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September 30, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/ Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (CMS-1734-P)

Dear Administrator Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare and Medicaid Services' (CMS) calendar year (CY) 2021 Medicare Physician Fee Schedule proposed rule (CMS-1734-P) published in the Federal Register on August 17, 2020.

The ACS is a scientific and education 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). 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 30, 2020, includes the ACS' comments to the QPP, the Merit-based Incentive Payment System (MIPS), Alternative Payment Models (APMs), MIPS Value Pathways (MVP) and the 21st Century Cures Act Final Rule. The College submitted a separate letter on September 22, 2020 which exclusively included the ACS' comments to other proposed CY 2020 MPFS payment provisions.

QPP Considerations During the COVID-19 Pandemic

Everyone often quotes Winston Churchill when he was working to form the United Nations after WWII, "Never let a good crisis go to waste." As terrible a pandemic that COVID-19 is, we should make note of several lessons learned in the pandemic when it comes to understanding quality and payment. As a planet, we knew almost nothing about the virus, how it spreads, the impact it has on humans, acute treatment and the consequences, or long-term sequela. The first order of care was to understand the medical condition and begin to formulate a care model. Resources played a major role in supporting care team needs, patients' needs, as well as clinical protection for caregivers. Data systems sprung up, and shared knowledge became the goal across the entire globe. The world turned into a massive observational data registry with every expert and every scientific filter applied. Revenue models and payment systems were secondary thoughts. The patient and their condition were the centerpiece. Surrounding these were the caregivers working as teams. And knowledge sharing could not have been more important.

Within all of these efforts, we find the ACS model for a quality program. It begins with the patient, their condition and their care team. The right structures and processes must be in place in order to effectively and efficiently deliver the intended outcomes. Knowledge sharing from all sources informs the care team and drives its improvement cycles. Then, a payment model is applied with incentives for optimally meeting the patient's goals and outcomes, while minimizing avoidable harms. Also, worth noting, COVID-19 was about success and rewarding success, not penalizing care. These are the QPP lessons learned from a pandemic. We should be careful to absorb them and not brush aside these lessons as a passing fad from the pandemic.

As we turn our focus to our QPP comments, our preface begins by stating up front that we have carefully considered the goals of the QPP alongside the demands the pandemic has put on our healthcare system, and surgical care in particular. During this time, it is of utmost importance that clinicians who are impacted by the COVID-19 pandemic are not additionally burdened by QPP reporting in an effort to avoid a penalty of up to 9% while they struggle to keep their doors open. Similar to 2020, 2021 will be a year where performance on

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QPP metrics will be unlike any other year, making it nearly impossible to equitably measure "value" for patients using the metrics developed outside a pandemic.

In 2021, the country will continue to struggle from the impacts of COVID-19. In order to control, address, and then begin to recover from the COVID-19 pandemic, extensive resources and efforts will be required from the entire healthcare industry. The pandemic has forced an extreme shift in how surgical care is delivered in areas with high incidence of COVID-19, including what services and programs can be prioritized during this time. During the pandemic, some health care services have diminished to meet the demand of the COVID-19 on a local level causing administrators to prioritize personal protective equipment (PPE) access and consider treatment modality—all while staying in business. Also, in areas of the country where the pandemic is more controlled, many patients continue to hold off on needed surgical services in fear of COVID-19 exposure. All these factors differ greatly at the local level, depending on which phase of the pandemic the health system is experiencing. These factors also make value assessments in the QPP incredibly complex and further bring into question whether the QPP is a meaningful program—during the pandemic it is seen as a distraction and the possible negative adjustment is insensitive to the overall impact that the COVID-19 crisis has had on the health sector.

As the country and our health system begins to recover in the coming years, we will need to consider various factors to ensure high-quality patient care. Quality infrastructures will have to go through a time of reconstruction to account for what was learned during the pandemic, and practices will need to determine what is necessary to restore revenue. We feel that it would be inappropriate for CMS to require physicians to invest in and ensure compliance with performance-based programs like MIPS, even if for an abbreviated performance period, while working to restore their practices. Entire care teams were lost to COVID-19 and must be reestablished as we go forward in business recovery. Instead, for physicians and facilities that are impacted by the pandemic, the sole focus should be rebuilding the infrastructure of healthcare systems and quality programs while providing safe care. For those who do want to participate in the QPP for 2021, there should be a "pause" on the program from 2020 to 2021. To this end, our comments support only minor changes to MIPS and Alternative Payment Models (APMs)—our support focuses on efforts to reduce burden. We also believe any QPP program changes for 2021 should be optional since it is an unnecessary burden during the pandemic to take the time to understand new requirements. To this end, we also strongly support the delay of the MIPS Value Pathway (MVP) program until 2022 or later.

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Importantly, we strongly encourage CMS to take this time to pause and rethink lessons from the pandemic and ask questions about what we have learned, including the system-wide vulnerabilities and strengths the pandemic has uncovered—such as which aspects in our health system are broken and inadequate, which aspects of care delivery have changed, and what strategies have saved lives during the pandemic. How can these lessons be leveraged in the QPP?

UPDATES TO CERTIFIED ELECTRONIC HEALTH RECORD TECHNOLOGY DUE TO THE 21ST CENTURY CURES ACT FINAL RULE

Since 2019, CMS has required the use of Certified Electronic Health Record Technology (CEHRT) to participate in the Promoting Interoperability Programs and QPP. The 21st Century Cures Act final rule included updates to the 2015 Edition CEHRT criteria and introduced new 2015 Edition criteria, referred to as the "2015 Edition Cures Update." The Office of the National Coordinator for Health Information Technology (HIT) (ONC) finalized that health information technology (health IT) developers have 24 months from the publication date of the final rule to develop and implement these updates into their systems. Due to the COVID-19 pandemic, ONC allowed a 3-month extension that allows the Agency to exercise enforcement discretion for compliance with making the technology available that is certified to meet the updated/new criteria. Therefore, health IT developers have until August 2, 2022 to make technology available that is certified to the new/updated criteria. During this transition period, health IT developers will be expected to continue supporting technology certified to the previous version for their customers and clinicians participating in Promoting Interoperability (PI) and QPP for the purposes of these programs and prior to implementing updates.

Updates to Certified Electronic Health Record Technology Requirements in the Promoting Interoperability Program, and Quality Payment Program due to the 21st Century Cures Act Final Rule

To align with the finalized implementation timeline for updates and new criteria to the 2015 Edition Cures Update, CMS proposes that healthcare providers participating in the Medicare and Medicaid PI programs and QPP would be required to only use technology that is considered certified under the ONC Health IT Certification Program. Therefore, up until August 2, 2022, program participants may use technology certified to either the current 2015 Edition criteria or the 2015 Edition Cures Update. After August 2, 2022, only technology certified to the updated version finalized in the 21st Century Cures

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Act final rule (i.e., 2015 Edition Cures Update) will meet the CEHRT requirements and demonstrate meaningful use.

The ACS appreciates CMS' efforts to align with the updated CEHRT criteria, as it supports increased interoperability and standardized exchange of patient health information (PHI). **However, given that many healthcare delivery systems are experiencing disruptions in their normal operations during the COVID-19 pandemic, we ask that CMS extend this timeline to allow delivery systems more flexibility to update their technology systems.** Based on experience with previous implementation of new electronic health record (EHR) certification requirements, physicians and hospitals need at least 12 months to get in the install queue before their EHRs are updated. Given that health IT vendors would need at least 18-24 months for development—even with the COVID-19 extension—this timeline does not allow 12-months to complete the necessary updates. In addition, patient care is extremely disrupted, and hospitals and delivery systems are financially burdened as a result of the pandemic, making affording and maintaining costly digital updates and versioning difficult during this time. With the requirement to update all EHR technology, vendors may try to lock hospitals into using vendor solutions, instead of promoting open markets, which would also lead to significant increases in cost.

