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September 13, 2021

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements (CMS-1751-P)

Dear Administrator Brooks-LaSure:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2021 Medicare Physician Fee Schedule proposed rule (CMS-1751-P) published in the *Federal Register* on July 23, 2021.

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 College 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.



PROVISIONS OF THE PROPOSED RULE FOR THE PFS

Changes to Direct PE Inputs for Specific Services

Clinical Labor Pricing Update

In 2019, CMS began a four-year phase-in of an update to the supplies and equipment prices used for code-level direct practice expense (PE) calculations. CY 2022 will be the final year of this four-year transition. In addition, for CY 2022, the Agency proposes to update PE clinical labor rates. This means that for CY 2022, changes would be made to the pricing of all three components of PE RVUs: clinical labor (CL), supplies, and equipment.

CMS states that the CL rates were last updated in CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available. A review of the full discussion in the CY 2002 MPFS final rule regarding the process of updating the CL rates shows that 12 (40 percent) of the 31 total staff types used “other sources” (e.g., SalaryExpert, powered by the Economic Research Institute) for pricing. Each of the examples of other sources represent data that are not readily available for public review to determine if the same process of collection is used. The Agency states that SalaryExpert salaries are developed using mainly government sources; however, the website for SalaryExpert indicates data are gathered from three sources: surveys conducted by SalaryExpert, surveys purchased from other organizations, and reports from publicly traded organizations.¹ This adds a layer into the process that is not transparent and could introduce bias into the pricing update. We question if CMS compared the data from SalaryExpert to the BLS data.

For CY 2022, 14 (44 percent) of the 32 single staff types are being updated using a BLS crosswalk because an exact match is not available. CMS solicits comments on the proposed updated CL pricing as well as methods to identify the most accurate types of BLS categories that could be used as proxies to update pricing for CL types that lack direct BLS wage data. The Agency is also interested in additional wage data that may be available. We provide comments in the table below on the proposed pricing source/crosswalk for select CL codes.

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¹ SalaryExpert. (2021). *About us: Our process*. Retrieved from <https://www.salaryexpert.com/aboutus>



ACS Comments on Proposed BLS Crosswalk for Clinical Labor Pricing Update				
Clinical Labor Code	Current Labor Description	2022 NPRM Update Source/ Crosswalk (Proposed)	BLS Update Source Description	ACS Comments
L037B	Histotechnologist*	BLS 29-9098	Health Information Technologists, Medical Registrars, Surgical Assistants, and Healthcare Practitioners and Technical Workers, All Other	Disagree: We disagree that BLS 29-9098 is a correct crosswalk for CL code L037B. We believe that BLS 29-2010 (Clinical Laboratory Technologists and Technicians) more accurately describes the clinical staff type associated with CL code L037B.
L037C	Orthoptist*	BLS 29-1141	Registered Nurses	Disagree: <ol style="list-style-type: none"> CL code L037C is incorrectly assigned to the Current Procedural Terminology (CPT) code 62304. The correct staff code for CPT code 62304 is L037D (RN/LPN/MTA), not L037C. CL code L037C is assigned to two other CPT codes (67343 and 67346). For these CPT codes, the “orthoptist” is a new staff type that was introduced to differentiate an orthoptist from CL code L038A (COM/COT/RN/CST) as a lower-level clinical staff. Therefore, it is not correct to crosswalk this staff type to BLS 29-1141, since it would elevate the staff type above L038A. We believe that BLS 29-2057 (Ophthalmic Medical Technician) more accurately describes the clinical staff type associated with CL code L037C.

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Clinical Labor Code	Current Labor Description	2022 NPRM Update Source/ Crosswalk (Proposed)	BLS Update Source Description	ACS Comments
L037E	Child Life Specialist*	BLS 21-1023	Mental Health and Substance Abuse Social Workers	Disagree: CL code L037E is related only to one CPT code (99170: <i>Anogenital exam of trauma to a child</i>). The description of work provided to the American Medical Association (AMA)/ Specialty Society RVS Update Committee (RUC) for this clinical staff was “primarily to provide distraction to patient during the physician's exam.” A child life specialist was described as a professional armed with a strong background in child development and family systems who promotes effective coping through play, preparation, education, and self-expression activities—not child mental health or substance abuse treatment. We believe that BLS 21-1021 (Child, Family, and School Social Workers) more accurately describes the clinical staff type associated with CL code L037E.
L038B	Cardiovascular Technician*	BLS 31-2011	Occupational Therapy Assistants	Disagree: BLS 29-2031 (Cardiovascular Technologists and Technicians) is a direct crosswalk for CL code L038B.
L039A	Certified Retinal Angiographer*	BLS 29-2010	Clinical Laboratory Technologists and Technicians	Disagree: CL code L039A is not related to clinical labs—instead, this staff sets up the IV for a patient, injects dye, and takes images of the eyes. We believe that BLS 29-9000 (Other Healthcare Practitioners and Technical Occupations) or BLS 29-2057 (Ophthalmic Medical Technician) more accurately describes the



ACS Comments on Proposed BLS Crosswalk for Clinical Labor Pricing Update				
Clinical Labor Code	Current Labor Description	2022 NPRM Update Source/ Crosswalk (Proposed)	BLS Update Source Description	ACS Comments
				clinical staff type associated with CL code L039A.
L039C	Psychometrist*	BLS 21-1029	Social Workers, All Other	Disagree: CL code L039C is only related to one CPT code (96138) for one minute of time for a technician to score a paper psychiatric test by hand. We believe that BLS 31-1133 (Psychiatric Aide) more accurately describes the clinical staff type associated with CL code L039C.
L041A	Angio Technician*	BLS 29-9000	Other Healthcare Practitioners and Technical Occupations	Disagree: CL code L041A was previously crosswalked to BLS 29-2034 (Radiologic Technologists and Technicians). We believe that BLS 29-2034 remains the correct crosswalk for an angiography technician.
L043A	Mammography Technologist*	BLS 29-1126	Respiratory Therapists	Disagree: Mammography technologists do not perform the same work as respiratory therapists. We believe that BLS 29-2034 (Radiologic Technologists and Technicians) more accurately describes the clinical staff type associated with CL code L043A.
L045A	Cytotechnologist*	BLS 29-2035	Magnetic Resonance Imaging Technologists	Disagree: The work performed by a cytotechnologist in a lab is not the same as that provided by an MRI technologist with a patient. CL code L045A was previously crosswalked in 2002 to BLS 29-2010 (Clinical Laboratory Technologists and Technicians) without objection by pathologists.

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ACS Comments on Proposed BLS Crosswalk for Clinical Labor Pricing Update				
Clinical Labor Code	Current Labor Description	2022 NPRM Update Source/ Crosswalk (Proposed)	BLS Update Source Description	ACS Comments
				We believe BLS 29-2010 remains the correct crosswalk for CL code L045A.
L045B	Electron Microscopy Technologist*	BLS 29-1124	Radiation Therapists	Disagree: For CY 2002, pathologists recommended that the labor rate for an electron microscopy technologist should be crosswalked to a cytologist. Therefore, BLS 29-2010 Clinical Laboratory Technologists and Technicians is the correct crosswalk for CL code L045B (i.e., CL codes L045A and L045B should have the same crosswalk and the same labor rate).
L063A	Medical Dosimetrist*	BLS 19-1040	Medical Scientists	Disagree: BLS 29-2098 (Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians, All Other) is a direct crosswalk for CL code L063A.
L152A	Medical Physicist	BLS 19-2012 (75 th percentile)	Physicists	Disagree: The rationale to use the 75 th percentile is based on maintaining the historical wage level for CL code L152A, which defeats the purpose of updating CL rates. In addition, the prior labor rate was set using a society salary survey from 1999. There are several types of physicists listed in the BLS files— BLS 19-2012 (Physicist) is the highest of the three options and would suffice as a crosswalk without using the 75 th percentile rate. Alternatively, BLS 19-1040 (Medical Scientist) would also be an appropriate crosswalk without more specific data.

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ACS Comments on Proposed BLS Crosswalk for Clinical Labor Pricing Update				
Clinical Labor Code	Current Labor Description	2022 NPRM Update Source/ Crosswalk (Proposed)	BLS Update Source Description	ACS Comments
L038A	COMT/COT/RN/ CST	BLS 29-2057	Ophthalmic Medical Technicians	Disagree: We disagree with crosswalking a certified surgical technician (CST) to BLS 19-4010. BLS 29-2055 (Surgical Technologist) is a direct crosswalk for CL code L038A.
		BLS 29-2061	Licensed Practical and Licensed Vocational Nurses	
		BLS 29-1141	Registered Nurses	
		BLS 19-4010	Agricultural and Food Science Technicians	

We highlight additional concerns with several proposed factors for the CL pricing update calculation below.

- Mean versus median BLS wage data: CMS proposes to use the average (mean) hourly wage instead of the median. We disagree that the mean is the correct data to use for the following reasons:
 - 1) The clinical staff time for codes is always based on the “typical” or median time when survey data are used. The most recent example of this is the clinical staff times assigned to activities for the office or other outpatient evaluation and management (E/M) visit code set updated for CY 2021; median survey times were recommended by the RUC and approved by CMS.
 - 2) The BLS survey data include rates for many “industries” including hospitals, physician offices, nursing care facilities, and government services. The data for registered nurses show that government and hospital pay rates are significantly higher than physician office pay rates. This discrepancy is similar for other clinical staff types. By proposing the mean salary instead of the median salary, equal weight is placed on the higher salaries in facility and government settings, even though the majority of CL changes will impact pricing for non-facility (office) settings. We do not suggest that any specific “industry” category be used for pricing but wish to highlight that the median rate will reflect the typical rate, and no additional code-level work would be required because the BLS



tables all list the median statistic. We recommend that CMS use the BLS median wage rate to update CL pricing.

- **Fringe benefit multiplier:** To account for employers' cost of providing fringe benefits, such as sick leave, CMS proposes to use the same benefits multiplier of 1.366 that was utilized in CY 2002. We disagree with this proposal as this multiplier is not accurate according to current BLS data. The most recent news release bulletin for "Employer Costs for Employee Compensation" from the U.S. Department of Labor indicates that the private industry worker's median and mean benefit cost was 29.6 percent.² We believe that the private industry workers rate is appropriate as it eliminates overemphasis on non-healthcare wages, such as those for farmers and federal employees. **We recommend that CMS use the current fringe benefit multiplier of 1.296 in the calculation to update CL rates.**
- **Pricing update implementation:** CMS notes that the potential effects of the CL pricing update on specialty payment impacts are largely driven by the share of labor costs associated with the direct PE inputs for each specialty. The specialties disproportionately impacted by this proposed update typically perform office-based services that utilize expensive supplies and equipment. The ACS, AMA, and numerous other medical societies have advocated annually for CMS to resolve the problem related to high-cost supplies by establishing Healthcare Common Procedure Coding System (HCPCS) Level II codes for supplies that exceed \$500. During the COVID-19 public health emergency (PHE), the ability to provide limb-saving interventions in an office kept many patients out of the hospital setting and away from COVID-19 patients. By not fixing the issue of high-priced supplies embedded in the PE for procedures in the office, the resulting direct PE payment for these services will now be 44 percent of the actual PE cost to provide the service. This cost inhibitive update will likely limit providers' ability to perform these services in the office, as the cost of providing such services will be higher than the office's income stream can justify. Providers will thereby be forced to send their patients to facilities where patient-care resources are already strained due to the PHE. **We strongly urge CMS to address this problem now by establishing HCPCS Level II codes for all supply items that exceed \$500.**

In addition, we note that there are several specialties that will be disproportionately impacted by both the CL rate update (due to the

² Bureau of Labor Statistics. (2021). *News release: Employer costs for employee compensation—March 2021* (USDLE-21-1094). U.S. Department of Labor. Retrieved from <https://www.bls.gov/news.release/pdf/eccc.pdf>

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embedded high-priced supply items) and the final transition year of repricing supplies and equipment. For example, the estimate for vascular surgeons is a 4 percent decrease due to changes in clinical labor and a 4 percent decrease due to changes in supply and equipment pricing. On top of these decreases is the scheduled expiration of the one-year 3.75 percent increase to the conversion factor provided by the Consolidated Appropriations Act for CY 2021. Therefore, the true impact on vascular surgeons is estimated to be a decrease of almost 12 percent. This percentage, however, is significantly greater (-20 percent) for those providers that perform limb-saving procedures that include high-cost supplies and equipment. We believe that a 20 percent decrease in reimbursement in one year will render many practices financially defunct, which will ultimately impact patients' access to timely care.

CMS also indicates that when updates to a payment methodology based on new data produce significant shifts in physician reimbursement, the Agency considers whether it would be appropriate to implement the updates through a phased transition across several calendar years. **We agree that it would be most equitable for the proposed CL pricing update to be phased-in over four years, and we request that the Agency delay implementation of the CL pricing update until CY 2023 after the final transition year of the supply and equipment pricing update.** If CMS were to delay implementation of the CL rate update for one year, stakeholders will have more time to respond to the Agency's request for additional information about other wage price data that may be more appropriate than the proposed BLS crosswalks. The sixty-day comment period allotted for the CY 2022 MPFS is not enough time to respond to a proposed update that decreases the direct PE scaling factor in the PE calculation by -25 percent, from 0.5916 to 0.4468.

To address the concerns described above, we strongly urge CMS to take the following actions:

- Consider recommendations for alternate BLS crosswalk labor categories for selected CMS PE labor staff types;
- Use the BLS median wage rate for updated pricing;
- Apply a fringe benefit multiplier of 1.296 in the calculation to update clinical labor rates;
- Establish HCPCS Level II codes for all supply items that exceed \$500;
- Phase-in the clinical labor rate update over four years; and
- Delay implementation of the CL pricing update until CY 2023 after the final transition year of the update to supply and equipment items.

