September 26, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Administrator Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS or the College), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services’ (CMS) calendar year (CY) 2020 Medicare Physician Fee Schedule proposed rule (CMS-1715-P) published in the Federal Register on August 14, 2019.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large portion of our members’ performance and reimbursement is measured and paid for under the provisions contained in this rule, the ACS has a vested interest in CMS’ Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP), and with our 100-year history in developing policy recommendations to optimize the delivery of surgical services, lower costs, improve program integrity, and make the U.S. healthcare system more effective and accessible, we believe that we can offer insight to the Agency’s proposed modifications to the PFS and QPP. Our comments below are presented in the order in which they appear in the rule.
Please note that this letter, dated September 26, 2019, includes the ACS’ comments to the Quality Payment Program (QPP), MIPS Value Pathways (MVP) Request for Information (RFI) and other RFIs and comments to “Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm” section of the PFS. The College submitted a separate letter on September 10, 2019 which exclusively included the ACS’ comments to all other proposed CY 2020 MPFS payment provisions.

**CY 2020 UPDATES TO THE QUALITY PAYMENT PROGRAM**

**Transforming MIPS: MIPS Value Pathways Request for Information**

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

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

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.

2. MVPs should include measures and activities that would result in providing comparative performance data that are valuable to patients and caregivers in evaluating clinician performance and making choices about their care.

3. MVPs should include measures that encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to Alternative Payment Model (APM) participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

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

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

**ACS THRIVE Project: Opportunities to Align with MVPs**

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

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

**ACS THRIVE: Assessing Quality and Improvement**

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

Clarifying the Term “Quality”

**Two Definitions of Quality**

1. **Hitting the specifications**
   *preventable or avoidable*
   “do no harm”
   Conformance Quality

2. **Superior performance**
   *achieving patient goals*
   Example: patient able to walk again as a result of surgery
   Performance Quality

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

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ACS THRIVE: Assessing Cost and Price

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

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

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

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

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

**ACS Recommended MVP Guiding Principles**

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

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

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

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

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

3. **Quality scoring based on participation in verification programs, conformance measures, and performance measures.** Scoring for quality should constitute three categories with shared attribution at the team level: participation in a verification program, conformance measures chosen from a list of CMS consistent metrics (Surgical Site Infection (SSI), Readmissions and Surgical Risk Calculator, etc.) and PROs applied as appropriate for the condition/procedure (e.g. PROMIS, elements of EORTC, or EQ 5D-5L). Note that there is a proposed framework detailed below.

4. **Test the attribution methodology for assigning clinicians to MVP(s).** Many surgeons will have a single dominant domain which will map to an MVP. However, depending on their practice, surgeons may not have a single dominant domain and will fit into multiple MVPs. Therefore, CMS will need to analyze the appropriate methodology for how to determine the appropriate MVP or mix of MVPs. For example, would CMS determine which MVPs clinicians fall into based on a percentage of cases? If so, will

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5. [http://www.healthmeasures.net/explore-measurement-systems/promis](http://www.healthmeasures.net/explore-measurement-systems/promis)
6. [https://qol.eortc.org/item-library/](https://qol.eortc.org/item-library/)
7. [https://euroqol.org/docs/EQ-5D-5L-User-Guide.pdf](https://euroqol.org/docs/EQ-5D-5L-User-Guide.pdf)
that result in accurately assessing their care? This must be carefully analyzed.

5. **Restructure the Promoting Interoperability performance category to enable true interoperability beyond electronic health records (EHRs).** To truly promote interoperability, CMS must incentivize the use of enhanced digital health IT capability. The functionality for digitally enhanced data aggregation should be a minimum standard for health IT in the MVP program. Functional EHR requirements should move toward verification and authentication of meeting national standards that enable the movement of health data across the digital environment. The goal for interoperability should be the digital transformation of data into knowledge and insights through the use of an open-source patient cloud. In this environment, Application Programming Interfaces (APIs) can flourish to deliver performance measures, inform patients, and to share knowledge with registries and other smart devices.

6. **A single source or entity to aggregate data for MVP benchmarking.** Measures should be analyzed and aggregated within a given domain or clinical service line by a single source and submitted to CMS for consistency in data interpretation. This includes standardized data definitions, standardized risk adjustment/data analytics, consistency of data ascertainment methods, and common normalization methods. It is nearly impossible (and overly costly) to create reliable and valid comparisons between care systems when multiple data aggregation systems are used for measurement. Examples include the Society for Thoracic Surgeons Registry, the ACS National Surgical Quality Improvement Program (NSQIP) and the American Academy of Ophthalmology IRIS® Registry each as single source. The importance of this cannot be overemphasized.

7. **Clinicians need to understand the cost of delivering outcomes for an episode, and the price to patients for shopability.** To move from fee-for-service into value-based care, delivery systems need support to understand both the cost and price aspects of care to optimize value. The tools for establishing production costs for facility-based care are possible using TDABC. Price models use episode groupers which are customizable by the clinicians using industry standards (such as the CMS-Episode Grouper Methodology (EGM)). CMS can enhance the CMS-EGM grouper use by moving it into position as a tool sitting over the CMS Virtual Research Data Center (VRDC).
8. **MVPs should be reviewed and endorsed by an agent for CMS.** For surgery, a library of pilot IPUs/episodes could be developed by ACS and HBS, then reviewed and endorsed by an agent for CMS. This will include the minimum criteria for quality and cost elements for CMS value-based care prior to inclusion into the CMS MVP program.

