will

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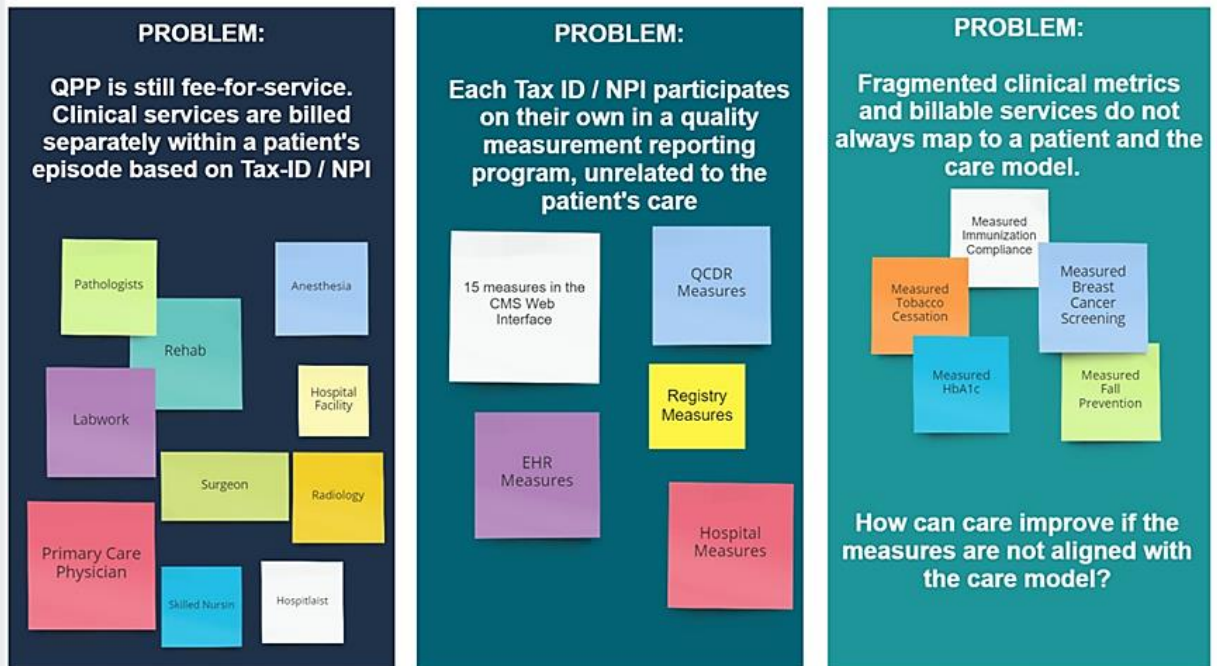
fail as a valued quality program if CMS continues on its current path. Misvaluing care by ranking and paying clinicians based on flawed measures and methodologies, while also adding to physician burden, could have grave impacts on Medicare beneficiaries.

Figure 1 below illustrates the chaos created by the MIPS program from the surgical patient and provider perspective. The program uses metrics broadly applied across physicians without a real appreciation for the details involved in surgical quality and improvement, despite suggestions from specialties to design the program as such. CMS has developed the MIPS measure framework based on clinical services billed to Medicare, not episodes of care. The measures are reported using a submission process that does not consider the care delivery model. The result is fragmented metrics that do not always map to the patient.

Figure 1: Why the QPP Fails to Get Us to Value or Improvement

The Quality Payment Program (QPP) measurement system is a payment program, not the patient-centric quality program as intended by law. QPP does not align with care models. It is designed around how services are paid for using aspects of claims transactions as a proxy for quality and measurement of "success." As such, QPP measure reporting options are designed around a clinician's tax ID or Medicare provider identifier, and do not consider the patient's care journey. This results in a fragmented measurement system with metrics which are disconnected from the patient experience.