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Comment Solicitation for Codes Involving Innovative Technology

As part of its proposal to establish values for remote retinal imaging, CMS requests broad comments on the resource costs for services involving the use of innovative technologies including, but not limited to, software algorithms and artificial intelligence (AI). **We provide feedback on the questions CMS presented in the rule, but we also urge CMS to examine the overall impact of new technologies on quality, cost, workflow, team-based care, physician burden, communication, and more.** These are interrelated issues, so it is not possible to examine the impact of new technologies in these areas in silos.

- 1. To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work?**

Advances in technology, software algorithms, and AI are seen across multiple sectors of the U.S. economy. These technologies can further productivity and enrich knowledge and applied science, but can also create new work needed to leverage the outputs from the technology. These technologies also impact workflows depending on the purpose of the technological advancement.

These principles of technology changing the work that humans do also apply to the use of innovative technology in healthcare. For example, advances in surgical instrumentation have led to our ability to reach more patients with more complex therapies. Technology has also led to greater customization of care and better management of various cohorts. But with these changes come changes to the work of physicians. When considering how such digital tools would change physician work, it is important to think beyond the current state of applied science and consider the applications of expanded technological capabilities and knowledge.

While use of innovative technologies should never substitute or supplant physician work, they can serve a vital role in aiding clinicians' function and can augment—and in some instances change—the nature of physician work. Examples include technologies and AI that read and process imaging or the IDx-DR device that can assist in detecting diabetic retinopathy.³ Surgical examples include the Predictive Optimal Trees in Emergency Surgery Risk (POTTER) risk assessment calculator app that uses AI to predict an emergency general surgery patient's risk of death, and the MySurgeryRisk

³ Digital Diagnostics (2021). IDx-DR. Retrieved from <https://www.digitaldiagnostics.com/products/eye-disease/idx-dr/>.

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machine learning (ML) algorithm that predicts risk scores for major postoperative complications.^{4,5}

These technologies can enhance, add to, or otherwise change the work that physicians do, but such tools will continue to require human oversight. In addition, physicians should always have the final say about if and to what extent to rely on digital tools. Differences in physician training, standards of care, care environments, patient goals, and more will have an impact on how clinicians view recommendations and outputs from digital health tools using innovative technologies. What works for one system or clinician may not work for another.

2. How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries?

New technologies do not categorically increase or decrease physician work time and intensity; rather new technologies change what physicians do.

There are many benefits to using digital health technologies in healthcare practices such as improved efficiencies, improved access, reduced healthcare costs, increased quality, and more personalized care for patients. These tools and technologies can also give healthcare providers a holistic view of their patients' health through data collected from wearables and personal health applications, as well as increased ability to readily communicate and exchange information with other providers. But care can become increasingly complex with additional data, recommendations, access to clinical practice guidelines, and more at the physicians' fingertips. With this more complete view of the patient comes a different type of work for the physician, and the amount of information being aggregated across time in a care plan could even be overwhelming. In some instances, using innovative technology might reduce work time, but it can also increase time and/or intensity due to the increased data to review and knowledge necessary to interpret the outputs and recommendations.

It is also important to consider that in the last decade, healthcare has focused on care coordination. Part of the reason for this is that care plans now involve care teams, each contributing services while patients travel across the care

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⁴ Maurer, L., Chetlur, P., Zhuo, D. et al. (2020). Validation of the AI-based Predictive OpTimal Trees in Emergency Surgery Risk (POTTER) calculator in patients 65 years and older. *Annals of Surgery*.

<https://pubmed.ncbi.nlm.nih.gov/33378309/>

⁵ Bihorac, A., Ozrazgat-Baslanti, T., Ebadi, A., et al. (2019). MySurgeryRisk: Development and validation of a machine-learning risk algorithm for major complications and death after surgery. *Annals of Surgery*, 269(4), 652-662. <https://pubmed.ncbi.nlm.nih.gov/29489489/>



continuum. New technologies and tools using AI and ML can play a role in allowing clinicians to expand their ability to coordinate care. These expansions represent opportunities to extend the care teams even further. So, it is not possible to think in terms of the way that care has been delivered in the past and how new technologies could affect the physician work time and intensity of specific CPT codes. Tools using AI and ML are not merely additions to a static delivery of care; rather, they represent a new set of instruments that will be used by the evolving care teams to better provide for patients.

3. How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time?

It is early in the adoption of tools using AI and ML in healthcare. Many of the costs related to these technologies are largely unknown. For now, we recognize that knowledge sharing enabled by AI and ML is tied to technology such as electronic health records (EHRs) and participation in health information exchanges (HIEs) or other state or federal data systems. In addition to the capital costs and maintenance of these aspects of technology, the licensing and maintenance of the intellectual property associated with AI and ML are unknown. Simply maintaining Fast Healthcare Interoperability Resources (FHIR) servers that allow for open standards-based data exchanges have proven costly. ACS members also frequently share that opening their EHR systems to AI and ML dramatically increases their costs with software vendors. Accessing openly available AI and ML may be so cost prohibitive due to EHR vendor demands that these could almost appear to be monopolistic. The results would create excessive recurring costs.

As the nation quickly rolled out EHRs, we never envisioned the environment for open-source software, FHIR, and other aspects of shared knowledge using digital services. The field of shared medical knowledge and knowledge management with AI and ML are nascent in healthcare and require that we retrofit these enhancements to care in a hardened environment of EHR vendors. Solutions from Amazon, Microsoft, and others are aiding in creating the necessary workarounds for a knowledge environment that relies on healthcare data lakes that exist outside the EHR walls. These are exciting enablers of sharing knowledge. However, it is difficult to say what the capital

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start-up needs are and what the recurring costs will be. There are still too many unknowns.

Turning more directly to the individual physician, we are still learning how the use of innovative technologies can change cost structures in the physician office setting. What we do know is that innovative technologies can change the overall workflow of a physician office, which can impact the cost structure in multiple ways. **Use of innovative technology is not just an added cost in exchange for making a current process more efficient. Rather, new technologies can change a physician's entire workflow, how physicians and patients communicate, and the data that clinicians and patients can access.** Digital health tools and technologies can enable complex data modeling, use of statistics and predictive analytics, access to the most current clinical practice guidelines and clinical decision support software, and ultimately knowledge sharing and knowledge management. The ultimate goal is to improve quality and value through providing the most relevant health care information to the right people, at the right time, in the right ways to enable them to make the most well-informed and cost-effective patient care decisions. As a result, reduced costs can come from improved patient care, decreased readmissions, reducing redundancy in knowledge, access to clinical pathways and guidelines, and more.

We also know that some of our members are experiencing much higher costs as they use innovative technologies. We have heard anecdotally that implementing the MySurgeryRisk risk score for postoperative complications can cost over \$100,000 for an IT team to map and validate. Then the tool must be reviewed every few months to ensure that recommendations of the AI algorithm are correct and that relevant factors for the use of this tool have not changed, which is not a one-time investment. Use of innovative technology has great potential to improve patient care, but it can come with high institutional and maintenance costs. Also, there is no guarantee that physicians or institutions will recoup their investment in new technology. Or worse yet, in some instances, investments in the new technology could be lost altogether if the technology itself does not function properly like the highly touted Epic Sepsis Model, which only poorly predicted sepsis.⁶ Finally, the costs of using innovative technologies might not be affordable for smaller practices, so the impact of these new digital health tools will be uneven for some time.

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⁶ Wong, A., Otlis, E., Donnelly, J., et al. (2021). External validation of a widely implemented proprietary sepsis prediction model in hospitalized patients. *JAMA Internal Medicine*, 181(8), 1065-1070. <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2781307>



4. How is innovative technology affecting beneficiary access to Medicare-covered services? How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI?

The questions posed are focused on the traditional face-to-face transactions of Medicare, which seems constraining to new technologies using AI and ML. In addition, beneficiaries are starting to seek more knowledge about their health and healthcare. **Technology can both improve access and create barriers to access.** On the one hand, we view digital services with AI and ML as able to provide three categories of knowledge enhancement that can also improve access:

- 1) Clinical decision support (CDS), which can provide patients with a better understanding of their care journey and expectations for care.
- 2) Population management, which can be improved using shared knowledge and fewer clinical resources. Understanding various cohorts, such as diabetes, ischemic heart conditions or cancer may inform patients and clinicians about their outcomes and care delivery.
- 3) Technology can also enhance research, which can eventually improve access. Patients and clinicians would have awareness of research opportunities, especially when traditional care pathways have been exhausted and patients inquire about what more may be available.

In addition, if a practice's business model cannot fully support the clinical needs of the community, it is possible that a digital tool could provide enhancements to increase access. Telehealth and remote patient monitoring devices can also expand access for patients who live in rural areas, are homebound, or have transportation or other obstacles to traditional delivery of healthcare services.

However, these benefits are limited by the digital divide, which prevents many who need it from being able to use these new technologies. Patients with limited access to broadband and other digital services may be left out as our health system continues to rely more on digital health. In addition, knowledge management in the complex disciplines of healthcare requires human-human interfaces to interpret the value of the knowledge imparted and to aid patients and their families in decision making. Approaches using new technology that specifically aim to improve access would likely drive significant improvement in quality of care for those patients given that access is often the limiting factor in their interaction with the system.

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- 5. Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? As CMS is considering appropriate payment for services enabled by new technologies, there are considerations for program integrity. To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?**

Any new technology will be at risk for fraud and overutilization. Particularly with the use of AI-based tools or CDS software, these technologies could recommend tests or services that are not needed. **As mentioned previously, the need for clinician oversight of the technology is key. Use of new technology should also be monitored closely as new reimbursement strategies and business models are employed.**

An example of a tool that uses standards to make sure it is safe and informative is the NSQIP Surgical Risk Calculator, which provides a patient-customized risk assessment for major surgical procedures and is maintained and openly provided by the ACS. Using this digital application in surgical decision-making and informed consent has become increasingly more common for patients with high-risk surgical needs. This clinical tool requires that the algorithms used to establish the risk results meet standards for clinical excellence, rely on current data, and are regularly reviewed and updated. Once these standards are met, the use of the tool is safe and informative to patients and the care team. Not all risk calculators for surgical care would stand up to the scrutiny applied to the ACS standard. Criteria are needed to assess and endorse the digital tools used in care environments.

- 6. Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?**

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This question asks about the effect of technology on healthcare quality, health equity, and bias. These are three separate and distinct issues that can often be intertwined.

Quality

There are many years' worth of data to suggest that technology has improved quality of care for patients. Healthcare is a knowledge-driven industry and delivery of quality services is heavily dependent on the ability of clinicians to access timely, relevant data and information. **One of the most important goals in improvements in technology is that it has the potential to drive optimal outcomes in the effectiveness, efficiency, and safety of patient care, all resulting in improvements in quality.** For example, technology can be used to assist institutions that are not providing guideline concordant care because they are in a rural setting, may be underfunded, or for other reasons. A tool that enables such institutions to access not only static guidelines, but continuous living assessments of knowledge could play a significant role in improving quality. The guidelines could be adjusted for various factors, such as demographics, social determinants of health (SDOH), completeness of therapy, compliance to therapy, and others to better guide physicians as they care for patients. But, as we described above, the improvements in quality could be limited to those who have access to technology, so it is also important to be aware of how technology could play a role in further widening the disparity gap.

Equity and SDOH

Although often conflated, addressing equity and SDOH are not the same. But, as discussed in other sections of this letter, there is a clear connection between SDOH factors and surgical outcomes. **Efforts to provide surgeons with accurate and real-time SDOH data could improve care delivery of healthcare and could in turn improve healthcare equity.**

We envision many instances where these data can be used to provide more personalized healthcare services for patients. For example, when a patient is admitted for a surgical procedure, having up-to-date information about the patient's chronic care management plans and patient-generated data that show their average activity levels, heart rate, insulin tracking, and other health information could greatly impact the way a surgeon decides how they educate and prepare the patients in the preoperative phase of care. The surgeon might also have access to self-reported information about social risk factors from patient surveys that could assist them in developing more personalized postoperative recovery and follow-up plans to ensure optimal recovery.

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If the collection of these data were more commonplace, we envision integrating it into clinical workflows through CDS modules available through the physicians' EHR and other platforms. The CDS tools could apply algorithms that evaluate the patient's electronic health information (EHI), including other risk variables, to trigger follow-up reminders and alerts for certain medications or interventions specific to the patient's needs.

To achieve more widespread collection, aggregation, and tracking of SDOH data, improvements in collection methodologies and standardization are necessary across the entire healthcare system. In many instances these data are not widely collected, and if they are, there is variation in how it is identified, classified, and what fields are used in EHRs and other systems. While some systems have taken steps to develop and implement internal processes to administer surveys and gather self-reported data from patients, these practices are not widely adopted and there is still much to be done to address the gaps.

Bias

It is critical to consider bias when designing, training, and using digital health tools. Various forms of bias based on race, ethnicity, gender, sexual orientation, socioeconomic status, and more can be perpetuated through using certain advanced digital health tools, especially those using AI/ML. Bias can manifest in digital tools in various ways. For instance, if an AI algorithm were trained with data that fails to include all patient populations for which the tool is used, this would introduce inherent bias. Bias could also be unintentionally written into algorithms, leading to outputs that could have a biased impact on certain populations. The context in which the tool is used should also be considered when trying to avoid bias. If the tool were trained on a certain population for a specific purpose and is instead applied in a different setting, with a different patient population, with varying risk factors, this could result in bias.