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

**MVP Framework for Scoring Quality and Improvement**

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

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

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

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

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

**SQVP Standards:**\textsuperscript{11}

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

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


surgical services for each of the MVPs she is eligible for (note: the appropriate methodology for how to determine the appropriate MVP or mix of MVPs must be analyzed). The MVP Score can be established with a total score by volume and weight assigned to: the SQVP Verification (or other relevant verification program), PROs, and the event rates. ACS weights the SQVP and PROs as the dominant elements. To meet the MVP’s program needs, the IA and PI categories are represented within the verification program. For an initial pilot year(s), these broadly applied components—verification, performance, and conformance measures can be a starting place. In future years, more detailed metrics could be refined for each MVP if needed. Inputs for how to measure and weight the components would require guidance from a multi-stakeholder community. ACS is currently working on how to determine differing levels of verification for the purposes of incentivizing high-valued surgical care, and how to assess performance and conformance measures as part of the Total Weighted Average MVP score. ACS continues to develop the ACS THRIVE framework and is eager to collaborate with CMS on the development of surgical MVPs.
Figure 3: MVP Scoring Example (for illustrative purposes)

<table>
<thead>
<tr>
<th>Verification Program: SQVP</th>
<th>MVP – Colon Cancer</th>
<th>MVP – Breast Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highest Weight in MVP Score</td>
<td>Score based on verification level</td>
<td>Score based on verification level</td>
</tr>
<tr>
<td>Performance: PROMIS, EORTC or EQ – 5D – 5 L</td>
<td>Medium Weight in MVP Score</td>
<td>Score based on performance</td>
</tr>
<tr>
<td>Conformance: SSI/Readmit/Risk Calculator (Event rates)</td>
<td>Lowest Weight in MVP Score (least important)</td>
<td>Score based on performance</td>
</tr>
<tr>
<td>Hospital A MVP Score (Y+Z)</td>
<td>Y</td>
<td>Z</td>
</tr>
</tbody>
</table>

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</tr>
<tr>
<td>Conformance: SSI/Readmit/Risk Calculator (Event rates)</td>
<td>Lowest Weight in MVP Score (least important)</td>
<td>Score based on performance</td>
</tr>
<tr>
<td>Hospital B MVP Score (A+B)</td>
<td>A</td>
<td>B</td>
</tr>
</tbody>
</table>

Surgeon Total MVP Score = Weighted Average of Hospital A and Hospital B

**Data Integrity as a Key Focus of MVPs**

ACS has stressed the importance of a “single source” or entity to aggregate data for benchmarking performance. In our experience with NSQIP and other ACS clinical data registries, we have demonstrated that it is critical for measures to be analyzed and aggregated by a single source for consistency in data interpretation, including standardized data definitions, standardized risk adjustment/data analytics, consistency of data ascertainment methods, and common normalization.
methods. It is otherwise virtually impossible (and overly costly) to create reliable and valid comparisons between care systems when multiple data aggregation systems are used for measurement. It is also critical to use the appropriate measure science when determining validity and reliability. Currently, the MIPS program requires a percentage of cases over a 12-month period to determine performance for a given quality measure. This is arbitrary and has no basis in measure science, resulting in inconsistent levels of statistical power. We have proven that the data completeness requirement is not reliable for most surgical measures as a result of the number of cases a surgeon completes in a 12-month period—this is the case for clinical outcome measures that monitor low event rates such as mortality and SSI in particular. We discuss this in further detail in our comments to the 2020 QPP program.

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

**MVP Population Health Quality Measure Set**

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

**MVP Framework for Cost and Price**

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

**Cost-of Delivering Services: TDABC**

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

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

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

**Price of Delivering Patient Outcomes**

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

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

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

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

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

The College believes that value is determined by an assessment that is made by the patient, and therefore must measure health outcomes that matter to the patient. Patients need information on care and outcomes that can be assessed, rather than a single score that represents the way in which CMS defines value. **Patients value aspects of care differently, and need information on multiple, meaningful, areas from which they can determine value as they define it.** To align with our recommendations for the MVP program, publicly reported information should include participation in a surgical verification program(s) for assurances in quality and safety, actionable cost measures, conformance measures, and performance measures (PROs). Information from these components will provide patients with meaningful information through which they can assess and determine value.

Below are two figures that could be helpful for patients to assess the value of care. Figure 4 compares quality and cost in a bar chart for hospital based episodes. Figure 5 is a radar plot which defines the various elements of care that may be of interest to patients. These representations are for illustrative purposes only and must be tested for their ability to help patients assess value.
Figure 4: Value Expression for Hospital-based Episodes

![Quality & Cost for hospital based episodes – Side by Side](image)

Note: These are mock results showing side-by-side NSQIP quality and claims based resource use measures for the same hospitals. Each letter represents an episode that has information in both NSQIP and claims.

Figure 5: Radar Chart Episode Value Expression

![Radar Chart Episode Value Expression](image)
MVP Framework for Interoperability

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

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

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

- **Require the use of open APIs using FHIR-based standards when ONC finalizes Cures regulations.** When the ONC finalizes the 21st Century Cures rule, the standards for implementing APIs using FHIR based standards will be clearly defined. We strongly encourage CMS to work with ONC to include the same standards as an attestation for the PI category, in which clinicians would attest to using APIs that adhere to the ONC standards. As the program progresses, the attestation could move from a yes/no to a scaled attestation, creating incentives for clinicians who are super-utilizers of these standards to facilitate care.