The ACS also challenges CMS to think beyond EHR-centric interoperability. Technology is advancing into healthcare at a rapid pace. There is an increasing appreciation that EHRs are transactional workflows designed to document care and assure payment, while new technology solutions appreciate a patient's journey through the various points of care. Technology is exposing knowledge in patient workflows and in clinical workflows spanning the larger perspective of the patient's care journey. With each connection across the patient journey, data systems, not EHRs, are more complete representations of a patient. **The focus has become one of knowledge sharing and knowledge engineering[1,2] of digital services that will decrease burden, and help clinicians deliver improved patient care. Instead of measuring the functionality of EHRs, we believe that CMS should begin considering how to measure the key aspects of shared knowledge as the modern pillars of informatics.** The seven pillars of informatics are defined by the American Medical Informatics Association

[1] Knowledge engineering (KE) is concerned with the development of knowledge-based information systems. It is closely related to software engineering and artificial intelligence (AI). KE creates computational methods, languages, and tools for knowledge representation and problem solving by computers. Retrieved from (https://link.springer.com/chapter/10.1007/978-3-642-36527-0_14)

[2] Raza Abidi, S. S. *Healthcare Knowledge Management: The Art of the Possible.* Knowledge Management for Healthcare Procedures. 2008; 4924: 1-20.

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(AMIA) as: Patient Empowerment, Health IT Safety, Workforce and Education, Data Sharing in Research, Biomedical Data Standards & Interoperability, Informatics-Driven Quality Measurement, and Population & Public Health.[3] For example, this could include questions such as, "Does the EHR meet open standards that allow the market to leverage clinical knowledge for the betterment of patient care?" **The ACS recommends that CMS work with other federal agencies, such as the ONC and Food and Drug Administration (FDA), to align their strategies on how to best promote the use of technologies that incorporate knowledge engineering digital services that can help physicians and patients reimagine how they manage care such as clinical decision support, clinical practice guidelines, predictive analytics, assessments and calculations such as in machine learning, and artificial intelligence.** Knowledge engineering technologies would be able to assemble all relevant information about the patient's care history and display data such as operative reports, referring physicians' notes, medication histories, etc. to guide treatment decisions.

Predictive analytics that are used in knowledge engineering technologies allow clinicians to get in front of a disease and anticipate sequela and risk, rather than responding to it. For example, this level of knowledge management can allow for predictive diabetes care. For surgeons this may mean having the ability to identify a cohort of diabetes patients with a higher risk of adverse outcomes for a given procedure and know what is needed to decrease patient risk through enhanced care pathways pre-operatively or postoperatively. When clinicians are able to realize the potential to assemble knowledge and expose critical information with a high level of reliability, healthcare will undoubtedly be transformed. The benefits and opportunities associated with these types of predictive analytics are endless.

QUALITY PAYMENT PROGRAM

ACS QPP Overview: *Quality is a Program, Not a Set of Measures*

For over half a century, the ACS has viewed quality as a program, with measurements serving as key components of such programs. Each of the ACS quality programs is built on a four-part model, known as the ACS Quality Model, that includes: 1.) program-specific standards, 2.) infrastructure needed for delivering high–quality care, 3.) data collection and its use for care delivery and improvement, and 4.) verification site visits to ensure implementation of the critical elements for optimal care. Amongst the most recognized of the

[3] American Medical Informatics Association (AMIA). *AMIA Public Policy Principles and Policy Positions.* 2018-2019. Retrieved from: https://www.amia.org/sites/default/files/AMIA-2018-2019-Health-Informatics-Policy-Priorities-final.pdf

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ACS programs are the Trauma Center Verification Program, the Commission on Cancer (CoC) Accreditation, and the Metabolic and Bariatric Surgery Verification program. **The evidence supporting this model strongly suggests quality is not just a "measure," as it is often defined. Rather, the evidence supports the concept that quality is a multi-component program that involves a team of clinicians and surgeons operating in a culture of excellence, with systems engineering for efficiency, appropriateness, proper resources applied within structure and processes, as well as measures for conformance and outcomes**. Integral to achieving high quality care, the "program" is informed through its data integration that leverages the knowledge gained through improvement cycles. In order to assure quality, the ACS' experience shows that setting standards for care (both at the facility and individual clinician levels) and assuring, with rigor, that those standards are implemented is indispensable.

For many years, the ACS has raised concerns to CMS that the quality metrics currently used across federal incentive programs have failed to drive improvement in surgery due to their disconnected and sporadic nature and general lack of cohesive framework. CMS measures components of care discretely such as the individual surgeon separately from the hospital, separately from the anesthesiologist, separately from the pathologist, etc., which creates an overly burdensome measurement system and a fragmented picture of "quality." In the case of MIPS, CMS has looked at assessing value across four buckets, each bucket containing a long list of columns and rows for clinicians/administrators to choose what to report, with the goal of ensuring each specialty can check off enough measures in the buckets to meet program requirements to "pass the test." However, this approach is disjointed, burdensome, of little value to patients and surgical teams, and has the unintended consequence of incentivizing gaming.

CMS has listened to these concerns, and the concerns of other stakeholders, and finalized the MIPS Value Pathway (MVP) concept which—though still in fee for service (FFS)—has promises of unifying value of care around a patient for a condition or episode in an innovative way, while working with specialty society organizations. Since the announcement of the MVP, ACS worked with CMS and submitted one of the first MVPs for consideration**. Our submission was founded on the concept that "quality is a program"—that a full accreditation or verification program should serve as the foundation for the MVP, conformance measures should be used to help identify deficiencies in care (measured at the hospital/facility level), and patient-reported outcomes (PROs) focusing on preoperative events and shared decision-making should be used to distinguish performance of surgical teams (measured at the individual level).** Our proposal put the quality

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program first and while it went outside the box of traditional MIPS, we believe it fits within statute. Although we will continue to work toward a solution with CMS, the response to our MVP was a reshuffling of the current MIPS program into a new bucket of measures—CMS responded with an approach similar to the MIPS Specialty Measure sets, but instead of limiting it to quality measures, it includes all of the four MIPS buckets (Improvement Activities, Cost, Promoting Interoperability, and Quality). We struggle to see a path toward building a culture of quality given the limitations of the current program.

During this year we have also had the opportunity to work with the Center for Medicare & Medicaid Innovation (the CMS Innovation Center) to develop a verification measure as part of the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model for the bariatric clinical episode. This is the first time this type of representative set of measures will be implemented and specifically include a component (i.e. a verification measure) that addresses the fundamental infrastructures of a quality program focused overarchingly on the care of the patient. The measures include the goals and outcomes important to the patient, while also valuing the infrastructure, resources, and processes needed to deliver optimal care and improvement. To report the verification measure, the facility or physician group practice must be a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accredited bariatric center, which means it has met all the 2019 MBSAQIP (or similar program) standards. The goal of the measure is to incentivize bariatric-accredited centers to go beyond basic compliance of standards and to consider how to further enhance their compliance or work towards being exemplary. The verification measure includes six structural domains to score the bariatric surgery clinical episode which were chosen because they are strongly linked to safer and higher quality of care.