While it is not possible to eliminate bias completely, steps can be taken to validate the quality of the data and reduce bias in AI/ML algorithms. **Building a framework, through collaboration with stakeholders with clinical and technical expertise, that guides the development and validation of algorithms can assist in reducing bias if done with a high level of rigor.** The framework could include a checklist with certain steps that developers would have to complete to ensure algorithms have gone through rigorous testing and validation. By following the processes and validation criteria set forth by the framework, developers can work to reduce bias and improve the accuracy of output predictions. This type of framework, coupled with external

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validation that utilizes data across various practice settings and demographics, can also be applied periodically following the implementation of the tool to ensure as the algorithms take in real-time data, they are still achieving a high-level of accuracy.

In addition to building a framework to validate these algorithms, efforts to expand the data infrastructure to capture validated clinical data as well as racial, ethnic, and SDOH variables, will support the development of accurate predictive algorithms. Instead of building databases in silos where some focus on capturing clinical and outcomes data and others capture public health and disparities variables, creating a master database that can integrate all these elements will be beneficial in developing digital tools and using data to better understand variation in outcomes across populations. These databases could integrate data from trusted sources such as patient surveys collected during visits and secure apps on personal devices. Using more expansive data sets will help reduce the gaps in data that are used to develop predictive models, therefore allowing the models to “learn” how to aggregate greater variations in data elements.

Telehealth and Other Services Involving Communications Technology

Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

CMS proposes to allow certain services added to the Medicare telehealth list to remain on the list to the end of December 31, 2023, so that there is a glide path to evaluate whether the services should be permanently added to the telehealth list following the COVID-19 PHE. **We thank CMS for its continued efforts to expand access to care via telehealth during the pandemic and encourage the Agency to thoroughly review all services temporarily added to the Medicare telehealth list to ensure such services remain safe and appropriate to furnish virtually post-PHE before they are made permanently eligible for telehealth coverage.**

Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)

The CAA of 2021 included a number of provisions pertaining to Medicare telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder that CMS proposes to enact for CY 2022. While these proposals are applicable only to mental health-related telehealth services, we believe that such provisions could eventually be more broadly applied to telehealth services at large, and we urge CMS to consider the

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following issues when establishing discrete and concise telehealth coding, billing, and documentation criteria.

- **Originating sites:** Medicare telehealth statute generally limits the scope of telehealth services to those furnished in rural areas and in certain enumerated types of “originating sites” including physician offices, hospitals, and other medical care settings. The CAA amended this statute to include the patient’s home as a permissible originating site for telehealth services furnished to treat mental health disorders. **The ACS believes that a patient’s home should be a permissible originating site for all telehealth services to reduce care barriers related to mobility and transportation, among others. However, we question if this specific statutory language referencing the “home” of the patient will inadvertently restrict beneficiaries’ ability to receive telehealth services at other locations they frequent, such as their place of work.** We seek clarity from CMS regarding its interpretation of the applicable CAA amendment text.
- **Conditions of payment:** The CAA prohibits payment for telehealth services unless the physician or practitioner furnished an item or service to the patient in person, without the use of telehealth, within 6 months before the first telehealth service. Thereafter, the Secretary has the discretion to specify the times or intervals at which an in-person, non-telehealth service is required as a condition of payment for these telehealth services. CMS proposes that, as a condition of payment for a mental health telehealth service, the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of the telehealth service. The Agency seeks comment on whether a different interval, whether shorter, such as 3-4 months or longer, such as 12 months, may be appropriate to address program integrity and patient safety concerns. **We recognize that the proposed 6-month interval aligns with that specified by statute, but we believe generally that it is an arbitrary time threshold set simply to require an established patient relationship before a telehealth service is eligible for reimbursement. The Agency should base the decision of an appropriate interval on applicable medical guidelines and typical patient needs.**

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Proposed Valuation of Specific Codes for CY 2022

Closed Treatment of Nasal Bone Fracture (CPT codes 21315 and 21320)

For both CPT codes 21315 (*Closed treatment of nasal bone fracture; without stabilization*) and 21320 (*Closed treatment of nasal bone fracture; with stabilization*), CMS agrees with the RUC recommendation to change the global period assignment from 10-days to 0-days to account for postoperative care that includes variable work within 10 days. **We appreciate that the Agency approved this request for a global period change for these two codes.**

- CPT code 21315 (*Closed treatment of nasal bone fracture; without stabilization*): CMS disagrees with the RUC-recommended work relative value unit (RVU) of 2.00 for CPT code 21315 and instead proposes a work RVU of 0.96 based on the reverse building block methodology (BBM) that removes the RVUs and time associated with the 10-day global period, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
21315	Closed treatment of nasal bone fracture with manipulation; without stabilization	1.83	2.00	0.96

CMS does not discuss or acknowledge the additional information provided by the RUC about how these codes were originally valued, and we do not believe that the Agency fully reviewed the compelling evidence testimony regarding the flawed methodology used to value this low-volume code. Specifically, details from the RUC summary of recommendation form indicate that CPT code 21315 was not reviewed during the Harvard study and indicated in the 1992 MPFS Federal Register that flagged the value for this code as “gap-filled:”

The proposed rule provided preliminary physician work, practice expense, and malpractice RVU values for services that had been studied by the Harvard research team and explained in general terms our proposed process for “gap-filling” values not expected to be provided by Harvard.⁷

We wish to highlight that the data available in 1991 to gap-fill a value for CPT code 21315 did not include any work or time information, and instead

⁷ Medicare: Physicians' Services; Fee Schedule, 56 F.R. 59624 (1991).



relative work was assigned using magnitude estimation—considering that this is a low-volume code, it is unlikely that the gap-fill estimate was informed by actual experience in the provision of the service. The gap-filling process was followed by a second Harvard review in 1993, through which a survey of oral and maxillofacial dental surgeons was conducted to collect time for CPT code 21315, even though these providers do not perform this nasal bone fracture treatment service. These late review Harvard supplemental time data were later used in 1997 to insert an office visit (without changing work RVUs) into the time/visit data details by a CMS contractor for the purposes of implementing a new Medicare PE methodology. These three separate activities—gap-fill, Harvard late review by wrong specialty, and addition of visits by algorithm for PE purposes—produced a work RVU that was extremely low, the intrawork for CPT code 21315 was negative (-0.006).

Using reverse BBM, CMS is perpetuating the flaws of the original valuation for this service, resulting in the same negative intraoperative work value. It is clear that the Agency did not take into consideration the fact that the work RVU, times, and visit associated with CPT code 21315 were developed using multiple flawed methods. CMS’ proposed work RVU of 0.96 for this code—a value almost equal to a level two E/M office/outpatient visit (CPT code 99202; work RVU=0.93)—does not accurately reflect the provision of the service. **We urge CMS to review this new information, along with RUC’s discussion about a correct relative value that is based on survey data for a 0-day global code in comparison to the intensity, complexity, and time of other 0-day global codes, and to accept the RUC-recommended work RVU of 2.00 for CPT code 21315.**

- CPT code 21320 (Closed treatment of nasal bone fracture with manipulation; with stabilization): CMS disagrees with the RUC-recommended work RVU of 2.33 for CPT code 21320 and instead proposes a work RVU of 1.59 based on the reverse BBM to remove the RVUs and time associated with the 10-day global period, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
21320	Closed treatment of nasal bone fracture with manipulation; with stabilization	1.88	2.33	1.59



CMS does not discuss or acknowledge the additional information provided by the RUC about how these codes were originally valued, and we do not believe that the Agency fully reviewed the compelling evidence testimony regarding the flawed methodology used to value this low-volume code. Specifically, details from the RUC indicate that CPT code 21320 was reviewed by 17 otolaryngologists as a 90-day global code during the Harvard study. No other code in the family was reviewed and the vignette used by Harvard was “*Closed reduction nasal fracture*”—notably, the manipulation and stabilization work inherent to this service was not included in such review. The Harvard survey intraoperative time from the 17 respondents was 29 minutes. Separately, Harvard collected postoperative data that included a mean office visit time of three minutes, which was later transformed by a CMS contractor for PE methodology implementation into 0.5 x CPT code 99212. Similar to the discussion above for CPT code 21315, the initial methodology to value CPT code 21320 and the subsequent addition of an office visit to implement a PE calculation is a flawed methodology.

The Agency uses reverse BBM to subtract minute-by-minute pre-, intra-, and post-service time from the current value of CPT code 21320 even though the original valuation for this low-volume code was not developed using a minute-by-minute building block approach. Furthermore, the latest survey for this code found that total time decreased by only three minutes (-4 percent), but CMS’ proposed reduction in time is -15 percent. In prior MPFS rules, CMS has acknowledged that “a minute worked is a minute worked” when referring to “work/time.” The Agency has also acknowledged that non-face-to-face time spent reviewing records or placing an order for a blood test for primary care office visits is the same intensity as face-to-face time spent with a patient. In this instance, however, CMS has ignored compelling evidence and has treated time components (face-to-face versus non-face-to-face) differently for CPT code 21320, significantly reducing the RUC’s recommendation by 15 percent for a service with just three minutes less total time (78 minutes versus 75 minutes).

We do not believe that CMS’ proposed value for CPT code 21320 accurately reflects the provision of the service. **We urge CMS to review this new information, along with RUC’s discussion about a correct relative value that is based on survey data for a 0-day global code in comparison to the intensity, complexity, and time of other 0-day global codes, and to accept the RUC-recommended work RVU of 2.33 for CPT code 21320.**

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The ACS also strongly objects to Agency's statement that the global period changes from 010-day to 0-days allow for separately billable E/M visits relating to CPT codes 21315 and 21320, which CMS uses to justify its proposed removal of RVUs it believes are attributable to the currently bundled E/M visits, totaling 1.30 RVUs for CPT code 21315 and 0.35 RVUs for CPT code 21320. **We find it egregious that CMS proposes to remove the 2021 increased work RVUs for office/outpatient E/M codes in the same rule that the Agency continues to refuse to update global code values commensurate with the CY 2021 office/outpatient E/M increases.** The nonsensical application of a reverse BBM for CPT codes 21315 and 21320 is compounded by the fact that clear evidence was provided that office visit assignment for these codes to implement a new PE methodology have no relativity to the original Harvard valuation of the codes, which was based on magnitude estimation. CMS has previously indicated that RVU proposals are developed based on internal review by the Agency's Medical Officers, and if CMS does not accept the RUC recommendations for CPT codes 21315 and 21320, **we request a peer-to-peer review** with the appropriate Medical Officers to discuss the rationale for the CMS-proposed work RVUs in addition to the compelling evidence for the work RVUs recommended by the RUC for these services.

Insertion of Interlaminar/Interspinous Device (CPT code 22867)

CMS proposes to accept the RUC-recommended work RVU of 15.00 for CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*). **We agree with CMS' decision to accept the RUC recommendation for this code.**

Treatment of Foot Infection (CPT codes 28001, 28002, and 28003)

Global Period Assignment

CPT code 28002 was identified by the RUC Relativity Assessment Workgroup through a screen of 10-day global codes with utilization greater than 1,000 and more than one postoperative visit. CPT codes 28001 (10-day global) and 28003 (90-day global) were added as family codes for review. The RUC recommended that all three codes be assigned a 0-day global period due to significant heterogeneity in the complexity of the patient population, making it difficult to identify the typical patient for the purpose of estimating typical postoperative hospital and office visits in a global period; the severity of underlying comorbidities require differing levels of follow-up care. **We**

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appreciate that CMS approved this request for a global period change for these three codes.

- CPT code 28001 (Incision and drainage, bursa, foot): CMS proposes to accept the RUC-recommended work RVU of 2.00 for CPT code 28001. **We agree with CMS’ decision to accept the RUC recommendation for this code.**
- CPT code 28002 (Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space): CMS disagrees with the RUC-recommended work RVU of 3.50 for CPT code 28002 and instead proposes a work RVU of 2.79, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
28002	Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space	5.34	3.50	2.79

The surveying specialty societies provided compelling evidence of prior flawed methodologies regarding the valuation for this code. Specifically, CMS identified CPT code 28002 as potentially misvalued in 2010 through a site-of-service anomaly screen from early 2009 claims data that showed 49.2 percent of Medicare patients receiving this service were under inpatient status. The final 2009 data indicated inpatient claims were greater than 50 percent, and the current 2019 Medicare data indicate over 60 percent inpatient status. However, because CMS erroneously flagged this code as an outpatient procedure, the RUC only allowed 0.5 x CPT code 99238 for facility work and recommended a reduction of 10 percent in the work RVU using magnitude estimation. This prior recommendation—made over 10 years ago—was based on faulty claims data and not on the RUC survey, resulting in an underestimation of work and time as CPT code 28002 was valued as an outpatient procedure despite typically and consistently being performed in the inpatient setting. In addition, prior to 2010, CPT code 28002 was misvalued based on a 1995 RUC survey by pediatricians who do not perform this service. The RUC accepted the pediatric survey data, including operative time and inpatient visits, but did not accept the pediatric-recommended work RVU because no compelling evidence was provided to increase such value.

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In developing its recommendation to CMS for CY 2022, the RUC acknowledged that both prior reviews for CPT code 28002 used flawed methodologies. The RUC considered the survey median work RVU too high and the survey 25th percentile work RVU too low in comparison to other 0-day global codes that are typically performed in an operating room on a patient with inpatient status. The RUC determined that CPT code 31287 (*Nasal/sinus endoscopy, surgical, with sphenoidotomy*; work RVU=3.50) was an appropriate crosswalk code. CMS states that because CPT code 28002 is converting from a 10-day global to a 0-day global, the Agency believes reference CPT code 43193 (*Esophagoscopy, rigid, transoral; with biopsy, single or multiple*; work RVU=2.79) is a more suitable value of 2.79 work RVUs with a similar 30 minutes of intraservice physician time and 106 minutes of total time.