- What matters most to patients and providers is safer, efficient and high quality care. -



Team Based Episodes of Care: Surgical Procedure (Hip Replacement, Appendectomy, Colectomy, CABG)



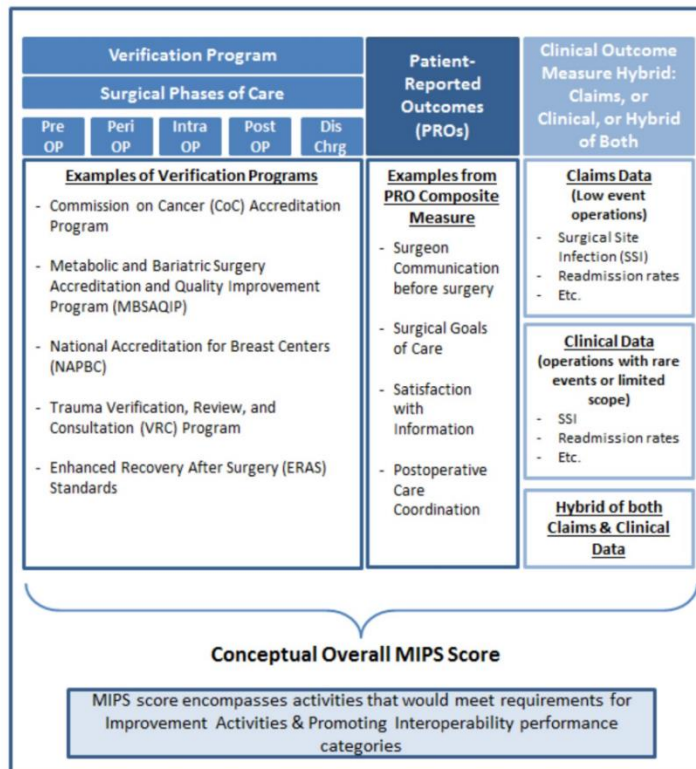
We ask CMS, how can care improve if the measures are not aligned with the clinical care model and fail to unify the entire care team around the patient in coordinated care? As illustrated below in Figure 2, we offer an alternative solution to the current QPP program. This alternative could act as a paradigm 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.

This framework is based on decades of research and implementation in verification programs, which have proven successful in driving better surgical outcomes, and is supported by over 2,000 publications in the literature. The proposed framework includes patient-reported outcomes into the framework as a new addition, which will need to be tested. Our proposal is based on the simple tenet that patient-centric quality should measure the patient outcome and incorporate shared accountability for the entire team.^{7, 8, 9, 10}

Figure 2: How to Achieve Value and Improvement

$$\text{ACS Value Statement} \\ \text{Value} = (\text{Quality} + \text{Service}) / \text{Cost} \\ \text{for the episode}$$

True patient-centric quality should measure the patient outcome and have shared accountability for the entire team.



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This framework can be applied to various clinical domains of surgery, such as cancer care, trauma care, bariatric care, frail/geriatric care, and be thought of as collections of team-based episodes of care. Within a given domain, such as cancer, are the various aspects of care. For cancer these are represented as prevention, screening, early diagnosis, treatment, post treatment surveillance and ultimately, end-of-life care. At any point along the patient's journey are episodes which highlight the team-based care a patient would expect to receive. For example, a surgical resection for cancer may involve debulking and staging the disease, while also including a method for tracking quality through verification of key standards, patient-reported outcomes and clinical outcomes. We envision three key components for the overall MIPS score:

1. **Verification of Key Standards of Care.** Since the inception of the ACS, we have built standards for clinical domains with the expectation of improving overall outcomes of surgical care. Through this work, we have gained over a half-century of experience in building clinical verification programs for specific clinical domains. Each of the major surgical domains contain a set of standards as part of a renewable, triennial verification program. These programs have proven to drive quality, improvement, and excellence in care. We envision long-term goals to include the ability to scale verification programs as part of a foundational component to a national quality system in surgical care.

2. **Clinical Outcome Measures.** We envision the use of administrative claims measures for low event rate care, and propose using programs such as the National Surgical Quality Improvement Program (NSQIP) to show risk-adjusted clinical outcomes for complex, high-risk care. This would require detailed piloting and testing before large-scale implementation.