We believe that we can find similar flexibilities in MVPs, but CMS must allow for innovation in the QPP and look to quality experts and clinicians for guidance, while also exploring ways to move past the siloed, 4-bucket mentality. **We urge CMS to approach MVPs sequentially by first defining what is quality and improvement, then how can it be measured, followed by what are the best reporting mechanics, how can the measure data be reliably normalized for scoring, then lastly, how this all fits into the QPP incentive program for payment. This might require different implementation guidance from CMS that is separate from the current MIPS requirements.**

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ACS Goal for CMS Implementation of a Quality Framework in MVPs

Below is a framework, based on the Donabedian Quality Model for Evaluating Care which illustrates ACS' long-term goals for implementing a quality program. Donabedian's structure, process, and outcomes quality model is a proven way to conceptualize quality of care.[4] The ACS' belief that surgical quality should be delivered (and measured) as a full program fundamentally operationalizes the entire Donabedian quality model. The figure below (Figure 1) conceptually demonstrates the layers for achieving surgical quality with the ACS Quality Verification Program at the base. This program sets the standards for structure and process components by defining the resources, infrastructure, and processes needed to achieve optimal quality improvement (QI). The ACS Clinical Programs set the standards for clinical care—these programs are where condition or specialty-specific standards are added (e.g. Bariatric, Trauma, Geriatrics). Layering on top of clinical accreditation are appropriate and adequate processes which further help to implement the care model. Moving up in the hierarchy of the key components are monitoring of clinical outcomes with accurate, clinical, risk-adjusted data (e.g. National Surgical Quality Improvement Program (NSQIP)) measured at the hospital level, followed by outcomes reporting by the patient, or PROs, measured at the individual level. Each component of the quality model builds on and is interrelated to the others, pulling the information to assess the essential components for a patient, allowing for patients, clinicians, and payers to assess (more completely) the quality of care. The ideal for the systematically organized set of measures is to represent the spectrum of an effective quality program by focusing on each layer of this pyramid.

It is critical that CMS appreciate that this concept cannot be taken apart into individual components for implementation because it is the four-part model that has demonstrated improvements in care and fits the delivery system. **Through the ACS experience in creating quality programs, we know that the optimal and most advanced clinical patient care is given by providers who routinely perform both optimal clinical processes and optimal quality evaluation/improvement processes ALL THE TIME—not just in an incentive program. This type of program culture is what should be incentivized in MVPs.**

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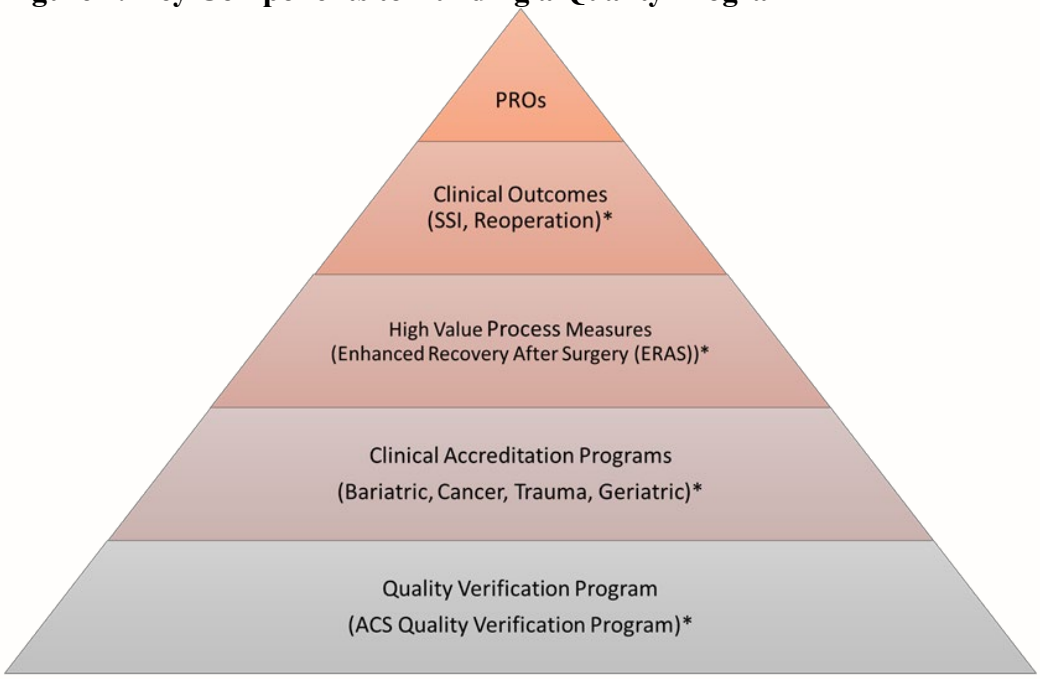
[4] Donabedian, A. *Evaluating the quality of medical care.* Milbank Q. 2005;83(4):691-729.

Figure 1. Key Components to Building a Quality Program



Transforming MIPS: MIPS Value Pathways

In the CY 2020 Final rule, CMS finalized the definition of an MVP as "a subset of measures and activities established through rulemaking" and stated its intent to apply the MVP framework in the 2021 performance year. However, due to the COVID-19 pandemic national PHE, CMS is limiting its MVP proposals to guidance necessary for the collaborative development of MVPs, including updates to the MVP guiding principles and development criteria, and process to guide MVP implementation. CMS intends to propose an initial set of MVPs and implementation policies in its CY 2022/2024 payment year rulemaking cycle. We urge CMS to think of MVPs as a quality program framework, as described in our strategic comments above. We also recommend CMS consider soliciting input on ways to innovate MVPs based on learnings from the COVID-19 pandemic. In addition to our comments on strategic direction, we provide some specific comments to the CMS MVP Guiding Principles and MVP Development Criteria below.

<u>MVP Guiding Principles</u>

In last year's CY 2020 proposed rule, CMS listed MVP Guiding Principles to define MVPs as part of a request for information (RFI). ACS provided extensive comments to those Guiding Principles. In this year's 2021 proposed

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rule, CMS proposes updates to the Guiding Principles to reflect feedback from the RFI and to further evolve the framework. Below we comment on specific MVP Guiding Principles:

#1 MVPs should consist of limited, connected complementary sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, align scoring, and lead to sufficient comparative data.

CMS proposes to change "simplify scoring" to "align scoring" in the first guiding principle to acknowledge that as it initially transitions to MVPs, it will not simplify but rather align scoring policies as it continues to offer the traditional MIPS pathway. CMS explains that although commenters requested that the Agency add clinician choice and remove the wording "eliminating burden related to selection of measures," CMS notes that the degree of choice of measures and activities within MVPs will be limited as it strives for standardization.

In our comments to the RFI in last year's 2020 proposed rule, we strongly emphasized the need for measures to 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. To this end, we encourage additional guidance on how CMS will ensure "sufficient comparative data," such as a single or limited set of sources to aggregate data. We discuss this in greater detail below in our comments to the MVP Development Criteria on page 14.

#2 MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty group.

CMS explains that this update would allow for the option of subgroup reporting for MVPs, permitting subgroups of clinicians within groups to select relevant MVP(s) to report measures and activities that are meaningful to their practices and to patients. And, although not currently an option, CMS believes an appropriate step is the collection and assessment of more individual clinician or specific specialty information from multispecialty groups to improve the meaning and robustness of the performance data used to

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incentivize high quality and cost-effective care and better provide information that patients can use to select clinicians.

ACS supports the addition of sub-group reporting to this MVP guiding principle, which will allow MVPs to be developed based on clinical service lines, not just the Tax Identification Number (TIN). This will also allow for inclusion of all individuals (i.e. through their national provider identifier (NPIs) within the sub-TIN who voluntarily choose to participate in a given MVP, thereby recognizing the multidisciplinary nature of surgical care. However, because this level of reporting is not currently an option in the MIPS program, testing the attribution methodology for sub-group reporting is critical. To reiterate our comments to the RFI, many surgeons will have a single dominant domain which will map to an MVP. However, depending on their practice, other surgeons may not have a single dominant domain and will fit into multiple MVPs. Participation based on a minimum volume threshold must be considered. Therefore, **CMS will need to analyze and test the methodology for determining the appropriate MVP or mix of MVPs.**

#5 MVPs should support the transition to digital quality measures.