We disagree with CMS' proposed crosswalk to CPT code 43193 and proposed work RVU of 2.79 for CPT code 28002. A work RVU of 2.79 is exactly equal to a calculated value based on reverse BBM and not on relativity within the MPFS. Furthermore, CMS could have chosen the next esophagoscopy code in the family as the reference—CPT code 43194 (*Esophagoscopy, rigid, transoral; with removal of foreign body(s)*) has the same 30 minutes of intraservice physician time and one minute more of total time (107 minutes) with a work RVU of 3.50—or the more recently-reviewed high-volume CPT code 58558 (*Hysteroscopy with biopsy*), which has the same 30 minutes of intraservice physician time, 106 minutes of total time, and work RVU of 4.17. We believe CMS' chosen crosswalk code was selected based on intra-time similarities after the Agency calculated a value using reverse BBM without also considering the relative intensity and complexity of work, prior misvaluation based on flawed methodologies, and compelling evidence for CPT code 28002. The RUC's review considered many 0-day global codes with 30 minutes of intraoperative time and determined that CPT code 31287, a therapeutic procedure, was a suitable clinical crosswalk. Specifically, the RUC considered all 0-day global codes with 30 minutes of intra-time and 90 to 110 minutes of total time and found 15 codes with a work RVU range of 2.47 to 6.00 and median work RVU of 4.00, placing the RUC-recommended work RVU of 3.50 for CPT code 28002 in the lower half of the code range. The diagnostic esophagoscopy code CMS chose for crosswalking purposes was second to the lowest code in this range and not consistent with the clinical work, intensity, complexity, mental effort, and judgment required for CPT code 28802.

The low work RVU of 2.79 proposed by CMS for CPT code 28802 ignores the compelling evidence regarding the prior work RVU reduction in 2010

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based on erroneous Medicare utilization claims information and survey data from the wrong specialty, both of which incorrectly devalued the code. **We urge CMS to review this new information, along with RUC's discussion about a correct relative value that is based on survey data for a 0-day global code in comparison to the intensity, complexity, and time of other 0-day global codes, and to accept the RUC-recommended work RVU of 3.50 for CPT code 28002.**

- **CPT code 28003 (Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas)**: CMS proposes to accept the RUC-recommended work RVU of 5.38 for CPT code 28003. **We agree with CMS' decision to accept the RUC recommendation for this code.**

Per-Oral Endoscopic Myotomy (POEM) (CPT code 434XX)

In May 2020, the CPT Editorial Panel created new code 434XX to describe a peroral endoscopic myotomy procedure and was assigned a 90-day global period by CMS. The Agency disagrees with the RUC-recommended work RVU of 15.50 and instead proposes a work RVU of 13.29 based on a direct work RVU crosswalk from CPT code 36819 (*Arteriovenous anastomosis, open; by upper arm basilic vein transposition*) with 120 minutes of intraservice time and 283 minutes of total time, which is 2 minutes more than the 281 minutes of total survey time for 434XX.

The Agency fails to provide justification on why the robust survey data from a validated RUC process is ignored in the analyses used to determine the work RVU for this service. A crosswalk based on time alone is not an appropriate justification for any code, especially a new code. In addition, the intensity of this service is not appropriately captured by CMS' crosswalk.

The clinical work, intensity, mental effort, and judgement required for 434XX are higher, along with greater risk due to potential severe adverse events (i.e., esophageal perforation), further increasing the intensity and complexity of the procedure. **We disagree with the flawed crosswalk used by the Agency and urge CMS to accept the RUC-recommended work RVU of 15.50 for CPT code 434XX.**

Placement-Removal of Seton (CPT codes 46020 and 46030)

Global Period Assignment

CPT code 46020 was identified by the RUC Relativity Assessment Workgroup through a screen of 10-day global codes with utilization greater than 1,000 and more than one postoperative visit. CPT code 46030 was added as a family code

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for review. The RUC recommended that both codes be assigned a 0-day global period. A seton is typically placed (CPT code 46020) under anesthesia in an operating room and is typically left in place for 8-12 weeks, or indefinitely in selected cases, with the purpose of providing controlled abscess drainage, thereby allowing all the inflammation to subside and form a solid tract of scar along a fistula tract. Follow-up care of the patient will be variable based on the complexity of the fistula and comorbid conditions (e.g., Crohn's disease). Removal of a seton (CPT code 46030) may not require an E/M follow-up visit related to the removal of the seton or may not require a follow-up visit within 10 days. A 0-day global period allows reporting postoperative care as medically necessary for both procedures. **We appreciate that CMS approved this request for a global period change for these two codes.**

- CPT code 46020 (Placement of seton): CMS disagrees with the RUC-recommended work RVU of 3.50 for CPT code 46020 and instead proposes a work RVU of 1.86, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
46020	Placement of seton	3.00	3.50	1.86

The ACS is disappointed that CMS ignored the significant compelling evidence provided regarding the original misvaluation of CPT code 46020, as described below.

- **Evidence was provided about an abnormal survey methodology that was used by the RUC for less than one cycle.** The RUC agreed the historical documents clearly showed a flawed methodology that resulted in an underestimation of work as highlighted by an intraoperative intensity that was nearly zero.
- **Evidence was provided describing a flawed reference service list (RSL) used in conjunction with the abnormal survey methodology being tested by the RUC.** In 2000, the standard RSL for all surveys included codes with each of the different global periods, including 0-day, 10-day, 90-day, and XXX. Only three 10-day global codes were included on the RSL for the survey of CPT code 46020, and all three such codes were Harvard-based. The survey instructions were clear that respondents should be mindful of the global period when selecting a reference code, compelling respondents to choose one of the three Harvard codes with a 10-day global as a reference.

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- **Evidence was provided regarding a flawed global period assignment when this code was newly implemented in 2002.**

Although the procedure is a major operation performed under general anesthesia, CMS assigned the code a 10-day global because the Agency believed it would be an office-based service. However, CMS' assumption was incorrect—not only is this procedure almost always performed in a facility, but the RUC also recommends that it no longer be priced in the office setting. CMS' assumption resulted in an incorrect comparison of the CPT code 46020 to other 10-day global minor procedures that were primarily office-based.

Given these numerous irregularities—an incorrect global assignment, a short list of Harvard comparator codes for selection, and a flawed survey instrument—the value for CPT code 46020 cannot be considered valid. We also note that all of these process irregularities have since been corrected through the following actions: (1) there is a recommendation for global period assignment and rationale required in a CPT code change application; (2) RUC survey RSLs almost always only include codes with the same global period; (3) inclusion of Harvard-valued codes on the RSL is strongly discouraged; and (4) more than three applicable codes are included on the RSL.

Instead of considering all the evidence of prior misvaluation for CPT code 46020, along with a change in the typical patient and the procedure itself, CMS proposes a lower value to account for the loss of the postoperative visits due to the change in global period. Specifically, CMS states it is subtracting 2.04 work RVUs from the current work RVU of 3.00 to account for 2 x CPT code 99212 (2 x 0.70 work RVUs) plus 0.5 x CPT code 99238 (0.5 x 1.28 work RVUs). It is not clear how CMS calculated its proposed work RVU of 1.86, as the equation described by the Agency would result in 0.96 work RVUs (3.00-2.04).

We strongly disagree with the application of reverse BBM to subtract work RVUs attributed to E/M visits that were not used to value CPT code 46020. In addition, even though the Agency's calculation is not transparent, it is obvious that when CMS states it subtracted 2.04 work RVUs related to the E/M services, its underlying methodology is intended to remove the CY 2021 increased work RVUs for office/outpatient E/M codes in the same rule that the Agency continues to refuse to update global code values commensurate with the CY 2021 office/outpatient E/M increases.

We also disagree that a value of 1.86 correctly reflects a relative value when compared with the key reference CPT codes 46607 (*Anoscopy with*

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HRA biopsy) and 45380 (*Colonoscopy with biopsy*). Specifically, CPT code 46607 is an office-based procedure with 5 minutes less intra-time, 38 percent less total time, and a work RVU of 2.20, which is 18 percent higher than the CMS-proposed value of 1.86 for CPT code 46020. CPT code 45380 is typically performed under moderate sedation—not general anesthesia—has 2 minutes less intra-time, 35 percent less total time, and a work RVU of 3.56, which is 90 percent higher than the CMS-proposed value of 1.86 for CPT code 46020.

We urge CMS to consider this new information and accept the RUC-recommended work RVU of 3.50 for CPT code 46020. If the Agency continues to disagree with this value, **we request a peer-to-peer review** with the applicable CMS Medical Officers to discuss their rationale and methodology for the CMS-proposed work RVU, the compelling evidence documents for the RUC-recommended work RVU that were provided to the Agency, and the appropriate relativity of the value for 46020 in the fee schedule.

- *CPT code 46030 (Removal of anal seton, other marker)*: CMS disagrees with the RUC-recommended work RVU of 2.00 for CPT code 46030 and instead proposes a work RVU of 1.48, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
46030	Removal of anal seton, other marker	1.26	2.00	1.48

The ACS is disappointed that CMS ignored the compelling evidence provided regarding the original valuation. Instead of considering the evidence of prior misvaluation for this legacy (pre-1990) Harvard-based low-volume code, the Agency proposes a lower value to account for the loss of the postoperative visits due to the change in global period. Specifically, CMS states it is subtracting 0.35 work RVUs from the current work RVU of 1.26 to account for the loss of 0.5 x CPT code 99212 (0.5 x 0.70 work RVUs). It is not clear how CMS calculated its proposed work RVU of 1.48, as the equation described by the Agency would result in 0.91 work RVUs (1.26-0.35).

We strongly disagree with the application of reverse BBM to subtract work RVUs attributed to E/M visits that were not used to value CPT code 46030. In addition, even though the Agency’s calculation is not transparent, it is obvious that when CMS states it subtracted 0.35 work RVUs related to the



E/M services, its underlying methodology is intended to remove the CY 2021 increased work RVUs for office/outpatient E/M codes.

We also disagree that a value of 1.48 correctly reflects a relative value when compared with the key reference CPT code 46607 (*Anoscopy with HRA biopsy*) which has a work RVU of 2.20, is a similar office-based procedure, and has slightly less total time. The Agency's proposed value is also significantly less than CPT code 99214, an office-based service requiring only 30-39 minutes of total time compared with 65 minutes of total time related to CPT code 46030. Furthermore, CPT code 99214 includes moderate level of medical decision making and more than 50 percent less total time, making it a suitable comparator code to support the RUC-recommended work RVU of 2.00 for CPT code 46030.

We urge CMS to accept the RUC-recommended work RVU of 2.00 for CPT code 46030. If the Agency continues to disagree with this value, **we request a peer-to-peer review** with the applicable CMS Medical Officers to discuss their rationale and methodology for the CMS-proposed work RVU, the compelling evidence documents for the RUC-recommended work RVU that were provided to the Agency, and the appropriate relativity of the value for 46030 in the fee schedule.

Practice Expense Inputs

For CPT code 46020, CMS proposed to decrease the RUC-recommended PE pre-service clinical staff times to reflect RUC package times for 0-day services instead of 90-day services. The RUC developed packages for preservice clinical staff times to reflect the typical work related to categories of procedures, and in the initial fee schedule, global periods were assigned to surgical procedures based on typical site of service, type of anesthesia, and typical follow-up care. Codes with a 000 or 010 global assignment were considered minor procedures, and codes with a 090 global assignment were considered major procedures. When CPT code 46020 was created in 2002, a 10-day global period was assigned with the assumption that it would be a minor procedure performed in the office. That assumption was incorrect, and as part of the current review for this service, the RUC recommended that CPT code 46020 is a facility-only procedure that will not have office pricing. Even though the original global assignment was 010-days, the RUC acknowledged that CPT code 46020 is a major procedure typically performed in the operating room under general anesthesia, and preservice clinical staff time was assigned commensurate with other major procedures. Under the current review for CPT code 46020, there was also significant discussion by the RUC Practice Expense Subcommittee about whether the preservice clinical staff time should be maintained given the change in global period. The Subcommittee agreed that

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nothing had changed about the preservice clinical staff work and that the clinical staff preservice activities were consistent with major surgical procedures. Therefore, they recommended that the preservice clinical staff time should not change and should reflect the times assigned to major surgical procedures.

The Agency's failure to consider the justification provided to maintain the preservice clinical staff time and instead default to programmatic application of a 0-day global package is disingenuous and calls into question whether there is truly a clinical review conducted when CMS makes valuation recommendations. In this instance, there is no reasonable explanation for assigning 60 minutes of preservice clinical staff time on December 31, 2021, and then decreasing that preservice time to 30 minutes one day later on January 1, 2022. **The ACS intends to coordinate with the RUC to develop an appropriate package for major surgical procedures that have changes made to the global period, but in the interim, we request that the Agency recognize that CPT code 46020 is a major surgical procedure and retain its 60 minutes of preservice clinical staff time.**

For CPT code 46030, CMS proposes to decrease the RUC-recommended PE preservice clinical staff times. The Agency indicates that sufficient evidence was not presented to warrant preservice time in the non-facility setting and proposes no clinical staff time for this setting. We believe there was sufficient information provided to the RUC and CMS to justify preservice extensive use of clinical staff in the office setting. CPT code 46030 is reported 100 percent of the time with no other code when performed in the office setting, meaning that it is not reported with an E/M or any other service on the same date. Therefore, any E/M-related work is included in the work of CPT code 46030.

Additionally, in the PE non-facility summary of recommendation form submitted for this code, the preservice clinical staff activities were described in detail. A total of 18 minutes, indicating extensive use, was recommended by the RUC to account for multiple phone calls to the patient, family, and other providers involved in the care of the typical patient, along with follow-up work to arrange for this office-based procedure that will include an anoscopy and other surgical care. More details about these activities are provided in the table below.