⁷ American College of Surgeons Commission on Cancer. (2016). *Cancer Program Standards: Ensuring Patient-Centered Care*. Retrieved from https://www.facs.org/~media/files/quality%20programs/cancer/coc/2016%20coc%20standards%20manual_interactive%20pdf.ashx

⁸ American College of Surgeons. (2016). *Standards Manual v2.0: Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient*. Retrieved from <https://www.facs.org/~media/files/quality%20programs/bariatric/mbsaqip%20standardsmanual.ashx>

⁹ American College of Surgeons. (2018). *National Accreditation Program for Breast Centers: Standards Manual*. Retrieved from <https://accreditation.facs.org/accreditationdocuments/NAPBC/Portal%20Resources/2018NAPBCStandardsManual.pdf>

¹⁰ American College of Surgeons Committee on Trauma. (2014). *Resources for Optimal Care of the Injured Patient*. Retrieved from <https://www.facs.org/~media/files/quality%20programs/trauma/vrc%20resources/resources%20for%20optimal%20care.ashx>

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3. **Patient-Reported Outcomes**. In addition to verification programs and clinical outcome measures, we propose inclusion of patient-reported outcomes (PROs) based on an episode of care in order to assess whether the team-based episode achieves the patient’s expectations. We have begun early testing and development of enriched PROs focused on surgical outcomes. 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.

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 is simultaneously integrated into surgical workflows, while reducing burden by measuring compliance with standards through triennial surveys, rather than measures linked to CPT or diagnosis-related group (DRG) codes. Such surveys exist in thousands of delivery systems today, with demonstrated success in trauma, cancer, and bariatric surgery.

We urge CMS to build a value framework based on what matters most to patients and providers—safer, efficient and high-quality care. For surgery, we believe the described ACS Value Statement should be tested for use in MIPS. We ask CMS, what would a patient undergoing a serious surgical procedure prefer? Do patients want to know information from the current CMS measures in the QPP prior to surgical treatment, or would patients rather have a clinical, valid representation of the care they are about to receive?

MIPS Program Details

Quality Performance Category

Topped Out Measures

The CMS topped out measure policy finalized last year sunsets topped out measures over a period of four years. The Agency’s definition of a topped out measure is one with a median performance rate of 95 percent or higher. After a measure has been identified as topped out for three consecutive years, CMS may propose to remove the measure through comment and rulemaking for 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 finalized an update to this policy for “extremely” topped out measures. Newly finalized for next year is an expedited pathway for extremely topped out measures, which are defined as measures with an average mean performance within the 98th to 100th percentile range. If a measure meets this definition, CMS can propose the measure for

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removal in the next rulemaking cycle, regardless of the point it is in the topped-out measure lifecycle. The Agency's rationale is that there is very little variation where meaningful distinctions and improvement in performance can be made when a measure is extremely topped out. In a recent meeting at the Surgical Quality Alliance (SQA), CMS also explained that they have heard feedback from physicians that reporting topped out measures is burdensome.

CMS also finalized a policy that excludes Qualified Clinical Data Registry (QCDR) measures from the topped-out measure lifecycle. The new policy states that once a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure. CMS explains that this is because QCDRs have more flexibility to develop measures.

From the ACS perspective, this policy is contrary to extensive literature and program success that aim for 100 percent compliance on meaningful surgical measures. A recent publication by Berian et al. demonstrated that length of stay (LOS) increased with decreasing adherence to 13 high value enhanced recovery protocol (ERP) process measures for elective colectomies. Hospitals with high adherence to ERPs resulted in fewer complications and patients achieved recovery milestones earlier when compared to moderate or low adherence to standards.¹¹

We ask CMS for evidence that their topped out policies (topped out measures and extremely topped out measures) actually improve patient safety or quality of care (or conversely, evidence that their removal from MIPS is not resulting in worse quality). We are not familiar with any evidence supporting this policy.

Promoting Interoperability (Previously Known as Advancing Care Information Performance Category)

Proposed Scoring Methodology Beginning with the MIPS Performance Period in 2019

CMS finalized a new scoring methodology for the Promoting Interoperability (PI) performance category, beginning with the 2019 performance year. The new methodology includes a combination of new and existing PI performance category measures, separating them into a set of four objectives: e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. MIPS eligible clinicians are required to report on certain measures within each of the four objectives, and their scores are derived

¹¹ Berian, J.R., Ban, K.A., Liu, J.B, et al. (2018). Adherence to enhanced recovery protocols in NSQIP and association with colectomy outcomes. *Annals of Surgery*. doi:10.1097/SLA.0000000000002566



from performance on each measure. The scores for each measure, excluding the Public Health and Clinical Data Exchange objective measure which require “yes or no” submissions, are based on the submission of a numerator and denominator. Performance scores earned for each required measure are then added together to calculate the PI category score of up to 100 possible points. Under the finalized scoring methodology, a clinician who fails to report on a required measure or claim an exclusion would receive a total score of zero for the PI performance category.