CMS proposes to add a new fifth guiding principle to support their future vision for reducing MVP reporting burden: the use of digital performance measure data submission technologies that indicate their commitment to leveraging digital innovations that reduce MIPS-related clinician burden. Under this guiding principle, CMS discusses using Digital Quality Measures (dQMs) to achieve this and define dQMs as measures that originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems.

The ACS appreciates CMS' commitment to prioritizing the use of digital innovations and believes that it is essential that CMS look beyond the current EHR-centric interoperability when thinking about the future of MVPs. As discussed, technology is advancing at a rapid pace and we should be leveraging the technological advancements to inform the delivery of high-quality care. **When implementing this guiding principle, we ask CMS to not limit this MVP requirement to reporting specific eCQMs or EHR-centric measures, instead CMS should incentivize building an infrastructure of digital systems that track patients longitudinally, inform care decisions, and support their quality improvement efforts.** These systems could include knowledge engineering technologies, health information exchanges (HIEs), registries, clinical decision support (CDS), clinical practice guidelines (CPGs), predictive analytics, reports from wearable devices, etc. and could be done by creating an attestation structure, with measures, similar to the newly proposed

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"*Engagement in Bi-Directional Exchange Through Health Information Exchange."* This would allow CMS to support the use of advanced digital health technology, and their initiatives for increased bi-directional exchange and access to data, without being too prescriptive and imposing additional burden on physicians.

MVP Development

Process of Developing MVPs

MVP Development Criteria

Beginning with the 2022 MIPS performance period, CMS proposes developing and selecting MVPs using a comprehensive set of criteria outlined to ensure they are constructed and implemented in a manner that is consistent and reliable. CMS solicits comment on these criteria.

In our overview comments of the MVP proposals we note that CMS has looked at assessing value across four buckets in MIPS, each bucket containing a long list of columns and rows for clinicians/administrators to choose what to report, with the goal of ensuring each specialty can check off enough measures in the buckets to meet program requirements to "pass the test." This current structure is disconnected, burdensome, of little value to patients and surgical teams, and has the unintended consequence of incentivizing gaming. When reading through the MVP Development Criteria, CMS struggles to think outside of the MIPS program and to allow for innovative approaches to assessing value in MVPs. The MVP Development Criteria is similar to the narrow CMS interpretation of the qualified clinical data registry (QCDR) provisions, in which CMS has overregulated, leading to the inability of many high-fidelity clinical data registries to qualify as a QCDR. These criteria do not lay out a path that builds a culture of quality. To appropriately build a quality program, we urge CMS to approach MVPs in the following order of priority:

1. Define what is quality and improvement for a given condition or episode of care;
2. Determine how can quality and improvement should be measured,
3. Determine the best reporting mechanics and data sources,
4. Determine how the measure data can be aggregated and reliably normalized for scoring,
5. Then align these elements to the QPP and facility-level CMS incentive programs (i.e. MVPs key measurements aligned with Hospital Value-based Purchasing Program (VBP), etc.)

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Measures and Improvement Activities Considerations: MIPS Quality Measures

As part of the MVP Development Criteria, CMS outlines criteria for including MIPS Quality Measures as part of an MVP. The Agency explains that while CMS is not prescriptive on the number of quality measures that are included in an MVP, it lays out several factors that should be considered when selecting quality measures. One of the questions proposed for considering a quality measure in an MVP is *"Have the quality measure denominators been evaluated to ensure the eligible population is consistent across the measures and activities within the MVP*?" ACS seeks clarification on if it is CMS' intent to ensure every measure and activity have the same denominators. Given the wide range of quality measures and highly nuanced specifications, we do not believe it is CMS' intent to have every measure in an MVP be required to have the same denominator.

This question also raises the general disregard for considering whether MVP measures include the appropriate risk adjustment and other statistical methodologies needed for reliable and consistent measurement. This seems especially confusing considering that CMS discusses including the entire MVP cohort of patients in the denominator. One example can be drawn from the ACS MVP submission. In the ACS Geriatric Surgery MVP, submitted to CMS in February 2020, any clinician who treats a geriatric surgical patient (defined as patients 75 years or older who undergo surgery) could join the Geriatric Surgery MVP. ACS did not include the MIPS Surgical Site Infection (SSI) (MIPS #368) in the MVP, but CMS revised our submission and recommended the addition of SSI.

The reason why ACS did not include SSI (MIPS # 368) as part of the Geriatric Surgery MVP is the lack of appropriate statistical methodology in the MIPS measure specification that is needed for acceptable reliability and validity. Simply following the current MIPS measure specification for SSI will not lead to consistent and accurate measurement of SSI. This is complicated by the possible number of registries or other data sources that could report on SSI. It is also unclear how it is possible to reliably measure SSI mapped clinical episodes, when the MIPS SSI measure doesn't include a procedure-specific risk model which also accounts for patient risk factors. This type of application that lacks validity is what creates distrust among the clinician community and can lead to gaming.

ACS has demonstrated in the peer reviewed literature that harmonizing clinical quality outcome measures 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

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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, results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry. Through further study, ACS found that this discrepancy was not because NSQIP participants had poorer surgical outcomes; instead, the discrepancy was due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP.[5] The MIPS SSI measure was developed by ACS and originally did include risk adjustment as part of the specification, but CMS removed it.

This leads to another key factor which was not included in the MVP Development Criteria—data aggregation. **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**. 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 of a single source include the Society for Thoracic Surgeons Registry, the ACS National Surgical Quality Improvement Program (NSQIP) and the American Academy of Ophthalmology IRIS® Registry. The importance of this cannot be overemphasized.

Additional Consideration: MVP Alignment with Hospital Quality Programs

In addition to the MVP Development Criteria CMS has outlined, we encourage CMS to consider measures that align with hospital quality programs. Incorporating alignment with hospital and other facility-focused quality programs will reduce administrative burden while providing multidisciplinary teams with one quality program to fully focus on. This will result in a more cohesive and comprehensive quality signal which centers on the patient, not the location of care or how it is being paid for (Medicare Part A vs Medicare Part B).

As an example, the ACS Geriatric MVP submitted in February 2020 proposes to verify hospitals while also incorporating a multidisciplinary team of providers into quality improvement and assurance efforts. In the context of quality evaluation, it is very reasonable, to give "credit" at both the hospital level and the individual provider level when good care and outcomes are achieved. Implementing the ACS Quality Model includes: 1.) program-specific

[5] Ju MH, Ko CY, Hall BL, Bosk CL, Bilimoria KY, Wick EC. *A Comparison of 2 Surgical Site Infection Monitoring Systems.* JAMA Surg. 2015;150(1):51-57. doi:10.1001/jamasurg.2014.2891