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Activity	Time
Complete pre-service diagnostic and referral forms	5 minutes: Prior to arrival at the office for the procedure, clinical staff reviews all preservice diagnostic and referral forms to ensure all relevant history and diagnostic information is included.
Coordinate pre-surgery services (including test results)	3 minutes: Staff coordinates collection and documentation of imaging/lab results, patient specific information and other relevant patient information from other providers. Enter and record all clinical updates in EHR.
Provide pre-service education/obtain consent	7 minutes: Staff reviews procedure, complication risk, process of recovery, and answers patient/family questions.
Complete pre-procedure phone calls and prescription	3 minutes: Staff reviews preoperative medication changes and dietary changes prior to this rectal procedure, reviews patient medical status and answers final family/caregiver questions. Enter and record in EHR.

While this procedure is not typically performed in an office setting (i.e., less than 50 percent), there is extensive use of clinical staff when it is safe to do so. **We urge CMS to consider this additional information and accept the RUC-recommended 18 minutes of preservice clinical staff time for CPT code 46030 when performed in the non-facility setting.**

For the facility setting, CMS proposes minimal use of clinical staff. We disagree that this accurately reflects the preservice clinical staff time for CPT code 46030. When a patient is required to undergo this procedure in a facility, it will occur under general anesthesia and all preservice clinical staff activities associated with readying a patient for a major surgical procedure in the operating room are performed. Other similar procedures with 60 minutes of preservice clinical staff include CPT codes 46260-46262 and 46270-46275. **We urge CMS to accept the RUC-recommended 60 minutes of preservice clinical staff time for code 46030 when performed in the facility setting.**

For both CPT codes 46020 and 46030, CMS proposes to refine the direct PE input for CA038 (Coordinate post-procedure services) to 0 minutes from the RUC-recommended 3 minutes to align with 0-day standards instead of 90-day standards. We disagree that CA038 is standard for 90-day codes, and further believe that time for CA038 is specifically not applicable to 10-day or 90-day codes. This activity accounts for office clinical staff phone calls to coordinate transfer of facility information to the surgeon's office medical records, including operative and discharge notes, medication list, other provider correspondence, and imaging or lab results pending at discharge. When

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performed with a 10-day or 90-day procedure, this work is accounted for in CA036 (*Discharge day management*) which does not apply to 0-day global codes. **We request that CMS accept the RUC-recommended time for CA038 for both CPT codes 46020 and 46030 when performed in the facility setting.**

Intracranial Laser Interstitial Thermal Therapy (LITT) (CPT codes 617X1 and 617X2)

Global Period Assignment

In October 2020, the CPT Editorial Panel approved new codes 617X1 and 617X2 to report intracranial laser interstitial thermal therapy (LITT) of lesion for multiple or complex lesion(s). Both major surgical procedure codes were correctly assigned a 0-day global period so that widely variable postoperative multispecialty teamwork can be reported as medically necessary. **We appreciate that the Agency approved this global period for these major surgical procedures.**

- CPT code 617X1 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion*): CMS disagrees with the RUC-recommended work RVU of 20.00 for CPT code 617X1 and instead proposes a work RVU of 19.06, as shown in the table below. CMS believes the RUC partially applied the 23-hour policy to the immediate post service time but not to the work RVU, and states that the 23-hour policy in its entirety should be applied to CPT code 617X1.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
617X1	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance	NEW	20.00	19.06

We disagree with CMS’ proposed work RVU of 19.06 for CPT code 617X1. The surveying specialties adjusted the survey data to conform with the Medicare 23-hour policy that does not allow inpatient services to be included in the time and visit details for a service that is typically performed in the outpatient setting, and then argued that their recommended work RVU of 20.00 was an accurate reflection of the relative work for this code based on magnitude estimation. The 23-hour



policy was initially implemented in response to the ACS’ objection to discounting postoperative inpatient visits by the development of postoperative observation visits for inclusion in services that are more than 50 percent outpatient-based. However, the Agency believes the acuity of a patient with outpatient status is not significant and therefore asserts that the 23-hour outpatient policy should apply. As such, CMS used its formulaic policy of shifting work from E/M visits to immediate postoperative time, reducing the work RVU for all of the codes submitted to the Agency that included inpatient or observation E/M codes.

The RUC rationale submitted to the Agency for CPT code 617X1 included extensive discussion regarding the changes to the survey visit and time data, along with separate and distinct details about the accurate relative value for the service referencing the key reference codes, MPC codes, and additional codes that closely bracket the recommended value of 20.00. The RUC typically uses a survey statistic (e.g., the median or 25th percentile) that reflects relative magnitude estimation or chooses a code with similar work and time to use as a direct crosswalk when valuing a code. In this instance, the RUC agreed that a work RVU of 20.00 was appropriate relative to many references of similar work for both time and intensity. **We urge CMS to accept the RUC-recommended times and work RVU of 20.00 for code 617X1.**

- CPT code 617X2 (Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)): CMS disagrees with the RUC-recommended work RVU of 24.00 for CPT code 617X2 and instead proposes a work RVU of 22.67, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
617X2	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)	NEW	24.00	22.67

We disagree with CMS’ proposed work RVU of 22.67 for CPT code 617X2. This procedure will not have outpatient status, as patients undergoing this procedure will be admitted to the intensive care unit (ICU)



and remain in the hospital for at least two midnights. Therefore, we do not believe that the 23-hour outpatient policy applies. The RUC rationale submitted to CMS for CPT code 617X2 included extensive discussion regarding the accurate relative value for the service referencing the key reference codes, MPC codes, and additional codes that closely bracket the RUC-recommended value of 24.00. Further, the Agency has previously approved inclusion of postoperative inpatient E/M CPT codes in the CMS work/time files for codes with 0-day global if the patient status was determined to typically be inpatient (e.g., CPT codes 32601, 32607-32609, 33361-33366, and 33951-33966). CMS has also allowed multiple inpatient E/M CPT codes in the CMS work/time files for codes with ZZZ global assignment (e.g., CPT codes 33257-33259 and 33517-33530). Like CPT code 617X2, all of the codes with 0-day global assignment are major surgical procedures performed on patients who have inpatient status. **As such, we urge CMS to accept the RUC-recommended times, postoperative E/M visit, and work RVU of 24.00 for code 617X2.**

Practice Expense Inputs

As some major surgical procedures may be assigned a 0-day global period, we do not agree that the Agency should steadfastly adhere to an interpretation that clinical staff pre-time packages are inflexible. The RUC has previously agreed that major surgical procedures that have a 0-day global assignment require the same typical preservice clinical staff time as major surgical procedures that have a 90-day global assignment.

There is a significant amount of preservice clinical staff work required prior to surgery for both CPT codes 617X1 and 617X2. These procedures are performed under general anesthesia and require specialized supplies and equipment, preoperative coordination between multiple specialists, and both an operating room and MR suite. These codes were assigned a 0-day global period instead of a 90-day global primarily to accommodate the postoperative multispecialty care that is shared when treating the patient after surgery. The RUC compared the preservice work for these codes to the transcatheter aortic valve replacement (TAVR) procedures and to CPT code 61720 when considering preservice clinical staff work. Detailed information was provided to CMS in the PE summary forms that support the RUC's recommendation. **Until such time that the RUC and the Agency can catch up with changes to global period assignment for major surgical procedures, we urge CMS to acknowledge that the postoperative packaged work related to different global periods is not correlated to preservice clinical staff work.**

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X-Rays at Surgery Add-On (CPT code 74301)

When CPT code 74300 was identified by the RUC for review via a screen of codes never reviewed (CMS/Other Source), low-volume CPT code 74301 was added to the review as a family code. Initially, societies that do not perform this service recommended deletion of CPT code 74301. The ACS disagreed, indicating that the code is still necessary and should not be deleted. The stakeholder specialty societies did not resurvey CPT code 74301 due to its low utilization (2019 Medicare utilization=63) and difficulties in obtaining 30 survey responses from providers with experience performing this service in the past 12 months. Although no survey was conducted, the work RVU and time for CPT code 74301 is directly proportional to the recently-surveyed base CPT code 74300, thereby supporting the current value for CPT code 74301. **We appreciate that the Agency acknowledges this relationship and proposes to maintain the current work RVU of 0.21 for CPT code 74301.**

Revaluing End Stage Renal Disease (ESRD) Monthly Capitation Payment Services (MCP) (CPT code 90954)

In the CY 2021 MPFS final rule, CMS revalued most, but not all, of the ESRD MCP services. The Agency's argument for increasing the values for these 30-day global codes was that they included office/outpatient E/M services, and because such office/outpatient E/M codes increased in value, the ESRD codes should also increase in value.

In our comments to the CY 2021 MPFS, the ACS indicated that not all ESRD-related service codes (e.g., 90951-90962) were based on a building block methodology of discrete E/M services and identified CPT codes 90951 and 90954 as examples of codes that were valued using a crosswalk methodology. We also noted that, for the rest of the ESRD codes, the numbers and levels of visits were not determined as a result of surveys that led to use of the building block methodology; rather, they were developed using magnitude estimation in comparison to the work RVUs of several reference codes. This is evidenced by the fact that the codes do not include visits in the CMS time/visit database, and instead the values are based on total time. We argued support for fair and consistent policy for all global codes, whether the value of the code is based on magnitude estimation, BBM, or a mix of both methodologies. For these specific codes, the RUC survey asked for time and levels of visits, similar to the RUC surveys for global surgical services. The survey times from the ESRD surveys were significantly less than the total times that were assigned to each code, indicating that all of these codes were based on magnitude estimation and additional negotiation at the RUC. **We urge CMS to use a fair and consistent**

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policy for all global codes and believe that if the Agency has decided to the values for ESRD global codes that were developed using magnitude estimation commensurate with the CY 2021 increases to office/outpatient E/M codes, there is no obvious reason as to why all other global codes should not follow the same path and be increased as well.

For CPT code 90954, CMS is compelled by stakeholder arguments that a rank order anomaly was created in the family of ESRD codes when the Agency declined to increase this code for 2021. CMS' rationale was that it was clear the code was crosswalked without a discussion of BBM. Stakeholders have gone directly to CMS to request an increase to the value for CPT code 90954 using a new crosswalk code to correct the anomaly. The Agency agreed and proposes a higher work RVU (20.86) using CPT code 33977 (*Removal of a ventricular assist device; extracorporeal, single ventricle*). However, we wish to highlight that CPT code 33977 has an XXX global period assignment and only includes work on the day of a major surgical procedure (pre/intra/post-service times of 95/180/60). Therefore, not only is the Agency proposing to arbitrarily increase the value for a code that is not under any review and has a 30-day global period using a stakeholder-advocated crosswalk, but the code chosen for crosswalk is a major surgical procedure for work essentially all on a single operative day. We strongly disagree with the proposed crosswalk code and with the process being used to propose an increase for the value of CPT code 90954. **If the Agency or stakeholders believe there is a rank order anomaly, then we request that the process of nominating a potentially misvalued code should be followed—CPT code 90954 should be nominated and the entire code family should be reviewed.** This is important given that the code family: (1) has not been reviewed since 2007; (2) had problems with 2007 survey data and ranking resulting in multiple nonstandard methodologies used to value the codes; and (3) the Agency arbitrarily increased the value for many of these global family codes even though other global codes did not receive the same consideration. **We urge CMS to not change the value for CPT code 90954 and instead nominate this code (and family codes) as potentially misvalued.**

Principal Care Management and Chronic Care Management (CPT codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25)

Expansion of Coverage

CMS indicates that, in recent years, it has engaged in efforts to update and improve the relative value of care management and coordination services within the MPFS by identifying gaps in payment and coding. Examples of such

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services include chronic care management (CCM), complex care management, and transitional care management, all of which could have been reported with E/M codes and prolonged services codes, but are now reported with hundreds of new codes that unbundle packaged services such as screening and remote monitoring services. We believe this is an expansion of coverage that has not been accompanied by additional funds to cover such newly-defined discrete work. Further, these unbundled services have never been audited to confirm that there is not duplicative payment for inadvertent reporting of overlapping services. However, for global surgical services, any work by the same provider or a different provider in the same group or specialty within the global period requires a modifier and justification or is otherwise not reimbursed. Similarly, for many years now, the CPT Editorial Panel and the RUC have been monitoring “billed with” codes to determine when different services should be bundled, which almost always results in reduced payment. **We urge CMS to publish data about all of the codes typically billed during the 30-day global at the patient level for care management services.** This information would be helpful to the entire medical community to better understand the effort of caring for complex patients and to provide transparency with respect to reporting unbundled services.

Care Management Work RVUs

In the CY 2020 MPFS final rule, the Agency created two new HCPCS G-codes—G2064 and G2065—representing comprehensive services for a single high-risk disease (i.e., principal care management). For CY 2022, the RUC resurveyed the CCM code family, including complex chronic care management (CCCM) and principal care management (PCM), and added five new CPT codes to the family. The Agency reviewed the RUC-recommended values for the 10 codes in this family and proposes to accept the RUC-recommended work values. The Agency believes that proposing to accept these updated values is consistent with its goal of ensuring continued and consistent access to these crucial care management services and acknowledges CMS’ longstanding concern about undervaluation of care management under the MPFS.