- **Incentivize bi-directional data exchange with patient cloud(s) built on open-source standards-based architecture through attestation.** This cloud-based architecture will send and receive data to and from EHRs, third-party applications, registries, Health Information Exchanges (HIEs),
and patient-generated health data (PGHD). We encourage CMS to include attestation of bi-directional exchange with a patient cloud environment as part of the PI program. Similar to the above, this attestation could also advance to a scaled attestation as the use of these tools matures.

- **Require the certification of digital health solutions and systems by a neutral certifying body for public assurance that applications are accurate and secure.** There are two important components to this: 1) CMS should work with the ONC to determine criteria and a process for certification of third-party applications to ensure appropriate clinical logic, technical specifications, and privacy standards, and; 2) Attestation from PI eligible clinicians to the use of certified third-party applications and devices as the final (3rd) attestation in the PI category.

- **Establish neutral governance of architecture and standards to ensure vendor-agnostic solutions and to avoid intellectual property being owned by single vendors.** CMS and ONC should work to develop and maintain a neutral governance of open-source standards through a public/private partnership, similar to Logica Health (formerly the Health Services Platform Consortium) or the Sequoia Project. The Sequoia Project will develop and enforce the Common Agreement for data exchange through the Trusted Exchange Framework and Common Agreement (TEFCA). Although this would not be component of the PI category, neutral governance is foundational to ensure that the above PI attestations do not result in undue burden on clinicians or health care organizations.

- **Identify alternatives to a Universal Patient Identifier (UPI) to ensure appropriate patient matching and increase patient safety.** Inaccurate patient matching leads to endless patient safety concerns, and enhanced interoperability will only increase these risks. In the absence of a legislative fix mandating the creation of a UPI for this issue—which is the ideal solution—we encourage CMS to work with the ONC and the private sector to continue to explore alternative solutions for this problem. A standard algorithm hosted in a cloud platform that assesses and determines patient matches based on identifying information, such as name, date of birth, Payer ID, or other unique identifiers could be a stop-gap solution.

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

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

Figure 6: Advanced Model of Interoperability

MIPS Performance Category Measures and Activities

Quality Performance Category

Contribution to Final Score

CMS previously finalized that the Quality performance category will comprise 50 percent of a MIPS eligible-clinician’s final score for the 2020 MIPS payment year (2018 performance) and 45 percent of the MIPS final score for the 2021 MIPS
payment year (2019 performance). The Bipartisan Budget Act of 2018 (BBA) requires that 30 percent of the MIPS final score be based on performance in the Quality performance category by year six of MIPS (2022 performance), but allows for the category weight to be adjusted for the first through fifth years. Using the authority granted in the BBA, CMS proposes to weight the Quality performance category at 40 percent of the final MIPS score for the 2020 performance year (a 5 percent decrease from the 45 percent weight in the 2019 performance year). The Agency also proposes setting the Quality category weight at 35 percent of the final score for the 2021 MIPS performance year, and 30 percent of the final score for the 2022 MIPS performance year to meet the timeline and requirement in BBA.

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

\textit{Quality Data Submission Criteria}

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

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

The College agrees with CMS that patient-generated data could have great value in MIPS. \textit{The ACS appreciates CMS’ efforts to provide more information to patients but we do not support the continued use of the Clinician and Group (CG) CAHPS survey. The CG CAHPS survey or “CAHPS for MIPS” falls short of the type of patient feedback that is meaningful to specialists, and therefore does not provide relevant information to patients on specialty care.} Additionally, CAHPS surveys are retrospective and therefore do not provide an
opportunity to drive improvement or inform care during the patient’s journey. CAHPS surveys also have many implementation challenges. There has consistently been a low survey response rate, which is an indication that CAHPS surveys are limited in their ability to capture a meaningful sample of patients—this may also indicate that the administration of these surveys lack meaning and are too burdensome. CAHPS has also not been able to keep up with current health IT opportunities.

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

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

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

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

**Managing Customer Experience and Improving Service Delivery**

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

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

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

The College acknowledges that these domains may be important when measuring patient experience and satisfaction, but—as discussed above—CAHPS already has low response rates with little valuable information on specialty care. If CMS chooses to test this, instead of adding additional questions or elements to the
survey, we recommend CMS examine sampling methodologies, such as computer adaptive testing (CAT). Choosing the correct sampling methodology would allow for shorter surveys that would keep patients engaged, but still provide the ability for statistically significant response rates.

Data Completeness Criteria

The Agency has incrementally increased the data completeness threshold since Year 1 of the QPP. In Year 1 (CY 2017) and Year 2 (CY 2018), CMS maintained a data completeness threshold that required physicians to submit quality measure data for 50 percent of all patients, unless reporting via Medicare Part B claims, which required 50 percent of all Medicare Part B patients. CMS states that the data completeness threshold was retained at 50 percent for the first two years to allow time for MIPS eligible clinicians to adjust to the program, but believes it is important to incorporate higher data completeness thresholds over time to ensure a more accurate assessment of a MIPS eligible clinician’s performance. Therefore, the threshold was increased to 60 percent of all patients (all payer) in Year 3 (CY 2019). For Year 4 (CY 2020), CMS proposes to adopt a higher data completeness threshold of 70 percent of the MIPS eligible clinician’s or group’s patients that meet the measure’s denominator criteria. CMS explains that they believe the increase in the data completeness threshold is reasonable based on CY 2017 average data completeness rates. The rates showed that on average, small practices reported 74.76 percent of data, individual clinicians reported 76.14 percent, and groups reported 85.27 percent. However, CMS did not include information on whether these percentages represent all reporting mechanisms combined or if these are a subset, such as claims. We seek further clarity on whether these numbers represent all MIPS eligible clinicians across reporting options.