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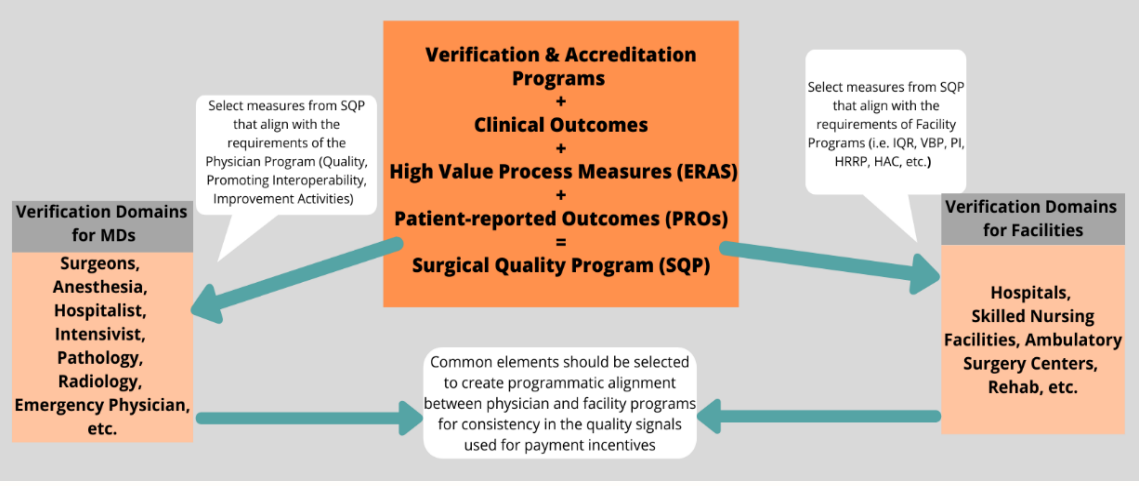
standards, 2.) infrastructure needed for delivering high–quality care, 3.) data collection and its use for care delivery and improvement, and 4.) verification site visits to ensure implementation of the critical elements for optimal care. Alignment of this model across hospital-based programs and a provider-based programs is not only achievable but will ultimately reduce duplicative measurement for the care of the same patient and reduce overall measurement burden.

Below, Figure 2 illustrates surgical quality program alignment across the hospital and clinician incentive programs. The graphic depicts a team-based effort for a patient's condition or procedure. **Before assigning and extracting random quality metrics, improvement elements, and interoperability as part of a rewards payment program, we encourage CMS to focus MVPs on building the quality program which holds all these elements as an interwoven, interdependent effort.** Then, when it comes to payment, dividing the clinical aspects for quality, improvement and interoperability from the program's pool of metrics. Similarly, we urge CMS to align the hospital measures in the hospital value-based purchasing program (VBP), and interoperability to come from the same pool, for example. The alignment could also include cost measures. Altogether, the impact would improve quality, greatly reduce burden by providing a consistent quality signal and fewer measures, lower costs, and fulfill the statutory requirements.

Figure 2: Framework for Alignment Across Physician and Facility Programs



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Capturing the Patient Voice

Beginning with the 2022 performance period, CMS proposes that the MVP proposals submitted to CMS should include patients as a part of the MVP development process. CMS explains that stakeholders should incorporate patients and/or patient representatives through means that may include, but are not limited to, technical expert panels or an advisory committee as they work to construct their candidate MVPs prior to reaching out to CMS with a candidate submission.

ACS asserts that the fundamental goal and purpose of healthcare is to create value for patient. The ACS strongly believes that value must be determined based on outcomes which accurately discriminate care delivery for things that matter to the patient. To do this, patient-reported outcomes measures (PROMs) and PROs are needed as a key part of MVPs. PROs necessitate transparency, increased accountability, and high-quality patient-focused care. PROs are not only critical for targeting improvements in the quality of patient care, but are also a critical aspect of helping patients make more informed decisions about treatment options since they capture valuable insights on factors of direct interest to the patient, including the achievement of patient goals from the perspective of the patient, and shared decision making. To this end, while including the patient perspective in the development of MVPs is important, it is equally (if not more) important that CMS consider the inclusion of well tested and nationally validated PRO tools such as PROMIS, SDM-Q-9, and CollaboRATE into MVPs[6,7,8,9]. We strongly encourage CMS to consider ways to include these tools as part of quality score in MVPs/MIPS without the requirement to develop a separate more traditional quality measure. Many PRO

[6] Barr, P. J., Thompson, R., Walsh, T., Grande, S. W., Ozanne, E. M., & Elwyn, G. *The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process.* Journal of medical Internet research. 2014; 16(1):e2. https://doi.org/10.2196/jmir.3085.

[7] Forcino, R. C., Barr, P. J., O'Malley, A. J., Arend, R., Castaldo, M. G., Ozanne, E. M., Percac-Lima, S., Stults, C. D., Tai-Seale, M., Thompson, R., & Elwyn, G. *Using CollaboRATE, a brief patient-reported measure of shared decision making: Results from three clinical settings in the United States.* Health expectations: an international journal of public participation in health care and health policy. 2018;21(1):82–89. https://doi.org/10.1111/hex.12588.

[8]Kriston L, Scholl I, Hölzel L, et al. *The 9-item Shared Decision Making Questionnaire (SDM-Q-9).* Development and psychometric properties in a primary care sample. Patient Educ Couns. Jul 2010;80(1):94-9. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/19879711.

[9] Rodenburg-Vandenbussche, S., Pieterse, A. H., Kroonenberg, P. M., Scholl, I., van der Weijden, T., Luyten, G. P., Kruitwagen, R. F., den Ouden, H., Carlier, I. V., van Vliet, I. M., Zitman, F. G., & Stiggelbout, A. M. *Dutch Translation and Psychometric Testing of the 9-Item Shared Decision Making Questionnaire (SDM-Q-9) and Shared Decision Making Questionnaire-Physician Version (SDM-Q-Doc) in Primary and Secondary Care.* PloS one. 2015;10(7):e0132158. https://doi.org/10.1371/journal.pone.0132158.

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tools have undergone extensive testing (more so than that most MIPS quality measures), are published in the peer-reviewed literature, and are well suited for inclusion in a program such as MVP. For conditions or areas that do not have an appropriate validated tool, we encourage CMS support and invest in the development of PROs/PROMs.

While we recognize that funding for measure development is limited at this time, one way to encourage stakeholder investment in the development of PROs/PROMs is to adopt scoring policies that reward clinicians who use PROs over other measures (e.g., in traditional MIPS, PROs could be eligible for bonus points, use of PROs could reduce the number of quality measures that a clinician or group needs to report, etc.). CMS could also encourage adoption of PROs through an implementation timeline to allow clinicians to become familiar and comfortable with reporting PROs. One option would be to start with attestation of collecting and reviewing PRO data with a validated tool, then the goal being that MVPs eventually recognize PROs as the highest weighted quality outcome because the patient is the ultimate judge for assessing the success of a surgical procedure.

Implementing Meaningful Measures in MVPs

Incorporating Population Health Measures into MVPs

In the CY 2020 PFS proposed rule, CMS expressed interest in incorporating population health measures calculated from administrative claims-based data as a part of the foundational layer within MVPs, in an effort to improve patient outcomes, reduce reporting burden and costs, better align clinician quality improvement efforts, and increase alignment with APMs and other payer performance measurement. However, they also explained that stakeholders expressed concerns with including population health measures due to concerns with reliability, validity, attribution, unintended consequences and/or risk adjustment of claims-based population health measures. In response, CMS is looking to address these concerns. Currently, the only population health measure that is being proposed for inclusion in MVPs is Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups. Although we do not generally oppose the inclusion of population health measures as part of MVP, including the HWR measure is not actionable to surgeons.

Instead, ACS is supportive of population health measures that better fit the condition(s) a particular set of specialties treat as teams. These measures should be relevant to the population and relevant to their expected clinical disciplines. The measures should leverage knowledge which promotes

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preventive measures and limits disease progression. A focus on early detection and timely intervention would seem appropriate. Population health measures that are relevant to a discipline would engage specialty clinicians—for example, trauma surgeons would be interested in population health measures related to gun violence or motor vehicle accidents, orthopedic surgeons would be interested in population health measure related to osteoarthritis and join replacement, and bariatric surgeons would be interested in obesity and vascular disease related to stroke.