The ACS agrees that focused patient care management can help create a healthier society, and we support any effort that can bring about such a change. However, we do not agree that changes should be made to increase reimbursement to any specific sector of medicine without sufficient supporting evidence. With respect to this family of 10 care management codes where CMS proposes to accept the RUC recommendations without discussion or objection, we are deeply concerned that CMS continues to ignore relativity and data when it comes to primary care services because there is a belief about undervaluation of primary care specialties compared with medical and surgical

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specialists. We note that CPT code 99490 was reviewed in 2014 and was originally written as a single code for reporting “at least 20 minutes” of CCM services. For CY 2022, this code is being split into primary CPT code 99490 for physician supervision of the first 20 minutes of clinical staff time and add-on CPT code 99439 for physician supervision of each additional 20 minutes of clinical staff time. When CPT code 99490 was previously surveyed, there were 338 responses to the survey and the RUC recommended 15 minutes of physician supervision time for 20 minutes of clinical staff time. Although this code had 4.1 million claims in 2019, the surveying specialty societies only collected 84 surveys. Only 4 (4.7 percent) of these surveys were from internal medicine and family practice, even though such specialties represent 71 percent of the total 4.1 million Medicare utilization. CMS does not discuss this discrepancy of fitness-to-rate nor does it question why the physician supervision time (25 minutes) is now greater than the clinical staff time (20 minutes). For any surgical code that is split, for example, into a simple and complex procedure, the Agency has always applied budget neutrality, thereby reducing the work RVU for both codes. However, in this instance, not only is budget neutrality not implemented or even discussed, but the original code has been increased by 64 percent based on two-thirds less surveys where most of the surveys came from specialties that do not typically provide the service. **Although CMS is only seeking comment on whether keeping professional PCM and CCM at the same value creates an incentive to bill CCM instead of billing PCM when appropriate, we urge the Agency to critically look at all of the work RVU values and survey times for this family of codes due to the physician/staff time discrepancies. We also urge the Agency to audit claims data during the 30-day billing period for these and other similar codes to confirm no overlap of work.**

Principle Care Management Work RVUs

CMS proposes to adopt the RUC recommendations for CPT codes 99X22-99X25. We disagree with the premise of these codes, which we believe unbundles work from other reportable services at the same time that the other services can be reported. We also believe the values for these codes are overstated. For example, we disagree with the proposed work RVU of 1.45 for 32 minutes of physician PCM services over a 30 day period for a patient who has a single chronic condition. The intrawork intensity and work per unit time (0.045) places the intensity of this work above a new patient E/M office visit requiring high medical decision making (MDM) (CPT code 99205; work RVU=0.040). The work over 30 days is described as requiring development or revision of a disease-specific care plan, but we do not understand how that can be accomplished outside of an E/M service. The work also describes frequent adjustments in a medication regimen; however, it is unlikely that this would

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typically occur within a 30-day span of time, or that this work could not be reported with other digital/audio codes. The code descriptor also describes ongoing communication and care coordination between all practitioners furnishing care; however, we do not understand how this multidisciplinary care should be reported for work related to this single chronic condition code, since only the single high-risk disease is being addressed. If other comorbidities and diseases were being addressed, then this work should be reported with complex care management codes. As such, PCM is currently reportable with many other patient care codes and valuing this nebulous work more than the highest office E/M visit intensity is not appropriate. **We urge CMS to reconsider whether these PCM codes are valid discrete services and to develop an audit mechanism to determine how this new unbundled coding paradigm works in the real world and whether it improves efficiency of care.**

Evaluation and Management Visits

Split/Shared Visits

CMS currently refers to a “split” or “shared” service as specific to E/Ms and as one that is performed by both a physician and a nonphysician practitioner (NPP) who are in the same group. In the office setting, current rules allow for the physician to bill for the service when portions of the service are performed by an NPP under the rule set for “incident to” services. In the facility setting, there is no provision for “incident to” billing, nor are there payments to NPPs for delivering this service with a physician. Medicare currently provides payment only to the physician or NPP who personally performs all elements of the facility service. In response to areas not addressed by the CPT Editorial Panel, CMS proposes to define split/shared services as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group in accordance with applicable laws and regulations.

As an overarching comment, we urge CMS not to make these changes to the billing rules for E/Ms provided in facilities at this time. The CPT Editorial Panel has approved revisions to the code descriptors for inpatient codes and related guidelines, which will be effective for CPT 2023. Changing the Medicare reporting instructions for 2022 in ways that may or may not be consistent with the CPT code set changes that will go into effect the following year will be confusing for physicians, NPPs, billers, and coders.

- **Same Group:** CMS proposes that the physician and NPP must be in the same group for the physician and NPP to bill for a split or shared visit, and CMS seeks comment on whether it should further define group for these purposes. CMS notes that defining a group as tax identification number

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(TIN) could create a group that is too large to assume that all the practitioners work closely enough to allow split/shared billing. We agree that defining a group by TIN has its challenges. A TIN can be quite large and encompass many different specialties. In an employed model, advanced practice practitioners (APPs) are commonly managed by the practice with the salary functioning as a pass through. They tend to be part of the same TIN, but not always. The use of Medicare specialty is another approach, but APPs may not declare a Medicare specialty. **A combination of TIN and Medicare specialty could be an option as well to capture the services from APPs that are truly working closely enough with the physicians in the group to share services.**

- **Substantive Portion:** CMS maintains that only the provider who performs the “substantive portion” of the visit (i.e., more than half of the total time spent by the physician and NPP performing the visit) may bill for the visit. However, the practitioner providing the substantive portion of the visit can select the level for the split or shared visit based on MDM. **Defining the “substantive portion” of the visit using time is not always appropriate, especially when the code level selection is based on Medical Decision Making (MDM) and not time.** In certain clinical scenarios, the determination of the “substantive portion” of the visit should not be based purely on time, and MDM should instead be the deciding factor of “substantial” rather than length of documentation or time. For example, an APP could spend considerable time gathering information for the physician to review, or accomplishing other similar activities, while the surgeon may come in, make several risky decisions, mobilize a whole operative team, decide on which incision or approach to use, and then prepare the patient for rapid exploration. These activities of the surgeon could take place in a short time span, but these are the critical decisions that make-or-break survival and lack of morbidity in a patient. In addition, some APPs tend to document more compared to physicians, which could inappropriately justify billing at a higher time. Finally, current CPT E/M Guidelines are clear that time is a factor only when time is being used to select the appropriate level of service for which time-based reporting of shared or split visits is allowed.
- **Qualifying Time:** CMS proposes a list of activities that could count toward total time for purposes of determining the substantive portion of a split/shared visit. This list, which is based on the current CPT E/M Guidelines for office or other outpatient E/M services, includes the following (regardless of whether they involve direct patient contact):
 - Preparing to see the patient (for example, review of tests)
 - Obtaining and/or reviewing separately obtained history

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- Performing a medically appropriate examination and/or evaluation
- Counseling and educating the patient/family/caregiver
- Ordering medications, tests, or procedures
- Referring and communicating with other health care professionals (when not separately reported)
- Documenting clinical information in the electronic or other health record.
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver
- Care coordination (not separately reported)

As stated above, we have concerns with using time for determining the substantive portion of a split/shared visit. A poorly informed clinician could spend more time coming to a wrong decision that is dangerous for the patient, while a smart and efficient clinician could take less time to arrive at the right medication, diagnostic test, or other treatment(s). Because MDM is the substantive physician work, MDM should take precedence over recording activities and the time spent by the various clinicians. Also, we request clarification on situations where a physician is participating in some of the activities on this list, but supervising APPs remotely. Specifically, we question if remotely supervised services would count as split/shared visits.

It is a mistake for CMS to move forward with this proposal for CY 2022, since these activities are currently only related to office/outpatient E/M visit codes. For example, only office/outpatient E/M codes describe “Performing a medically appropriate examination and/or evaluation.” All other E/M codes still require specific levels of examination. We understand that there are changes approved for other E/M codes for CPT 2023. **We urge the Agency to delay changes to split/shared visit to reduce reporting confusion.**

We also draw CMS’ attention to and question the time parameters for these services. For example, the time in the CMS time file for office or other outpatient visit E/MS include three components (Pre=3 days before; Intra=day of; and Post=7 days after). However, for facility E/M codes that are not reported as "other outpatient," the current code descriptors typically state "per day" of care. **What are the time parameters for capturing qualifying time for these activities under this new policy for each family of E/M codes?**

CMS seeks comment on whether it should create a separate list of qualifying activities for split/shared emergency department visits. **We do not believe there are “visits” for emergency medicine services, rather this work is more similar to the inpatient care services, which are “per day” codes.** Further, much of the emergency department work is performed by NPPs based

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on a team model and CMS should consider establishing code descriptors to better reflect this care model.

- Application to Prolonged Services: CMS is proposing to change its policy to allow a practitioner to bill for a prolonged E/M visit as a split or shared visit. **This is yet another area where the Agency's proposal will be problematic and will cause confusion due to expected code descriptor and guideline changes for CPT 2023.** Changing the Medicare reporting guidelines for CY 2022 in ways that may or may not be consistent with the changes that will go into effect for CPT 2023 in the following year will be confusing.
- Documentation Requirements: This proposed rule does not speak to how providers should document the qualifying time that was used to determine whether the physician or the NPP is the billing provider. Such information is important for providers to have in order to avoid inappropriate or incorrect billing. In instances where MDM is used to select the level of code to be billed, time may not necessarily be recorded. **The qualifying time requirement will be difficult to audit and will create more administrative burden because it is adding a reporting requirement that did not previously exist.**

Critical Care Visits and Global Surgery

CMS proposes to bundle critical care visits with procedure codes that have a global surgical period. CMS' first rationale is that critical care visits are included in some 10- and 90-day global codes. CMS' second rationale is that the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requirement to collect data on the number and level of postoperative visits provided within 10- and 90-day global periods is ongoing. CMS refers to previous concerns related to lack of sufficient data on the number and level of visits typically furnished during a global period, questions whether CMS will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and expresses concern about how global payment policies could affect services that are actually furnished.

CMS should not finalize this policy as proposed. We strongly oppose a proposal that would prevent surgeons from being able to appropriately use modifier -24 (*Unrelated E/M Service During Post-Operative Period*) or modifier -25 (*Significant Separately Identifiable E/M Service on the Same Day of a Procedure or Other Service*). Not only do CMS' rationales not support this policy, but this policy will prevent surgeons who provide both operative and critical care services from being fairly reimbursed for their time

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spent legitimately caring for some of their sickest patients in and out of the operating room. CMS should instead maintain the current provision in the Medicare Claims Processing Manual that specifically allows modifiers -24 and -25 to be used to indicate that the critical care service can be billed when unrelated to the procedure. This section states:

Critical care services provided during a global surgical period for a seriously injured or burned patient are not considered related to a surgical procedure and may be paid separately under the following circumstances.

Preoperative and postoperative critical care may be paid in addition to a global fee if:

- *The patient is critically ill and requires the constant attendance of the physician; and*
- *The critical care is above and beyond, and, in most instances, unrelated to the specific anatomic injury or general surgical procedure performed.*

Such patients are potentially unstable or have conditions that could pose a significant threat to life or risk of prolonged impairment.

Modifier -24 (post-operative) or -25 (same day pre-operative) is used to indicate that the critical care service is unrelated to the procedure.⁸

CMS' Rationales Are Not Sound

CMS states that “because critical care visits are included in some 10- and 90-day global packages, we are proposing to bundle critical care visits with procedure codes that have a global surgical period.”⁹ This rationale is not valid. **If critical care visits are included in *some* global codes, that has no bearing on whether critical care visits should be included in the remainder of the 10- and 90-day global codes, let alone in *all* global codes.** Few global codes include critical care visits because few procedures require critical care

⁸ Centers for Medicare & Medicaid Services. (2018). *Medicare Claims Processing Manual, Chapter 12, Section 40.1*. U.S. Department of Health and Human Services. Retrieved from <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>

⁹ Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements, 86 Fed. Reg. 39211 (Proposed Rule July 23, 2021)



services. This policy would presume that because *a few* 10- and 90-day global services typically require critical care services, then *all* 10- and 90-day global procedures require critical care services, which is not true. Whether or not 10- and 90-day global codes require postoperative critical care related to the operation is discussed on a code-by-code basis as part of the AMA/RUC deliberations on valuation of codes, and only included if the typical patient requires critical care services directly related to the procedure.

CMS' second rationale, in reference to the MACRA data collection on number and level of post-operative visits, is that "because this work is ongoing, we are proposing to bundle critical care visits with procedure codes that have a global surgical period."¹⁰ CMS also cites "lack of sufficient data on the number of visits typically furnished during the global periods" as support for the ongoing MACRA data collection.¹¹ Not only does this rationale not support the proposal to bundle critical care into visits with global codes, it is a strong justification for *allowing* critical care services to be billed separately when the use of modifiers -24 and -25 is appropriate. **If there is a lack of sufficient data on the number and level of postoperative visits as well as ongoing work to study these visits, CMS should not preemptively assume that it is appropriate to bundle all critical care into 10- and 90-day global surgical packages.**

Undervaluation of Surgical Care

This policy grossly misvalues/undervalues the care provided by surgeons and surgical teams to the sickest patients in the hospital, some of whom become sick unpredictably. **Specifically, this policy undervalues the ICU care required for some post-surgical patients and undervalues the expertise of those intensivist surgeons caring for the most complex patients.** As described above, most surgical patients do not require ICU care, and ICU care is not included in the value of most 10- and 90- day global codes. But some patients are either already critically ill when requiring surgery or become critically ill unpredictably after surgery. In these cases, surgeons and surgical intensivists are best equipped to manage the critical care services for these patients postoperatively. The surgeons are most familiar with their patient's case and their postoperative course. They are also most familiar with complex operations, the impact of comorbidities, and surgeons have the best skillset to identify and manage postoperative issues as well as recognize the expectations/pitfalls of surgery. The critical care that surgeons provide accounts for the constant attention, availability, interaction, and coordination

¹⁰ *Id.*

¹¹ *Id.*

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with multiple other specialties that may be required for these patients. The result of this level of care is that high intensity staffing (ICUs where intensivists manage or co-manage all patients) versus low intensity staffing (where intensivists manage or co-manage some or none of the patients) is associated with 30 percent reduction in hospital mortality and a 40 percent reduction in ICU mortality.¹² We are concerned that this proposal, which would deny reimbursement for this vital work, reveals CMS' lack of understanding of the clinical environment and the complexity of care of patients today.