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

In our decades of experience in quality measurement, increasing data submission thresholds based on a percentage of cases applicable to all quality metrics has not demonstrated variation in one clinician and/or group from another clinician and/or group, unless the goal is to identify the bottom 3-5 percent of clinicians (poor performers). In other words, ACS has not generally been able to determine statistically relevant differences across average and high performing clinicians on
an individual level of measurement. Challenges related to measuring the performance of individual clinicians results in data being heavily skewed towards high performance, which decreases the ability to show variance among physicians. Our work has shown that reliability must be determined on a measure-by-measure basis, taking into account event rates for a specific procedure.

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

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

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

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

Selection of MIPS Quality Measures

Call for Measures and Measure Selection Process

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

- Measures are not duplicative of an existing or proposed measure.
- Measures that are beyond the measure concept phase of development, with a strong preference for measures that have completed reliability, feasibility, and validity testing.
- Measures that are outcomes-based rather than process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnoses and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.
- Measures that address significant variation in performance and are not considered topped out.
In addition to these previously finalized factors, CMS proposes to require measure stewards to link MIPS quality measures to existing and related MIPS cost measures and IAs, as applicable and feasible, beginning with the 2020 Call for Measures process.

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

1) **There are very few measures in MIPS that map to the surgical patient and therefore, most existing measures do not provide meaningful and actionable information to surgeons for quality and cost—information that is required for quality improvement actions.**

2) **While we agree that measure stewards should identify improvement activities and cost measures that align with quality measures, it is important that it is clarified that this is the role of the measure steward which includes physicians and clinical expert representatives and not the measure methodologist alone.** Measure stewards can oversee a process in which clinicians identify which improvement activity and cost measure are appropriately relevant to the quality measure they steward.

Proposed changes to quality measures

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

*Proposed for Addition:*

**Multimodal Pain Management**

CMS proposes the addition of the *Multimodal Pain Management* measure beginning with the 2020 MIPS performance year. This process measure accounts for the percentage of patients, aged 18 years and older, undergoing selected surgical procedures whose pain was managed with multimodal pain medicine.
ACS has consistently promoted the use of multi-modal analgesia as a way to reduce opioid prescribing and improve patient outcomes. Multimodal pain management is an essential element of Enhanced Recovery After Surgery (ERAS) and is defined as “the use of multiple, simultaneous mechanisms of pain control acting synergistically to improve analgesic effect and reduce the focuses of any single agent.” Multimodal pain management techniques are tied to the reduction of unnecessary opioid-use, excessive post-operative prescriptions, and length of stay. The College supports the addition of this measure in MIPS and thanks CMS for acknowledging it as a high priority measure.

General Surgery Specialty Set

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

- Removal of Sentinel Lymph Node Biopsy for Invasive Breast Cancer

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

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

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

- **Addition of Adult Immunization Status**

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

The **College does not support the inclusion of this measure in the General Surgery Specialty Set because it does not aid surgical teams in providing improved surgical care and it adds an unnecessary task to a surgeon’s workflow that provides little value to surgical patients or their goals for surgery.** We believe this measure is more appropriate for measurement of primary or chronic care. Additionally, the 2018-2019 Measure Application Partnership (MAP) did not support the inclusion of this measure in rulemaking, calling for additional specification and testing of the measure for clinician-level analysis. MAP states that the measure specifications require more detail to account for variability of benefits (i.e., reimbursement for vaccinations), vaccine shortages, data availability/feasibility, and more clarity into the timeframe of
reporting. MAP also noted that the composite measure required internal harmonization of its component parts.\textsuperscript{15}

- **Addition of Anastomotic Leak Intervention**

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

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


Global and Population-Based Measures

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

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

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

Topped Out Measures

In the CY 2019 QPP final rule, CMS finalized that once a measure reaches extremely topped out status (measures with average mean performance within the 98th and 100th percentile range), it may be proposed for removal in the next rulemaking cycle regardless of how long it has been in the topped out measure
The ACS has expressed concern about this policy and the removal of measures based on topped out status in our comments on the CY 2018 and CY 2019 QPP Proposed and Final Rules. In this proposed rule, CMS states that stakeholders have expressed concern that physicians’ ability to self-select measures they expect to perform well on may contribute to many measures’ topped out status. Based on this concern, CMS seeks comment on whether they should increase the data completeness threshold for quality measures that are identified as extremely topped out, but retained in the program due to the limited availability of quality measures.

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

Additionally, while we appreciate CMS’ efforts to respond to stakeholder concern with self-selection, the College does not believe increasing the data completeness threshold for extremely topped-out measures addresses the reliability and validity issues with topped out measures. We believe this proposal is inherently flawed. Under this proposal, MIPS clinicians and groups who score well will likely continue to report on the measure, while those who do not are even more likely avoid it so this proposed policy won’t achieve the goal of
getting a more complete picture of performance. As long as payment is tied to performance on specific measures and valuable, actionable data is not produced through program participation, payment will drive participant’s reporting strategies and physicians will “study to the test.” Physicians will continue to select measures they know will best position them to score well in the program and lead to positive payment adjustment.