It is also important to note that the goal of population health measures has traditionally included chronic conditions and patients with poly-chronic conditions. For decades, American healthcare has focused on acute conditions and specialty medicine. It is important to draw attention to these chronic conditions and the impact poly-chronic disease patients have on overall healthcare resources. We simply cannot expect acute care medicine to afford or fund all aspects of poly-chronic disease patients. Therefore, efforts to track these patients and reduce their overall impact on the US healthcare system seems essential.

An additional factor now additive to the overall cost of care involves the social determinants of health (SDOH). We know that when European health systems add in the cost of acute care, poly-chronic care and their programs in support of SDOH, their overall healthcare costs exceed the USA. Thus, it is important to realize the overall impact for all three aspects of healthcare—acute care medicine, chronic and poly-chronic medicine and the cost impact of the social determinants of health.

APM Performance Pathway

Beginning with the 2021 MIPS performance year, CMS proposes to establish an APM Performance Pathway (APP) under MIPS. The APP is designed to be complementary to MVPs and would be composed of a fixed set of measures for each performance category. CMS believes that the proposed pathway will reduce reporting burden for clinicians by limiting the number of measures necessary to meet quality reporting requirements in the Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), as well as for groups participating in the CMS Web Interface. In this proposal, clinicians participating in the MSSP would be required to report though the APP to be assessed on their quality performance for MSSP. The APP would also be an optional reporting and scoring pathway for MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the four snapshot dates during a performance period.

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While CMS believes that these updated policies will reduce reporting burden, understanding the reporting requirements of a new performance pathway and implementing new reporting mechanisms to meet requirements will be extremely burdensome on physician practices and their administrators, especially while practices are not operating under normal conditions during the pandemic. **Given the major disruption in care caused by the COVID-19 pandemic, the ACS does not support the timeline in which CMS is proposing to adopt this new reporting pathway. ACS suggests that CMS delay any major changes to reporting requirements in the QPP until practices have begun recovering from the disruptions caused by the pandemic.** In addition, to align with this new reporting pathway, CMS also proposes to eliminate the CMS Web Interface reporting mechanism. It is unreasonable to require practices to change how they report in the QPP, while also removing a primary reporting mechanism while practices are operating with many challenges. **We recommend that CMS should maintain the Web Interface as a reporting mechanism, even if they do finalize the APP, to allow a transition period for practices that are not able to implement these changes in 2021.** Because a finalized policy would not be released until late 2020, the expectation for practices that have relied on the Web Interface to find an alternative reporting mechanism is unreasonable, especially if practices choose to report via qualified registries (QRs) or QCDRs. It is important that CMS remember that to meet reporting requirements, registries have to implement specific deadlines to register for reporting, which could limit the reporting options for practices looking for new reporting mechanisms depending on when the 2021 Final Rule is released. There are also additional costs associated with reporting via registries that practices may not have accounted for, especially when they are recovering from the financial burdens of the pandemic, factors such as this should be considered when implementing major changes to the QPP in 2021.

Quality Performance Category

CMS proposes that beginning with the 2021 performance period, MIPS eligible clinicians scored under the APP would be scored on the following set of six quality measures. Given that these measures are focused on measuring population-health and preventative care, there will be limited opportunities for specialists to participate in this pathway. **The ACS recommends that CMS consider developing a separate pathway for APM (including ACO) participants who work in more specialized pathways so that they can benefit from the efficiencies of the APP (i.e., 0% weighting of the Cost performance category and full credit under the Improvement Activity performance category) while also using quality measures relevant to their specific APM.**

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Quality Measure ID	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
# 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
# 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/ MIPS CQM	APM Entity/Third Party Intermediary	Mgt of Chronic Conditions
# 134	Preventative Care and Screening: Screening for Depression and Follow-up Plan	eCQM/ MIPS CQM	APM Entity/Third Party Intermediary	Treatment of Mental Health
# 236	Controlling High Blood Pressure	eCQM/ MIPS CQM	APM Entity/Third Party Intermediary	Mgt of Chronic Conditions
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions

MIPS Performance Category Measures and Activities

Quality Performance Category

Category Weight

CMS proposes to weigh the quality performance category at 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year. CMS explains that section 1848(q)(5)(E)(i)(I) of the Act requires that 30 percent of the final score shall be based on performance for the quality performance category, in which the percentage points attributed to the final score for the quality and cost performance categories will both be equivalent at 30 percent, totaling 60 percent of the final score. However, for each year within the first five years of the MIPS program, the quality performance category performance percentage can be increased to more than 30 percent of the final score.

Although we understand that CMS has made incremental changes to the Quality performance category over the years in order to gradually transition toward the equivalent 30/30 Cost/Quality score required after

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the first five years of MIPS, we think that it is critical to put a "pause" on the MIPS CY 2021, as a result of the pandemic, to let clinicians and their practices focus on serving patients safely and keeping their doors open. Furthermore, in the Cost Performance Category Section we note that to the extent the category relies on broad cost metrics such as those currently applied to most MIPS participants, even such a gradual transition will not get us to where we need to be for value improvement.

Groups and Virtual Groups Reporting via the CMS Web Interface

Beginning with the 2021 performance period, CMS proposes to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians. CMS states that they have noticed a substantial decrease in QPP participation via the CMS Web Interface reporting mechanism. Citing that from the 2017 to 2019 performance period, the number of groups registered to utilize the CMS Web Interface decreased by approximately 45 percent and the number of groups utilizing the mechanism decreased by approximately 40 percent. CMS explains that they intended to align the discontinuation of this reporting mechanism with the proposal to implement the APP, because the Web Interface would no longer need to be used to assess ACOs under the MSSP. The Agency also states that with the implementation of the APP and removal of the Web Interface, participants will experience less reporting burden because the number of required measures will be reduced. **The ACS supports the removal of the Web Interface in the future, but it does not believe that CMS should remove this reporting mechanism at this time.**

While CMS believes that these updated policies will reduce reporting burden, identifying and implementing new reporting mechanisms necessary to meet the program requirements will be extremely burdensome on physician practices and their administrators, especially while practices are not operating under normal conditions. As stated previously, with the expected timing of the release of the 2021 Final Rule, the expectation for practices that have relied on the Web Interface to find an alternative reporting mechanism is unreasonable, especially if practices choose to report via QRs or QCDRs. It is important that CMS remember that to meet reporting requirements registries must implement specific deadlines to register for MIPS reporting, which could further limit the reporting options for practices looking for new reporting mechanisms depending on when the 2021 Final Rule is released. There are also additional costs associated with reporting via registries that practices may not have accounted for, especially when they are recovering from the financial burdens of the pandemic. The ACS believes that factors such as this must be considered, and CMS should allow practices to recover from the financial

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burden and disruptions in care caused by the COVID-19 pandemic before implementing major or burdensome changes to MIPS reporting requirements.

Selection of MIPS Quality Measures

General Surgery Specialty set

For the 2021 performance period, CMS proposes the removal of 14 measures, addressed substantive changes to 112 existing measures, added 2 new administrative claims outcome measures, and modified many existing specialty and new specialty sets. While we understand that CMS did not add or remove any measures that are included in the General Surgery specialty set, it is proposing substantive changes to multiple measures within the set. All the measures with proposed changes measure preventative care services, which as we have expressed in previous comments, do not directly align with most surgical workflows. The ACS believes that administering and measuring population health and preventative care activities are important, but these measures should not make up the majority of the general surgery measure set as they offer little support in understanding the quality of surgical care. Incorporating preventative care and population health measures that are directly associated with the services a surgeon provides would be of more value to a surgeon's practice. For example, a population health measure associated with injuries caused by gunshot wounds or motor vehicle accidents would be of interest to a trauma surgeon. As CMS explores other pathways for measuring value, such as in MVPs, we ask that it consider exploring how to align population health and preventative care measures with the interest of the surgeon and the surgical patient.