Critical Care in Various Settings

Surgical teams and surgical intensivists are aggregated in major trauma centers and teaching hospitals. Today's care models occur in these large centers that take care of the most complex patients, and appropriately incorporate surgeons into the ICU team. The Leapfrog Group's ICU initiative recognized this ICU model as a significant patient quality improvement and, in fact, recommended it as a requirement.¹³ In these large centers, the doctors can all be in the same physician group or faculty plan leading to a team approach to the work. In such cases the surgeons and/or their group partners perform both global surgical procedures as well as provide critical care that is unrelated to the procedure.

For example, it is not uncommon for practices in these large centers to have a Medical ICU team as well as a surgical critical care team all in the same physician group. Similarly, many severely injured patients are unstable and managed non-operatively in the surgical ICU for their multiple trauma. It is not uncommon for a member of the surgical team to perform a surgical procedure with a global period, such as tracheostomy or laparotomy, on a trauma patient who had not previously required surgery, and then surgical team members will continue to provide critical care services, unrelated to the tracheostomy or laparotomy, until the patient is stabilized. **Eliminating appropriate separate billing for critical care services, simply because there was a procedure performed on the patient by one of their partners, would be unfair to those surgeons who provide these needed services to critically ill patients.**

Outside large centers in mid-sized regional hospitals, the ICU census will be smaller but nonetheless managed by board certified intensivists whether they be medically trained or surgically trained. In these settings the surgical critical

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¹² Pronovost PJ, Young T, Dorman T, Robinson K, Angus DC. (1999). Association between ICU physician staffing and outcomes: a systematic review. *Crit Care Med.*; 27:A43.

¹³ Leapfrog Group. (2021). *Factsheet: ICU Physician Staffing.*

https://preview2021.ratings.leapfroggroup.org/sites/default/files/inline-files/2021%20IPS%20Fact%20Sheet_3.pdf.



care is heavily dependent on the expertise of the surgeon. Their ability to manage these patients in the ICU with or without medical colleagues is certainly in the best interests of quality patient care.

Finally, in smaller hospitals where no intensivists are on staff and a surgical patient requires intensive care, it will largely be in the setting of waiting for transfer to a higher level of service. It is not unusual for transfer to take 24 to 48 hours to complete. In these situations, clearly it is in the best interest of the patient for the surgeon to provide critical care services without concern for unfair reimbursement.

There are approximately 5,000 surgeons who are board certified in surgical critical care through the American Board of Surgery. For most of these surgeons, “critical care” or “intensivists” is their secondary Medicare designation, not their primary. The secondary Medicare designation is not captured through billing, so it is likely that CMS does not have data on the number of surgical intensivists providing critical care and the number of services they provide. Therefore, it is possible that CMS does not fully understand the impact that this policy will have on surgical intensivists.

Clinical Examples

The table below lists clinical examples where surgeons provide necessary critical care services for which reimbursement would be eliminated by this policy.

Clinical Examples of Critical Care Cases That Should Not Be Bundled Into The Global Period	
• Critically ill patients that require a global surgical procedure in addition to unrelated critical care services	
1.	A patient with multiple co-morbidities presents in hemorrhagic shock from a ruptured splenic artery aneurysm. The general surgeon performs an exploratory laparotomy and splenectomy with temporary abdominal closure. Patient is returned to OR in 24 hours for removal of packing and abdominal closure. The patient requires complex postoperative critical care for the next 10 days for ventilation, correction of coagulopathy, and management of pre-existing portal hypertension and encephalopathy related to known cirrhosis. This surgical critical care is provided by the same surgeon/team that performed the operative procedure.
2.	A patient presents in delayed fashion in septic shock with a perforated duodenal ulcer. The general surgeon performs graham patch closure of the ulcer and then provides critical care services for management of septic shock.
3.	A patient with perforated colon cancer presents to ED with septic shock, acute respiratory failure, and acute kidney injury (AKI). Patient undergoes a

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	colectomy for the perforated colon, but also requires septic shock management, ventilator management and continuous renal replacement therapy for AKI. An ICU team, including the general surgeon who performed the colectomy will be providing all the critical care support for the patient that is unrelated to the operative procedure.
4.	Burn surgeons also provide ICU care and operate on nearly all their ICU patients multiple times during their hospital stay. They would be perpetually in the global period and not able to bill for the very labor-intensive ICU care that is not related to the procedures for burn treatment.
5.	A patient with intraabdominal trauma and an open abdomen due to sepsis requires trips back to the OR on a frequent basis for washouts, debridement, etc. This is all done by the general surgeon, who also attends to and cares for the critically ill patient in ICU post-op, providing critical care services, which typically include blood transfusions and treatment of shock.
6.	A multi-trauma patient receives complex ventilator support from a trauma surgeon after exploratory laparotomy for a crush injury.
7.	A patient has a pulmonary contusion, chest trauma, closed head injury and orthopedic injuries. This patient goes to OR for orthopedic fixation and then the ICU surgeon from the same group takes the night shift and spends time in the ICU stabilizing the patient.
	<ul style="list-style-type: none"> • Patient becomes critically ill due to an unrelated issue or unexpected postoperative course following a procedure that warrants escalation of care
8.	The general surgeon performs a laparoscopic appendectomy. On postoperative day 1 the patient has an aspiration event requiring critical care including intubation and management of mechanical ventilation.
9.	Patient with septic shock due to a gangrenous gallbladder, underlying diabetes mellitus had an open cholecystectomy, developed AKI, requiring continuous renal replacement therapy, on top of chronic kidney disease and continued respiratory failure.
10.	A postoperative pancreaticoduodenectomy patient ruptures a gastroduodenal artery pseudoaneurysm and requires resuscitation for hemorrhagic shock and follow-up critical care services by the surgical ICU team.

In summary, we urge CMS not to finalize this policy as proposed, which will prevent surgeons from being properly and fairly reimbursed for providing critical care services to their patients. **Instead, CMS should continue to allow physicians to bill for critical care services within a global period using modifiers -24 and -25, when appropriate.** CMS has not presented a rationale for why this proposed policy is needed. The policy provides no benefit and would cause potential harm to surgical patients and have significant impact on the surgeons who care for them.

Payment for the Services of Teaching Physicians

Stakeholders have asked CMS how teaching physicians who involve residents in furnishing care should consider time spent by the resident in selecting the



office/outpatient E/M visit level under the current policy that allows visit level to be selected based on time or MDM. CMS proposes that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. CMS also proposes that under the primary care exception (services furnished in certain teaching hospital primary care centers for certain services of lower and midlevel complexity without the teaching physician present), only MDM can be used to select the office/outpatient E/M visit.

Generally speaking, we support the use of MDM for the work that surgeons do. In many cases, the amount of time a surgeon spends on a case could be small relative to the importance of the MDM involved. **We also ask for clarification on the part of the definition related to “teaching physician was present.”** Specifically, we question if “present” means present in the same room as the resident during the visit, or present with the patient, or present somewhere nearby. In addition, we ask for clarity on what activities of the teaching physician count toward the time the teaching physician was present, and question if face-to-face time is required or if non-face-to-face time as described in CPT guidelines count. With respect to the primary care exception, we agree that only MDM should be used to select the lower/midlevel code given that residents in training may require more time than is reflected in the code descriptor to furnish a visit that has a low-level of MDM. We also urge CMS to not make changes or clarifications to this policy for CY 2022 given that CPT could make substantial changes as it continues to review and revised the E/M code set for CPT 2023.

Office Visits Included in Codes with a Surgical Global Period

We continue to voice our disappointment that CMS has failed to incorporate the RUC-recommended work and time incremental increases for the revised office/outpatient visit E/M codes into the global codes. CMS has failed to address this issue in both the CY 2021 and CY 2022 MPFS rules. While CMS did finalize adjustments for other bundled services, such as maternity codes, in the CY 2021 MPFS, organized medicine has been united in its recommendations that CMS incorporate the incremental revised office/outpatient E/M values into all of the 10- and 90-day global surgical package codes, as evidenced by the many comment letters and meetings over the past several years.

The proposed 3.75 percent reduction to the CY 2022 conversion factor will further add to cuts that many physician specialties have been experiencing for years. **We reiterate that it is inappropriate for CMS not to apply the RUC-recommended changes to global codes.** To do otherwise will continue to:

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- Disrupt the relativity in the fee schedule: Applying the RUC-recommended E/M value increases to stand-alone E/Ms, select global codes (e.g., monthly end-stage renal disease and bundled maternity care), and select bundled services (e.g., monthly psychiatric management), but not to the E/Ms that are included in the global surgical package will result in disrupting the relativity between codes across the MPFS, which was mandated by Congress, established in 1992, and refined over the past 27 years.

In 1991, a CPT revision of the E/M codes required Harvard and CMS to add work to global codes for the E/M. CMS assigned to the global codes what the Agency believed to be the equivalent to the work value for the discrete E/M codes. But then following this assignment, the work for the discrete E/Ms was increased slightly in the first fee schedule in 1992 and then increased again in 1993. These two changes by Harvard in 1991 and CMS in 1992 were never translated back to the global codes. So from the very beginning of the fee schedule, the postoperative E/M work relative value was discounted by 15-20 percent. The full value of the E/Ms has never been added back to global codes because the RUC doesn't use the BBM. But each time that E/Ms increased and CMS adjusted the global code values, only the incremental increase was applied, maintaining relativity. In summary, since the inception of the fee schedule, the E/Ms in the global codes have been discounted, but the original relativity has always been maintained. By not increasing the global by applying the incremental increase, the Agency has essentially established two separate fee schedules that are no longer relative.

- Create specialty differentials: Per Medicare statute, CMS is prohibited from paying physicians differently for the same work, and the “Secretary may not vary the . . . number of relative value units for a physician’s service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.”¹⁴ Failing to adjust the global codes is tantamount to paying some doctors less for providing the same E/M services, which is in violation of the law. In the CY 2021 MPFS proposed rule, CMS pointed to the method of valuation (i.e., building block vs. magnitude estimation) for a rationale as to why some bundled services should be increased in value to reflect the revised office/outpatient E/M values, while global codes should not. However, this statutory prohibition on paying physicians differently for the same work applies regardless of code valuation method and the incremental increases should apply to all physicians.

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¹⁴ 42 U.S. Code §1395w-4(c)(6).



- Ignore recommendations endorsed by nearly all medical specialties: The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) in 2019 to recommend that the full incremental increase of work and physician time for office visits be incorporated into the global periods for each CPT code with a global period of 10-day, 90-day, and MMM (maternity). The RUC also recommended that the practice expense inputs should be modified for the office visits within the global periods. In the CY 2021 MPFS, CMS used the RUC recommendation as part of the rationale for proposing to increase the values of the maternity services codes and select other bundled services, but not the global bundled codes.

Again, we strongly urge CMS to apply the RUC-recommended changes to the E/M component of the global codes to maintain the relativity of the fee schedule congruent with the revaluation of the office/outpatient E/Ms.

While we believe the Agency should have made the adjustments to the globals in CY 2021 rulemaking rather than in CY 2022, we would highlight that it would not be without precedent to address the valuation of the global codes in the subsequent year. After changes were made as part of the first Five-Year Review of the MPFS, CMS (formerly the Health Care Financing Administration (HCFA)) initially declined to apply the E/M increases to the globals. However, the following year, in the CY 1998 MPFS final rule, the Agency directly stated, “Upon further examination of this issue, we are increasing the work RVUs for global surgical services to be consistent with the 1997 increases in the work RVUs for evaluation and management services.”¹⁵

As we have consistently held, it has been the Agency’s policy to make these changes to the global codes, and it would not be without precedent to make them in the year subsequent to the revaluation of the E/Ms. We implore the Agency to follow its own precedent and resolve this issue.

Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Section 122 of the Consolidated Appropriations Act (CAA) of 2021, Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Social Security Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is

¹⁵ Medicare: Physician Fee Schedule for Calendar Year 1998; Payment Policies and Relative Value Unit Adjustments and Clinical Psychologist Fee Schedule, 42 C.F.R. § 400 (1998).



furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test.¹⁶ Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance), results in the beneficiary having to pay coinsurance. The reduced coinsurance will be phased in beginning January 1, 2022.

We thank CMS and Congress for addressing surprise medical bills related to colorectal cancer screening and diagnostic services, and support the elimination of coinsurance for such services to reduce out-of-pocket costs for Medicare beneficiaries. We encourage the Agency to consider how to address additional cost-sharing issues that may arise as new colorectal cancer screening technologies (e.g., Cologuard) continue to emerge and increase in Medicare utilization relative to flexible sigmoidoscopies and screening colonoscopies.

OTHER PROVISIONS OF THE PROPOSED RULE

Appropriate Use Criteria for Advanced Diagnostic Imaging

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

Due to numerous delays in implementation, CMS did not require ordering professionals to consult AUC using CDSMs or furnishing professionals to report information on consultation by January 2017. On January 1, 2020, the program began with an educational and operations testing period for the claims-based reporting of AUC consultation information. In response to the COVID-19 pandemic, the educational and operations testing period was extended through CY 2021, and CMS proposes to further delay implementation of the AUC program claims processing edits and payment penalty phase to begin the latter of January 1, 2023, or the January 1 that follows the declared end of the PHE.

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¹⁶ Pub. L. No. 116- 260



In recognition of the ongoing pandemic, during which the medical community is already dealing with tremendous financial and care delivery issues due to COVID-19, we support CMS' proposed penalty phase delay to allow time to address key workflow challenges and costs associated with AUC consultation and reporting requirements. During the PHE, neither provider nor government resources should be diverted to putting in place the systems and processes necessary to implement the AUC program.