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

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

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Removal of Quality Measures

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

Request for Information on Potential Opioid Overuse Measure

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

The College appreciates the intent of the measure, and believes that it is important to understand the patient population on long-term, high-dose opioids in order to prevent Opioid Use Disorder (OUD) and find effective pain management strategies and therapies. However, similar to the concerns that CMS identified when the measure was piloted, the ACS believes that it will be challenging to capture and report the data-elements related to prescription start and stop and patient initiation (both date and time beyond the general prescription length, as well as patient pick-up). These data are within pharmacy systems and/or e-prescribing systems (such as Surescripts)—not only from physician prescriptions,
meaning the data in a physician’s EHR would be incomplete for reporting this measure.¹⁸

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

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

**Cost Performance Category**

**General Comments**

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

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

¹⁸ [https://surescripts.com/enhance-prescribing/](https://surescripts.com/enhance-prescribing/)
a physician or care team currently uses resources and allow for comparisons with others who may be more efficient. Broad cost metrics such as those currently applied to most MIPS participants, do not break down all the services billed related to the patients’ experience in a care model. ACS defines costs related to the five phases of surgical care: preop, periop, intraop, postop and post discharge. We are able to consolidate these into costs defined more simply as prehospital, hospital-related services, and post discharge. Further breakdown of all the services, adjusted for the patient’s co-morbid conditions, allows the clinicians to benchmark prices, identify wasteful expenditures, and create alternative solutions. Without this level of detail, cost or price becomes a burden and therefore unmanageable. Clinicians do not possess the resources to dissect their patients’ total cost, and therefore must rely on payors to provide benchmark comparisons of these complex expenditures. In addition, the knowledge around cost must be presented in such a way as to avoid disruptions to clinical care or to patients.

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

**ACS THRIVE**

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

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

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

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

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

Participating practices armed with this information on both cost and price along with meaningful quality measures can redesign care models to deliver the same or, preferably, better outcomes with a lower-cost mix of resources—especially personnel, equipment, devices and drugs. This is a value expression that is truly meaningful to patients.
While this level of detailed cost measurement may not be feasible in the current MIPS framework, the results from the ACS THRIVE pilot will be used to create a scalable approach that other hospitals can use to measure and improve value. The method will include risk-adjusted benchmarks, so hospitals can compare their value with one another to generate system-wide improvement. The lessons learned will hopefully lead to best practices that can then benefit a wider range of practices and delivery systems. If elements similar to these were incorporated into the proposed MVP in 2021, they would be strong foundation for the future transition to higher value care in MIPS and a stepping stone toward participation in Advanced APMs.

Weight in the Final Score

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

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

Attribution of Cost Measures

In response to concerns about the current cost measure attribution methodology, CMS proposes a new approach to cost measure attribution by including attribution methodology in the specifications of each measure. Under this proposal, each cost measure would be attributed according to the measure specifications for the applicable performance period, and could allow for different considerations and methodologies depending on whether a participant reports data as an individual clinician or a group under MIPS.
The ACS appreciates CMS’ recognition of the shortcomings of the current methodology for attribution of cost measures. However, this proposal falls short of achieving the shared accountability needed to incentivize greater care coordination and fails to adequately recognize the team-based nature of care. Patients and payers have a shared interest in better understanding the total cost experienced in treating a condition or keeping a patient healthy. Cost measurement should facilitate this understanding by measuring cost around the patient and scoring clinicians based upon their role and their success in providing high value care by keeping down costs and providing high quality care.

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

MSPB Measure

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

As noted above, the ACS agrees with the intent of better measuring the entire care team involved in providing care to the patient. However, we disagree with the decision to split surgical episodes from medical episodes. Surgical intervention is frequently the continuation of care for an ongoing medical condition. For example, a patient might suffer from a massive upper gastrointestinal hemorrhage. This patient will have a primary care clinician, an intensivist, and a
gastroenterologist carrying for them with the surgical consultation on the side, in case the hemorrhage is not controlled. Or a patient with new onset, severe ulcerative colitis will have an entire team trying to reverse the condition of the colitis and avoid an emergency surgical resection. In both instances, at certain points, these patients are at risk to a surgical hand-off to assume the lead role in care and save a life. Is it CMS’ contention that the best ways to manage costs are to pull the teams apart and assign services as medical and others as surgical? ACS opposes this approach in principle.

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

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

New Episode-based Cost Measures.

CMS has worked with a measure development contractor, Acumen, to continue the development of episode-based cost measures. For 2020, CMS proposes to add ten newly developed episode-based cost measures shown in CMS Table 37 below to the MIPS cost category.
TABLE 37: Episode-Based Measures Proposed for the 2020 Performance Period and Future Performance Periods

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

*This measure is being proposed only for groups. Please reference section 111.3 K.3(c)(2)(iv)(B) of the proposed rule.

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

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

**Improvement Activities Performance Category**

**Improvement Activities Data Submission**

**Group Reporting**

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

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

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

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

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

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

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

**Promoting Interoperability**

*Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians*

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

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

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

Proposed Changes to Measures for the e-Prescribing Objective

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

- **Query of PDMP Measure**: Based on comments and stakeholder concerns regarding the lack of integration between EHRs and PDMPs and challenges in documenting the review of the PDMP, CMS is proposing to not require this measure for CY 2020. Instead, this measure is proposed to remain optional in CY 2020 and eligible for 5 bonus points, and will be attestation only.

- **Verify Opioid Treatment Agreement Measure**: CMS is proposing to remove this measure in CY 2020 due to feedback from stakeholders on the challenges with documentation that prevent the ability to adequately report on this measure.