The College believes that the PI category perpetuates the continued development of one-off inoperable and siloed EHR products that are not easily integrated into a surgeon’s clinical workflow. It adds to the excessive burden placed on physicians by the MIPS program because it is not a useful tool for providing all relevant data at the point of care. While lacking in value, the PI program continues to require a large investment in 2015 certified EHR technology (CEHRT) without providing a return on investment for most surgical practices. For example, even with the addition of an API function, 2015 CEHRT is still not useful to surgeons because there are not well-developed apps in the marketplace to leverage the API functionality within surgical care.

We also have concerns regarding the rigid, all-or-nothing scoring methodology of the PI category. **As stated in our previous comments to the proposed rule, the ACS believes that CMS should align with the inpatient PI program and only require 50 performance category points to fully satisfy the PI category and receive 25 points towards the final MIPS composite score.** At the recent SQA meeting on November 29, 2018, the Agency encouraged public comment on a 50 performance point PI policy. CMS staff acknowledged that they are looking to align aspects of the Hospital PI program with the physician PI program. The ACS supports the implementation of a 50-point minimum to meet the definition of “meaningful user” and avoid a penalty. This would align with policies finalized in the 2019 Hospital Inpatient Prospective Payment System (IPPS) PI program requirements. We believe that it is inappropriate for individual clinicians to be held to a higher standard than hospitals, because they often have fewer resources.

The College also believes that clinicians should be able to choose the PI measures they report based on relevance to their practice. Clinicians should not be required to report on any single measure in order to satisfy the minimum requirements. For example, if the 50-point threshold can be achieved with high performance on three measures, this should be sufficient for full credit in the PI category. Allowing clinicians to choose the measures that are meaningful to their practice and lowering the point minimum for this category would significantly reduce burden.

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Qualified Clinical Data Registries

QCDRs Seeking Permission from another QCDR to Use an Existing, Approved QCDR Measure

In the CY 2019 PFS proposed rule, CMS proposed to require a QCDR to agree to enter into a license agreement with CMS that would allow any approved QCDR to submit data on the QCDR measure. If the QCDR refused to enter such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic could be approved in its place. The ACS strongly opposed this requirement and appreciates that CMS did not finalize this proposal and instead decided to retain its current policy, which requires a QCDR to seek permission in order to use measures owned by other QCDRs. However, we are concerned by CMS' suggestion that it might re-visit this policy in the future. **As we stated in our comments to the proposed rule, we strongly oppose requiring free licensure of QCDR measures because it undermines QCDR measure development and ownership by increasing the risk of inaccurate benchmarks and other measure integrity issues, dissuading QCDRs from investing in the development of measures.**

We urge CMS to continue to 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. If measures are used by multiple stakeholders in an inconsistent and unstandardized manner, they will result in inaccurate measurements. 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 surgical site infection (SSI) measure with the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (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, the ACS found that this discrepancy was not because NSQIP participants had poorer surgical outcomes, but instead was due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP.¹² In other words, NSQIP was better at following patients and identifying SSIs.

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¹² Ju, M.H., Ko, C.Y., Hall, B.L., et al. (2015). A comparison of 2 surgical site infection monitoring systems. *JAMA Surgery*, 150(1), 51-57.



Requirement for QCDR Measure Specifications

CMS has also requested comment on implementing a policy similar to the requirements of MIPS quality measures. The Agency notes that the current MIPS quality measures provide a detailed measure specification to allow consistency in implementation, but that data abstraction may include multiple methods. CMS solicits feedback on requiring QCDRs to follow a similar approach where QCDRs would need to provide detailed specifications to the QCDRs approved to use their measure(s), including International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes, CPT codes, required clinical data elements, and others to reduce variance in implementation. CMS has asked QCDR vendors if this would be useful or increase burden during measure development. CMS also seeks input on how it can reduce benchmarking issues to incentivize QCDR measure reporting. We believe both of these scenarios are directly related to each other.