Administrative Claims Measure: Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

For the 2021 performance year, CMS proposes a new administrative claims measure, Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for MIPS. This measure is a re-specification of the existing, publicly reported hospital-level total hip/knee arthroplasty (THA/TKA) 90-day complication measure and has been designed to align with the cohort and methods of the hospital measure. This measure uses 36 months of administrative claims data to calculate risk-standardized complication rates RSCRs for MIPS eligible clinicians and MIPS eligible clinician groups with 25 or more cases within the 3-year performance period. CMS believes that this approach balances measure

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reliability with maximizing the number of clinicians or clinician groups measured.

For many years, ACS has urged CMS to consider measure reliability on a measure-by-measure basis and applauds CMS for incorporating a 3-year window to increase the integrity of this measure. Based on our experience analyzing clinical data in the ACS National Surgical Quality Improvement Program (NSQIP), we have been able to conduct evaluations on a measure-by-measure basis to determine the number of cases needed for a given surgical procedure. Year after year, we have expressed concerns to CMS about the difficulty of calculating a high level of reliability and validity with 12 months of data for an individual clinician, and have urged CMS to measure surgical care at the group or facility level in order to increase statistical power. This is especially important for procedures with a low complication rate. **Although we continue to advocate for measuring surgical outcomes at the group or facility level to better reflect team-based care, we support the direction of this measure since it evaluates individuals and groups over a longer time period for increased reliability, and also aligns with the hospital measure**. We recommend that CMS allow for a longer look back period for other MIPS measures, where appropriate.

Lastly, although risk-adjusted clinical data from a high-fidelity registry is often preferred to claims data, a 36-month collection period of claims data can be used as a proxy for quality outcomes with low event rates. Clinicians can use claims to monitor events and determine where risk-adjusted clinical data is needed in order to identify the problem and develop a plan for QI.

Cost Performance Category

Weight in the Final Score

CMS proposes to weight the Cost performance category at 20 percent for MIPS payment year 2023 and 30 percent for MIPS payment year 2024 and subsequent years. ACS has commented extensively in prior letters on the need to measure cost and quality over the same episode of care in order to achieve higher value. Furthermore, 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 a physician or care team currently uses resources and allow for comparisons with others who may be more efficient. While ACS understands the logic of gradually transitioning to the statutorily mandated weight of 30 percent, we do note that to the extent the category relies on broad cost metrics, such as those currently applied to most MIPS

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participants, even such a gradual transition will not get us to where we need to be for value improvement.

ACS has previously expressed our support for an alternative cost measurement methodology, based on the CMS Episode Grouper for Medicare (EGM) currently developed and maintained by the PACES Center for Value in Healthcare. The PACES Center's tools are capable of producing detailed, patient-specific price information with a breakdown for all services assigned to the episode within prehospital, hospital, and post-discharge phases of care.

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.

Multiple efforts are currently ongoing to demonstrate the effectiveness of the EGM-based grouper built on standardized, universal episodes. Incorporation of standard episode definitions would allow for value comparisons not just between physicians, but also across payers. Furthermore, the information generated would have applications in other HHS priorities. For example, patient-facing information derived from cost measure data could be used to create true price transparency, helping to inform Medicare patients and others as they make decisions about their care. Current CMS cost measures are narrowly targeted and therefore grossly underestimate the true price for an episode of surgical care. The PACES methodology not only provides standardized costs for consideration in the MIPS program, it would also align consistently with the national efforts to benchmark price transparency. Such an episode-based approach to price would also better suit patients and avoid itemized price lists for hundreds of line-items in a patient episode of care. Transparent cost information based on standard episode definitions could further provide patients with a prospective estimate of what care for an individual with their specific condition might cost, by providing either an average, or median range of prices based on real data. This in turn could help blunt the blow associated with unanticipated medical costs and surprise billing. We urge CMS to consider the benefits of such a system for MIPS participants, Medicare patients, and others.

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ACS remains concerned that there will not be sufficient information available from currently developed MIPS cost measures 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. Furthermore, ACS remains concerned that the Medicare Spending Per Beneficiary (MSPB) measure, which will form the basis for cost measurement for many surgeons, still lacks a close relationship to quality measurement and will not produce actionable data. 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. Additionally, as discussed in the quality category section, CY 2021 will still be heavily impacted by the COVID-19 pandemic, and it is imperative to put a pause on the MIPS program to allow administrators to focus on ensuring access to PPE, appropriate treatment modalities during the pandemic and survival of their business rather than having to focus on deciphering the nuances of a constantly changing program. Therefore, **we encourage CMS to maintain the weight of the Cost category at 15 percent of the final MIPS score for the 2021 performance period as CMS works with stakeholders to make improvements to the inventory of cost measures**. We would further request that CMS exercise flexibility in MVPs to allow for testing of alternative cost measurement methods such as PACES alongside existing MIPS measures.

Promoting Interoperability Performance Category

Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

Proposed Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure Under the Electronic Prescribing Objective

For the CY 2021 performance period, CMS proposes to maintain the *Query of Prescription Drug Monitoring Program (PDMP)* measure as an optional measure under the Electronic Prescribing objective. CMS also proposes to increase the amount of bonus points available for reporting this measure from 5 points to 10 points to incentivize clinicians to perform queries of PDMPs. The Agency cites stakeholders' past concerns about the lack of PDMP integration in EHR workflows and wide variation of PDMP implementation across states. Because there are still many technical and operational concerns around how to optimize a query of PDMP, CMS states that it does not feel that this measure should be required.

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As stated in our past comments, ACS supports the proposal that this measure should not be required because it is challenging to electronically report due to the additional documentation and verification with an external system, which creates unnecessary documentation burden for clinicians. We challenge CMS to consider how PDMPs can be optimized with knowledge engineering. Knowledge engineering solutions would be extremely helpful in tracking and analyzing narcotic prescribing practices and a patient's risk for Opioid Use Disorder (OUD). For example, a physician would input prescribing information for a certain patient into the patient's record, which could be sent directly from their EHR to the PDMP. Then the PDMP, through analytics built within the PDMP, could review the patient's record within the system and flag any variables that would signal the patient's risk for overuse or OUD. These analyzed data and any other variables the physician requests would then be sent back to the physician at the point of care to support clinical decision-making. A system such as this, could optimize PDMP's ability to exchange meaningful knowledge for better clinical care.

Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)

Beginning with the 2021 performance period, CMS proposes to add a new measure, *Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE),* under the HIE objective of the PI performance category. HIEs allow PHI to be shared between clinicians, hospitals, labs, and many other health care providers in an electronic and secure manner that enables clinicians to use the most recent patient data to longitudinally track patients as they move through each phase of care. The ability to bi-directionally exchange PHI with the HIE presents an opportunity for physicians to send, receive, and incorporate the patient's entire health record in their EHR, which presents a full picture of the patient's history to inform proper care, and can assist in the reduction of duplicative services. Within the proposed rule, CMS describes the advancements in HIEs, and states that there is now a wide availability of HIEs across the United States. To show this, the Agency cites a study that found that 45 states, including the District of Columbia, were covered by one or more operational HIEs.

To incentivize MIPS-eligible clinicians to engage in bi-directional exchange through an HIE, CMS proposes to add this new *HIE Bi-Directional Exchange* measure as an optional alternative to the two-existing measures: *the Support Electronic Referral Loops by Sending Health Information* measure and the *Support Electronic Referral Loops by Receiving and Incorporating Health Information* measure. Therefore, clinicians may report either the two existing

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measures OR may choose to report the new measure which would be worth 40 points and reported by attesting to the following statements:

- I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period.
- The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange patterns.
- I use the functions of CEHRT for this measure, which may include technology certified to EHR certification criteria.