ACS supports both of these proposed changes because these measures are challenging to electronically report due to the additional documentation and verification with an external system requirements, which create undue administrative burden. Additionally, ACS recommends postponing the creation of new MIPS measures that require integration with PDMPs until after the finalization of the 21st Century Cures regulations, which will affect the integration of PDMPs and EHRs. Future considerations for the development of new measures...
should also account for updates and standardizations made to state-level PDMPs through the implementation of programs included in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

Health Information Exchange Objective

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

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

Additional Considerations

Hospital-Based Eligible Clinicians in Groups

CMS defines a hospital-based individual eligible clinician as a clinician who furnishes 75 percent or more of professional services at an inpatient hospital, outpatient hospital, or emergency room. CMS proposes to change the definition of a hospital-based group so that such a group would be identified as hospital-based and eligible for reweighting of the Promoting Interoperability category if more than 75 percent of the NPIs in the group meet the definition of a hospital-based individual MIPS eligible clinician. For those individual eligible clinicians and hospital-based groups that meet the definition of hospital-based, the Promoting
Interoperability category will be at a zero percent weight, and the associated PI points will be distributed to the quality performance category. The College supports this proposal and thanks CMS for the adjustment.

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

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

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

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

ACS appreciates the opportunity to propose opioid measures for future program inclusion. We recommend developing a measure titled Observed versus expected opioid usage in post-surgical cases. This measure concept would track the expected versus observed opioid usage, defined per surgical type and case, based on morphine equivalent dose (MED) over a 30-day period. CMS could identify
expected opioid usage per surgical case based on existing claims and pharmacy data, while patient-reported and pharmacy data would provide actual opioid usage post-surgery. Studies have found that 6% of patients become persistent opioid users following surgical procedures.\textsuperscript{20} The ACS is dedicated to helping surgical patients manage pain safely, and to set expectations for pain management. This measure would help physicians understand the volume of patients who exceed expected and recommended opioid doses post-surgery, and work to determine alternative pathways to better manage post-surgical pain in these patients.

\textit{Proposed Measure 2: Screening for Substance Use Disorder in pre-operative appointments}

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

\textbf{RFI on NQF and CDC Opioid Quality Measures}

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

\textbf{NQF:}

\begin{itemize}
  \item Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940)

  \textit{The proportion of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120 mg Morphine Equivalent Dose (MED) for 90 consecutive days or longer.}
\end{itemize}

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

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

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

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

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

CDC:

Check PDMP Before Prescribing Opioids (Measure 2)

The percentage of patients with a new opioid prescription for chronic pain with documentation that a PDMP was checked prior to prescribing.

Evaluate within Four Weeks of Starting Opioids (Measure 4)

The percentage of patients with a follow-up visit within four weeks of starting an opioid for chronic pain.

Check PDMP Quarterly (Measure 11)

The percentage of patients on long-term opioid therapy who had documentation that a PDMP was checked at least quarterly.
- Counsel of Risks and Benefits Annually (Measure 12)
  The percentage of patients on long-term opioid therapy for whom the clinician counseled the patient on the risks and benefits of opioids at least annually.

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

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

RFI on a Metric to Improve Efficiency of Providers within EHRs

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

- What are useful ways to measure the efficiency of health care processes due to the use of health IT?
- What are measurable outcomes demonstrating greater efficiency in costs or resource use that can be linked to the use of health IT-enabled processes? This includes measure description, numerator/denominator or “yes/no” reporting, and exclusions.
What do stakeholders believe may be hindering their ability to achieve greater efficiency (e.g., product, measures, CMS regulations)? Please, provide examples.

What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability Program) that can increase the efficiency of health care provider interactions with technology systems, for instance, alternate authentication technologies that can simplify health care provider logon? How could we reward health care providers for adoption and use of these technologies?

What are key administrative processes that could benefit from more efficient electronic workflows, for instance, conducting prior authorization requests? How could CMS measure and reward health care providers for uptake of more efficient electronic workflows?

Could CMS successfully incentivize efficiency? What role should CMS play in improving efficiency in the practice of medicine? The underlying goal is to move to a more streamlined, efficient, easier user experience, whereby providers can input and access a patient’s data in a reliable, timely manner. CMS seeks feedback on the best way(s) to get there.

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

Technologies, capabilities, and system features that would increase efficiency: The ACS supports the CMS goal of efficient and effective use of technology to improve quality of care, decrease costs, and reduce administrative burden. We believe that incentives for physicians and systems for early adoption of APIs and standards, such as FHIR and USCDI, would encourage early uptake of these standards, promote data exchange across the care continuum, and allow for EHRs to incorporate external data for a complete patient record. Additionally, integration of digital tools and external data within the surgical workflow could be incentivized to encourage early adoption of technology, and increase efficiency of EHRs for surgery. Examples of surgical specific enhancements that could be incentivized include: risk calculation within EHRs, electronic workflow integration of the ERAS protocols, telehealth and other digital care service options, electronic Prior Authorization process, and Electronic Prescribing for Controlled Substances (EPCS). Incentivizing these types of digital services can result in increased use of these technologies to optimize patient care, and encourage physicians and hospitals to be innovative in their care options.
CMS’ efforts should focus on the entire digital workflow and avoid being constrained by EHRs. A patient-cloud example which demonstrates a clinician and patient workflow solution for surgical care is Meges Health’s “iPostop” solution. This is a platform-based digital workflow which begins preoperatively for countless surgical procedures. In this instance, the platform surrounds the patient with the care team, which includes the surgeon and the supporting cast of nurses and office staff. Numerous events are tracked up to the day of an operation. Once the operation is complete, patients are often discharged early. With iPostop, a digital connection remains constant with periodic check-ins by the patient, the staff, or the surgeon. This allows for asynchronous engagement of patients in clinical workflow solutions which are not possible within everyday EHRs. It is these solutions which require customization, governance, and updating by the clinical teams constantly. These solutions are digitally bolted onto the EHRs.