To start, it is critical to step back and acknowledge that many of the current MIPS measures, despite the availability of the measure specifications, are unreliable and invalid because CMS has allowed multiple entities to report on these using only simple measure specifications (common data elements). We believe that the use of standardized data elements is just one critical requirement for increasing measure integrity in the MIPS program. **If data are collected by various sources for use in MIPS, there must be consistency in data aggregation, analytics, and reporting.** The College has continued to advocate for the use of a single source of truth for each specific clinical domain when establishing quality measure benchmarks. In our comment letter to the CY 2019 PFS proposed rule, we cited the Society for Thoracic Surgeons (STS) National Database as an example of a single source of truth, because they remain the only data system for a small number of operations. STS allows the utilization of a single method for data aggregation, analytics and reporting. **We believe that medical societies with clinician-led QCDRs are well positioned to serve as a trusted source of truth based on their proven expertise in their clinical domains and their commitment to quality improvement. The College believes that implementing a model in which CMS designates trusted entities in their field to serve as a single source of truth would resolve many of the issues surrounding MIPS quality measurement, such as duplicative measures, meaningfulness of measures, and benchmarking.** In this example, the trusted entity, or single source of truth, could come to an agreement with another entity that wants to report their QCDR measures. Between the two entities, they can decide the appropriate safeguards needed to ensure rigor in data aggregation, analytics, and reporting for their particular measure set.

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It is also important to consider that there is great diversity in the way QCDRs collect, analyze, and aggregate data. We believe if CMS were to audit and compare QCDRs with a single source to those with multiple vendors, the Agency would easily recognize the limitations of the CMS model, which relies solely on measure specifications and ignores the other critical components basic to any clinical registry. We refer CMS to the Agency for Healthcare Research and Quality (AHRQ) to validate the ACS' assertions; specifically, we wish to direct CMS to AHRQ's Effective Health Care Program and their body of work on registries and evaluating patient outcomes.¹³

We also have serious concerns with how CMS is implementing the QCDR program. CMS has loosely interpreted who could become a QCDR, which has allowed for-profit companies with little to no expertise in quality measurement to qualify. This has led to companies competing with clinical experts and developing slightly modified measures, resulting in thousands of QCDR measures. This makes it impossible to reliably benchmark the conditions captured in QCDRs. According to CMS staff, it has also created too much of a burden for the Agency to review and track. This has led CMS to greatly reducing incentives to become a QCDR and report via the QCDR. The Agency has been rejecting measures due to lack of performance data, and it continues to adopt policies that disincentivize the use of QCDR measures, to reject measures based on flawed "topped out" determinations, and to request unreasonable timelines, such as a 48-hour turn-around, for QCDRs to update, harmonize or identify alternative measures. This is counterproductive to measuring specialty care. For example, CMS deemed two of the ACS' trauma measures topped out and told the College to provide more data to demonstrate a gap, or to choose to report a MIPS measures to meet the 6 measure QCDR minimum. We attempted to substitute one MIPS measure to meet the 6 measure minimum, but could not easily do so because the trauma registry captures ICD-10 codes and does not capture CPT codes. Since ICD-10 codes are primarily used in trauma care, we would have had to significantly modify our long-standing business and operations model to collect the data for a single MIPS measure. As an alternative, we slightly modified both measures to focus on the patient populations that are higher risk, and a subsequent data analysis showed a much more considerable performance gap. The modification to each measure in question was a single denominator criterion, which focused on the more at-risk patient population. Within CMS' initial deadline, we provided the modified measures and a rationale for the simple modifications. However, CMS refused to consider these modifications. Despite our efforts, the ACS Trauma QCDR will not be available in 2019.

¹³ Agency for Healthcare Research and Quality. (2018). Registries for evaluating patient outcomes: A user's guide: Prior editions. *Effective Health Care Program*. Retrieved from <https://effectivehealthcare.ahrq.gov/topics/registries-guide-4th-edition/prior-editions>

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

Sincerely,

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