The ACS has advocated for the increased use and integration of HIEs into the clinical workflow and we applaud CMS for taking steps to incentivize bi-directional exchange with these systems. Bi-directionally exchanging health information with HIEs is essential to longitudinally tracking patients' comorbidities, risk factors, and past treatments, which will better inform treatment decisions. **The College supports CMS' proposal to apply this new measure as an attestation and believes this measure shows CMS' commitment to alignment with increased data exchange as outlined in the ONC 21st Century Cures final rule. Although we support the intent of this measure, we ask that CMS refine the attestation statement language that explicitly requires exchange with disparate EHRs.** There are many examples where clinicians encounter challenges while trying to share data with other providers using the same EHR vendor. In some cases, EHR vendors may even require their clients to purchase add-on services to exchange with other facilities using the same vendor, putting expensive barriers on easily sharing data. Instead, we recommend that CMS focus on bi-directional data exchange with unaffiliated entities and unrestricted exchange on networks that share the same vendor. **It is also important to note that the ACS has received reports from end users that vendors are locking in their clients for data exchanges. That is, in order for a vendor's database to be accessed, the client is tied to the vendor's Fast Healthcare Interoperability Resources (FHIR) server and its current release. ACS believes it has been CMS and ONC's intent to allow for open access of a vendor's database from any open compliant FHIR server and restricting access of any FHIR server to a vendor's database seems to be a form of data blocking. We encourage CMS and other related government agencies to bring clarity to providing open access to a patient's data for exchange to and from HIEs and other data, without being tied to the other add-on services of a single vendor.**

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The ACS also challenges CMS to build on this measure by setting a goal that ALL certified EHRs would be actively exchanging data with HIEs within the next 3 years. We believe that patients and providers will only benefit from the increased use of HIEs which can eventually be leveraged to generate knowledge engineering for patient care by moving data into patient-centric mappings hosted in mid-tier clouds.

MIPS Final Score Methodology

Scoring the Quality Performance Category

Quality Measure Benchmarks

Under previously established policy, CMS uses performance in the baseline period for the MIPS payment year (the 12-month calendar year that is 2 years prior to the performance period) to set benchmarks for the quality performance category. The ACS recognizes this, in part, is consistent with statute which calls for prior year's comparisons. The intent to measure a mature measure year after year and compare results to prior year's benchmarks seems reasonable. CMS would expect improvement to occur. Yet, benchmarking in such a manner is challenging when the measures are in an early or developmental stage and have not yet matured as time-tested and valued measures. In addition, care delivery continuously changes, and measurement science evolves rapidly. To further complicate this, individuals and health systems select different measures for various reasons which adds to the challenges of retrospective or historical benchmarking. It is also noteworthy that CMS uses performance year benchmarks when faced with new quality measures, when quality measures lack historical data, or measures do not have comparable data from the baseline period. All of these factors add to the lack of a true quality signal for quality comparisons on a national level.

In this proposed rule, CMS notes that because of the flexibility provided to MIPS-eligible clinicians effected by the COVID-19 pandemic which allowed for no data submission for the 2019 performance period, CMS does not believe it will have a representative data sample to reliably calculate quality scores for the 2021 performance period. To account for this, CMS intends to use performance period benchmarks for the CY 2021 performance period. The Agency also asked for feedback on an alternative approach that would utilize the historic benchmarks from the 2020 MIPS performance period (which are based on the 2018 MIPS performance period) for the CY 2021 performance period.

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We appreciate CMS analyzing different methodologies in an effort to best benchmark MIPS performance during the pandemic. We support benchmarking with data from the same performance year for measures associated with high-volume cases because performance year data will reflect the most accurate and actionable data, and performance year data also allows changes in measures or an easier incorporation of new measures, thereby allowing the MIPS program to include more relevant and meaningful measures. However, it will be extremely challenging to achieve reliability and validity for measures associated with low-volume, especially at the individual provider level. As such, how would CMS account for measures with low-volume cases that would not capture enough data to reliably benchmark measures in a performance year?

This presents a challenge for CMS when relying on the same measure for historical benchmark comparisons from an overall policy perspective (regardless of the PHE). Therefore, ACS wishes to ask CMS to consider the initial years of performance measurement to be ideally suited for benchmarks linked to the same performance year and rate the outcomes in quartiles or deciles for overall performance in the MIPS quality performance category. This type of historical benchmark comparisons can rate performance by quartiles for a clinician or a facility overall, without regard to specific measures. Once measurement science has matured and a stable set of measures becomes more commonplace, then historical comparisons of the same measure year after year would be more meaningful and actionable.

For years impacted by the PHE, another option is for CMS to calculate both historic (i.e., based on 2019 data) and performance year (i.e., based on 2021) benchmarks for each measure and use whichever results in a more favorable score for a clinician. This will provide clinicians with a baseline of information to guide measure selection decisions going into the 2021 performance year. In addition, to account for the PHE's impact on benchmarks, we recommend that CMS adopt a one-time scoring floor of 5 points for any reported measure that meets data completeness, even if it doesn't have a benchmark. This one-time policy could help clinicians avoid payment reductions during this challenging time, but also incentivize participation among clinicians who might have otherwise opted to apply for a hardship exemption. It could also incentivize clinicians to report more specialized measures that have historically lacked a benchmark.

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APM Entity Groups and APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

CMS proposes to eliminate the MIPS APM scoring standard and replace it with a MIPS APM Performance Pathway and scoring rules. The proposal further would allow eligible clinicians who are on the APM entity's participant list during any of the snapshot dates to be considered participants in the APM entity group and makes other changes to align the APM entity group participation pathway with existing MIPS participation pathways.

ACS acknowledges that elimination of the MIPS APM scoring standard and the other changes included in this proposal will help to simplify the MIPS program, while granting additional flexibility for eligible clinicians to transition to APMs mid-performance period. This proposal seems in line with the underlying goals of the QPP to help physicians transfer from fee-for-service to Advanced APMs. Special consideration should be taken to ensure that all participants in the APP are able to benefit from the streamlined advantages of APM participation regardless of what APM they are participating in or whether they choose to report at the individual, TIN or APM Entity level to ensure fairness. Unfortunately, the requirement in the proposal that in order to participate in the APP, certain primary care focused population health measures must be reported regardless of the conditions and patients targeted by the APM, will either limit the ability of specialists to benefit from the APP, or will be seen as unduly burdensome since they are not directly related to the care provided. Due to limited time and resources, requiring these measures could also have the unintended consequence of physicians ceasing to report other measures directly related to the care they provide and therefore more meaningful to Medicare patients. CMS should instead consider allowing participation in the APP by reporting measures directly related to the target population and conditions covered by the model.

In addition, as noted above, the ACS does not support the timeline in which CMS is proposing to adopt this new reporting pathway given the major disruption in care caused by the COVID-19 pandemic. ACS suggests that CMS delay this and any other major changes to reporting requirements in the QPP until practices have recovered from the disruptions caused by the pandemic**.**

ACS would also reiterate that in order to achieve the goal of creating a clear pathway from MIPS to APMs, more APMs need to be tested and made available to eligible clinicians. To that end, **ACS continues to assert that CMS should partner with stakeholders to test models previously recommended for testing or implementation by the Physician-focused Payment Model Technical Advisory Committee (PTAC).**

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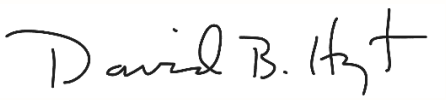
The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Jill Sage, Quality Affairs Manager, at jsage@facs.org.

Sincerely,



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