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

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

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

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

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

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

Figure 6: Advanced Model of Interoperability

RFI on the Provider to Patient Exchange Objective

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

Since this proposal, both ONC and CMS released proposed rules on the 21st Century Cures Act. These rules focused on creating standards for data exchange,
including FHIR-based APIs, which are meant to lessen the burden and complexity of data exchange. If these provisions in the Cures rules are finalized, these standards will be incorporated into the 2015 CEHRT definition, making them a requirement for participation in the PI category. CMS requested feedback on functionality and standards for data exchange using FHIR-based APIs.

**Immediate Access**

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

**Persistent Access**

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

1. **Industry-recognized development guidance** (e.g., Xcertia’s Privacy Guidelines);
2. **Transparency statements and best practices** (e.g., Mobile Health App Developers: FTC Best Practices and CARIN Alliance Code of Conduct); and,
3. **A model notice to patients** (e.g., ONC’s Model Privacy Notice).
The certified app could then be acknowledged or listed by the health IT developer (e.g., in an “app store,” “verified app” list). EHR vendors could also publicize app developers’ attestations.

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

Standards-based API

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

Available data

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

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

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

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

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

Bidirectional Exchange

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

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

The College appreciates CMS’ focus on utilizing data exchange to improve the quality of patient care and reduce physician burden. There has been great progress made in the implementation of digital health services through EHRs and advances in interoperability through ONC and CMS proposed 21st Century Cures rules. However, the College believes it is time to recognize EHRs as one data source
among many for an individual patient. Patients exist in multiple bits and bytes in disparate EHR systems. The best way to create a digital account for a patient is the movement of pertinent patient knowledge into a semantically interoperable, digital information system as a service in a patient cloud. The patient cloud aggregates data to create a single, unique, and more complete patient medical record, providing physicians with the information they need to deliver the highest quality care while keeping costs low, and gives the patient agency over their own data. Further, this better enables and facilitates the sharing of health information between physicians and levels of care; physicians would be able to pull needed data and patient health information from the cloud to their system, rather than needing to initiate exchange from another physician and their system. This infrastructure streamlines care coordination and care management, reduces clinician burden, and ensures more complete and accurate patient data within the longitudinal health record.

We should be cautious in recognizing EHRs as the single source of patient truth; the EHR data models are constructs from decades past, built initially for billing, and can no longer serve as the sole digital architecture representing the workflows of tomorrow. They will remain a point of data entry at a care site, but need to connect to patient-cloud platforms to share clinical information, expand data liquidity, and make patient health information more accessible by both patients and clinicians. Patients do not live in one health system or one EHR; they live in five, six, or more EHRs. They have data in third-party applications, wearable devices, and payer claims. The next generation of digital health services has to create a single, unified patient record in a cloud platform. Using a Linux-like architecture\(^2\) for an open-standard cloud architecture creates a patient unified record upon which all EHRs can provide data, all smartphones can interact, and all API developers can drop in their services for patients and clinicians. The patient cloud would work as an aggregator, able to pull data through APIs from any database with patient information, and then process, convert, and exchange data as appropriate—much like the way the banking industry has made it possible for individuals to withdraw money from any ATM, or transfer money to any external account. With shared standards, any digital information company can apply the standard and create a semantically interoperable cloud. The free market can then employ these standards and avoid overbearing, inefficient, and costly duplicative services. Digital services like third-party applications and wearable devices can also build upon these clouds to further accelerate the advancement of the industry. The ACS supports attestation and incentivizing the use of a patient cloud based on shared standards and built on an open platform to facilitate data exchange.

\(^2\) https://www.linux.com/what-is-linux/
with open APIs, rather than the creation of additional process-based measures and objectives that attempt to reward connections between disjointed platforms and systems.

**Patient Matching**

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

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

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

As wearable devices and third-party health applications become increasingly common and available, the data generated from these products could introduce
new ways to monitor and manage patient care between visits. While challenges with receiving and incorporating this information remain, CMS is interested in feedback on how the Promoting Interoperability Program could incorporate measures, activities, and elements that further the use and best practices on PGHD.

CMS asks for feedback specifically on the below questions:

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

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

Incentives and bonus points are productive ways to encourage early adoption of PROs and use of PGHD incorporation into CEHRT. In early stages, attestation, rather than measurement, is a more effective way to measure uptake of PGHD, allowing physicians to test and become more comfortable with PGHD implementation before using measurement to affect reimbursement. It is also critical that the applications and devices used to capture PGHD are certified, to ensure that 1) they use data-exchange standards and 2) that the data are
validated and the clinical algorithms are verified before incorporation into the EHR. It will be important to learn from these early adopters, as the use and incorporation of PGHD into the EHR and clinical workflows remains in early stages. There are many lessons to be learned regarding the appropriate incorporation and utilization of these data.

Additionally, given the proliferation of wearable devices and third-party applications and the challenges with these data, physicians should not be required to collect or share data with any device or application requested by a patient. And, there should be a certification process in place for these applications to ensure that the third-party is a safe steward of patient data, as discussed in more detail in the Persistent Access section of this letter.

However, regardless of certification, there should not be a requirement to collect this data from patients, but rather it should be an option for patients and physicians to utilize devices and applications as a care management tool to maintain communication and care between visits. It is also important to recognize that not all patients have the resources, capacity, or ability to utilize technology that generates these data, and others will choose not to do so. As such, it cannot be required of physicians to use technology that patients may not be willing or able to utilize for care purposes.

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

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

CMS is seeking comments for strategies to further mitigate risks to patient safety stemming from technology implementation and usage, specifically on options that reduce clinical errors. CMS references the ONC SAFER guidelines as a possible tool to utilize for health care organizations to complete and receive points towards their Promoting Interoperability score. While the SAFER guides are comprehensive, several of the assessments contain information that should be the responsibility of the vendor to meet and complete, rather than the hospital, specifically the items in the High Priority Practices Checklist. This highlights that health IT safety is not just the responsibility of the user, but also of the vendor.
Any strategy or program that incorporates safety standards should share responsibility with the appropriate party, including third-party developers, vendors, physicians, and patients. Additionally, the SAFER criteria were last updated in 2016, and should be made current if they are used in the PI program to ensure that they include patient safety threats that stem from increased interoperability and expanded use of new technologies.

**MIPS Final Score Methodology**

**Performance Category Scores**

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

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

Modifying Benchmarks to Avoid the Potential for Inappropriate Treatment

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

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

Redistributing Performance Category Weights

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

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

MIPS Payment Adjustments

Establishing the Performance Threshold

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

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

**Third Party Intermediaries**

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

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

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

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

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

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

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

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

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

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

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

Figure 6: Advanced Model of Interoperability

**Enhanced Performance Feedback Requirement**

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

CMS asks for feedback on if eligible clinicians and groups should be able to submit data to a QCDR or QR throughout the performance period, starting April
1, and before the close of the period on December 31. This would allow QCDRs to have additional time to provide feedback and benchmarking to participants before the data submission deadline.

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

Public Reporting on Physician Compare

Final Score, Performance Categories, and Aggregate Information

Quality

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

As discussed in the CAHPS for MIPS section above, the ACS has concerns about the inclusion and validity of patient narratives. The College strongly recommends that the inclusion of patient narratives be tested prior to large scale implementation and for use in a pay-for-performance program—it is unclear how and whether CMS would incorporate patient narratives as part of the MIPS Quality score. In addition, we ask for clarity on how CMS plans to manage false or inappropriate narratives? For example, could a false narrative misguide patients? How would a physician appeal a false narrative? Will these false narratives become a disruption to the trust in a physician-patient relationship, or worse, create defamation suits? We also ask CMS for examples of where raw patient narrative data has been used successfully to drive improvements in care. Although the validated PROs we discussed above still need to be piloted prior to use in the QPP program, ACS supports testing PROs.
It is also crucial for CMS, along with stakeholders, to leverage digital health platforms to collect information from patients. By leveraging health IT, patients can be asked fewer questions more frequently through easily accessible platforms (such as smart phones), rather than distributing a large retrospective survey after the completion of care. This format also allows physicians to gather real-time data directly from patients to inform care decisions at various points of treatment, and increase communication between patients and physicians, while reducing administrative burden. **Utilizing a standardized, open source patient-cloud as the centralized, standard platform would allow PRO implementations through open APIs across all EHR platforms.** Responses from patients would allow flow back to the EHR through an open API in the patient-cloud and allow for PRO communication to be pulled by the EHR internally to present patient reports to the clinical teams. Cloud-based patient reports could also be sent to other third-party applications. In the patient-cloud, data from multiple sources could be aggregated and analyzed, and the open architecture allows for widespread, vendor-agnostic use of successful survey tools. With a patient-cloud, with permission from the patient, any EHR can deliver a report to any entity—the patient portal, another EHR, CMS, etc. The College continues to develop and test open source patient-clouds and inclusions of care tools such as PROs for surgical care and is eager to collaborate with CMS.

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

**Advanced APMs**

**General Comments**

The ACS applauds the increase in the number of QPP-eligible clinicians who were Qualified Participants (QP) in Advanced APMs between 2017 and 2018. However, we note that it will become more difficult for surgeons and other clinicians to achieve QP status as participation thresholds increase. The ACS therefore remains concerned with the general lack of physician-focused payment models in MACRA both in MIPS as MIPS APMs and in the Advanced APM
track of participation. The Physician-focused Payment Model Technical Advisory Committee has received more than 30 proposals from stakeholders for APMs, many of which have been reviewed favorably and recommended for testing or implementation. Unfortunately, this has not resulted in the expected or intended buildup of a library of payment models for physicians to test.

MVPs as a Pathway to A-APMs

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

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

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

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

CMS regulations set forth a number of reasons why a provider or supplier’s enrollment in Medicare may be either revoked or denied. In this section, CMS proposes a new revocation reason and a new denial reason to permit CMS to revoke or deny, as applicable, a physician’s or other eligible professional’s enrollment if he or she has been subject to a prior action with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm from a state oversight board, federal or state health care program,
Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. **We urge CMS to not finalize this ill-defined and overly broad proposal that could have a devastating impact on physicians, and to instead focus on ways to identify and discipline the truly bad actors.**

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

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

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

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

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

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

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

Sincerely,

David B. Hoyt, MD, FACS
Executive Director