The ACS also continues to have concerns about physicians' ability to meet CMS' AUC program requirements post-PHE. While the Agency asserts that using coding structures that are already in place will ease reporting processes, it has not specified what G-codes or modifiers would be required for reporting. Further, this approach has already been rejected by the National Uniform Claim Committee (NUCC) and National Uniform Billing Committee (NUBC), which stated that the use of G-codes and modifiers would be administratively burdensome and that all options to report AUC data will be costly and operationally difficult for physicians to implement. If CMS finalizes its AUC proposals without additional delay, physicians will have limited time to determine how to comply with these policies, assess available CDSMs with such policies in mind, select the CDSM most appropriate for their services and practice, integrate the CDSMs into their practices—including with their EHRs and billing systems (assuming G-codes and modifiers are finalized at the same time)—and train clinicians on their use.

Given the substantial burden and practice expenses that we anticipate the AUC requirements will create, the College believes that it is important that physicians are afforded the opportunity to adjust to the program in a thoughtful and deliberate manner that would allow for interoperability (i.e., integration of CDSMs into practices' EHRs and practice management systems). Practices should also have the opportunity to develop solutions for data exchange between the ordering and furnishing physicians in order to leverage health information technology to reduce burden. To accommodate all of the above, we believe it will be important for CMS to allow for gradual implementation of the AUC requirements. Under such a policy, CMS would pay claims for advanced diagnostic imaging services regardless of whether the required information about the AUC consultation is included in the claim. In addition, it is critical for CMS to test that submitted claims with the AUC information are correctly processed before the program is implemented. As CMS moves toward full accountability under the AUC program, we also recommend that CMS carefully consider the extent to which the Agency can continue to align the goals and requirements of this program with quality reporting programs and alternative payment models in order to minimize burden and limit duplication of effort.

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ADVANCING TO DIGITAL QUALITY MEASUREMENT AND THE USE OF FAST HEALTHCARE INTEROPERABILITY RESOURCES (FHIR) IN PHYSICIAN QUALITY PROGRAMS – REQUEST FOR INFORMATION (RFI)

As part of CMS’ Meaningful Measures Framework, the Agency aims to transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. To plan this transition, CMS asks for input on various areas that will provide pathways for greater quality data collection and advanced interoperability.

In general, the ACS is supportive of using digital tools to capture the full scope of patient data to inform patient care and quality improvement efforts, but as stated in our following comments, the **ACS believes that the current structure of CMS programs forces physicians to chase metrics for payment purposes instead of implementing quality programs that leverage digitally derived knowledge to drive continuous quality improvement. We believe that when planning the transition to digital quality measures, CMS should not focus solely on how to advance to digital quality measures that only account for single metrics.** Single metrics offer little value to patients when they are seeking high-quality care and little value to physicians for driving quality improvement cycles. Creating a digital framework to aggregate data for single metrics will make it easier and less burdensome to collect data but if the measurements do not drive meaningful quality improvement or appreciate the comprehensive patient journey and patient goals, we are left with the same problem we have now. Instead, **we suggest focusing this transition on utilizing digital tools to enhance more comprehensive quality improvement programs that have proved to drive improvements in care.**

Quality improvement using digital services should focus on supporting a digital services landscape that goes beyond simply aggregating quality metrics. Instead, it should leverage digital services by building knowledge around a patient’s care pathway through aggregating clinical care on open standards-based platforms that can ingest data from numerous sources. These digital services are nascent and hold great promise to enhance knowledge sharing around care to enable the following services:

1. Support the use of CDS to make clinical guidelines and pathways available as a digital service through platforms that are not constrained by proprietary efforts from EHRs.
2. Support the ability to gather condition or procedural cohort data for outcomes reporting and to assess conformance with guidelines-based care.

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3. Support data aggregation and analytics for near real-time research and clinical trials for expanding sample sizes in randomized clinical trials (RCTs) and observational studies.
4. Support quality metrics payors seek for their payment incentive programs in a patient centered manner.

These open architecture platforms are essential to expand medical knowledge management and optimize care. By using open standards-based platforms, data can be assembled for the individual patient (not the single EHR level) to build a patient perspective inside HIEs and allow for more shared and coordinated care. This architecture can meet and exceed payor needs for quality metrics, as well as enrich clinical knowledge. Retooling the healthcare industry for digitally supported knowledge enhancements takes considerable capital investment. If Medicare continues to distract the health informatics development and operations (DevOps) by focusing merely on metrics tied to payment activities, these capital needs to support better outcomes will be delayed. **We encourage the Agency to think more broadly about the underpinnings of digital healthcare so that the four aspects of care outlined above—CDS, cohort analytics, research, and payor metrics—are recognized in the same capital plans.**

Furthermore, digital tools that enhance quality programs or enable payor metrics should be engineered with an architecture that can be implemented and scaled on an open standards-based platform that deploys open source, standards-based infrastructure, such as FFHIR, HL7 V2 messaging, etc. The Amazon Health Lake¹⁷ is an example of this architecture that offers such engineering and an array of advanced digital services, such as natural language processing and more.

Additionally, as CMS continues to require that certain digital services be implemented in EHRs, we ask that they consider all aspects of implementation, including cost to the system. Many EHR vendors have added these required digital services to their systems at a cost beyond reason for an open market. Their proprietary, closed systems still have not fulfilled the intent of the Congressional efforts to overcome the bidirectional impacts of EHR vendor data blocking. To fully reduce the burdens of implementation, the digital environment needs an open marketplace that can absorb these costs. It is not enough to reduce clinical burden of data aggregation if the fiscal burden of constrained, proprietary vendor actions consumes more and more precious healthcare resources. In addition to affordable digital services, as data flows from the EHRs into clinical analytics, the EHRs should also provide a

¹⁷ Amazon Health Lake. Retrieved from: <https://aws.amazon.com/healthlake/>

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reasonable and affordable environment for data to become available to the EHR from other sources, such as the platforms and data lakes mentioned above. Without this ability, the EHRs will continue to data block elements of care.

Definition of Digital Quality Measures

CMS requests input on developing a definition of a digital quality measure (dQM). The Agency considers defining a dQM “as a software that processes digital data to produce a measure score or measure scores.” They also describe possible data sources for dQMs as:

- Administrative systems,
- Electronically submitted clinical assessment data,
- Case management systems,
- EHRs
- Instruments (such as, medical devices and wearable devices),
- Patient portals or applications,
- HIEs, and
- Registries, etc.

To support a “quality program” framework as described in the MVP sections, we suggest that CMS change its emphasis from aggregating data with dQMs that focus on single metrics to developing a definition for the digital enhancement of quality improvement programs. Regarding the data sources that can be used to gather EHI, we suggest that CMS expand this list further to include not only case management systems, but case management software as well, such as BPM+ Health. In addition, we believe that patient portals and applications should be considered separate data sources, instead of grouping them together. Further, we ask that CMS include other patient-centered platforms, such as those hosted by specialty societies.

The ACS believes that digital tools will be an essential part of the continued enhancement of quality programs. We envision utilizing digital tools to track progress (such as clinical care or improvement cycles) and attest to meeting standards within the domains of quality verification programs. Not only could digital tools be used to attest to certain activities, but with the proper algorithms, the tools could automatically track relevant patient outcomes in real-time. This information could be displayed as a dashboard in the physicians’ EHR to track quality goals, easily access relevant patient information, SDOH metrics, and ensure successful completion of care plans. In

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many ways, using these tools could eliminate excessive administrative and reporting burden by allowing physician and hospital participation in quality programs to be maintained and assessed automatically.

Use of FHIR for Current eQMs

Area #1: Leveraging and advancing standards for digital data and obtaining all EHR data required for quality measures via provider FHIR-based APIs

To achieve this transition, CMS is considering targeting the data required for their quality measures that utilize EHR data to be data retrieved via FHIR-based application programming interfaces (APIs) based on standardized, interoperable data. CMS states that the data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs.

The ACS agrees that CMS should not limit the data capture for dQMs to EHRs, or other traditional clinical settings. Today, there are many opportunities to leverage other data sources, such as risk-adjusted clinical registry data, patient-generated health data (PGHD), HIEs, and digital platforms hosted by specialty societies. ACS has developed a means for structured data capture (SDC) of key operative reports in a digital platform and is making these available for import and exchange using open standards, such as FHIR. SDC is also used and sanctioned by federal agencies in cancer pathology reports. These provide reliable and valid means for staging cancer, which is an essential step in determining treatment options and tracking survival and long-term outcomes. Optimizing data from all relevant sources will allow for a more comprehensive view of the patient through all phases of care. As CMS begins to transition to dQMs and consider data sources outside the EHR, it is important for CMS and Office of the National Coordinator for Health IT (ONC) to continue to acknowledge and address the potential challenges that may arise as digital health platforms and applications are developed. **In many cases, it can be extremely costly and unsustainable for hospitals and clinicians to establish agreements with EHR vendors that enables bidirectional exchange or access to their proprietary platforms. Therefore, CMS and ONC should work to create pathways for bidirectional data exchange with EHRs and other data sources.**

We appreciate that CMS has taken these steps to move towards promoting a broader use of the FHIR standards, but **we also recommend that CMS additionally consider ways to exchange data with digital health tools that are not just limited to FHIR-based standards. There are many other sources of patient data in standardized formats aside from FHIR that**

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would be useful to quality measurement, such as Operative Reports using SDC, clinical protocols, enhanced recovery after surgery (ERAS), and clinical CDS tools.

Area #2: Redesigning Quality Measures to be Self-Contained Tools

In this RFI, CMS discusses potential approaches for including quality measures that use standardized data and interoperability requirements that have expanded flexibility and functionality beyond CMS' current electronic clinical quality measures (eCQMs). The Agency is considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payors, CMS, and others that can calculate measure scores, and produce reports. The ACS believes that this is an extremely important step in redesigning digital quality measures and supporting the data flows needed for running a comprehensive quality program. **Transitioning to self-contained tools that can track patients across the care continuum by gathering and analyzing data for quality metrics and patient reported outcomes (PROs), as well as assessing conformance with the care plan will be highly valuable in driving improvements in care.**

Area #3: Building a Pathway to Data Aggregation in Support of Quality Measurement

CMS is considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. CMS also states that they are considering similar policies for third-party aggregators. **The ACS suggests that CMS also consider clinical association platforms, patient ID hubs within the HIE, and other similar patient-centered platforms as other sources of data aggregation for quality measurement.** We also have the technology to support tracking patients within appropriate firewalls to protect their identity while also leveraging knowledge and outcomes experience across the entire cohort. These platforms are being developed by specialty societies to offer clinicians personal analytics with systems rooted in Health Insurance Portability and Accountability Act (HIPAA) to better inform patients, payors, the care team, etc. Platforms such as this can use secure APIs to bidirectionally exchange data with HIEs, taking advantage of the longitudinal data captured in the HIE. The data are then sent to a data lake where the data are aggregated and can be shared back to the platform where physicians can view the analyzed data in a dashboard.

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The ACS urges CMS to recognize the need for a knowledge management strategy that is all-encompassing and not piecemeal. It would be burdensome if each delivery site had to meet differing requirements to interface with each data aggregator to suit the emerging needs of data in knowledge management. These needs involve care process management, case management across the care continuum, outcomes assessment, safety, conformance with guidelines, and so forth. Any quality measure aggregation initiated by a payor should have the ability to reduce data management burdens clinically and administratively.

Area #4: Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

The Agency is considering the future potential development and multi-staged implementation of a common portfolio of dQMs across its regulated programs, agencies, and private payors. This common portfolio would require alignment of:

- measure concepts and specifications including narrative statements, measure logic, and value sets; and
- the individual data elements used to build these measure specifications and calculate the measure logic.

The ACS has been a strong advocate for alignment across CMS quality programs. If CMS moves forward with this concept, CMS should not only align the current CMS quality measures across their programs, but also develop new measures that are aligned across a condition or the patient's total episode of care for purposes of quality improvement including key process, structure, and outcome measures as part of a comprehensive quality program. These types of measures can then be used as actionable feedback for care teams in addition to meeting reporting requirements for federal programs.

The ACS takes measure of CMS payment incentive programs by assessing how useful the information that emerges would be for patients and for their clinical teams. Do the CMS measures bring the various teams and elements of care together to inform care and drive teams to deliver care more optimally? The ACS wonders how CMS measures success of their program. Does CMS measure success based on the level of participation in measurement, the number of participants who received payment awards? We also ask how CMS evaluates the patient's use of Care Compare website and the value of the information they offer? **It would be helpful for CMS to provide more clarity on how they assess the successes and failures of their payment incentive programs.**

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CLOSING THE HEALTH EQUITY GAP IN CMS CLINICIAN QUALITY PROGRAMS – RFI

Low patient socioeconomic status (SES) has demonstrated adverse impacts on surgical outcomes. Limits on resources, lack of preventive care, poor early detection, and limited chronic care maintenance are some of the factors that contribute to inequities. Part of CMS' strategy to address health inequities is to improve data collection and consider ways to measure and report on equity in the CMS programs to better identify and understand health disparities, develop and disseminate solutions to achieve health equity, and implement sustainable actions to achieve health equity. The ACS commends CMS on the issues and questions raised in this RFI and is committed to closing the health equity gap. As the American College of Surgeons, we witness the many dimensions of inequities in surgical care and seek to use all our resources to help the nation overcome the barriers of inequities.

When considering the recent history of the US healthcare system prior to specialty medicine, we were a nation of home cures, local 'docs,' and simple remedies. With the advancements of science came specialty medicine. It brought acute care advancements that reversed serious acute illnesses such as cancer, heart disease, renal failure, and so forth. We now live in a world of specialty medicine for acute diseases and preventive/maintenance therapies for chronic care. Care has grown in complexity and price but lacks meaningful, relevant, and understandable data available to patients to access care and navigate the system. In specialty medicine, we see more advanced disease and higher rates of complications in racial and ethnic minorities, indicating that certain patient groups lack access to preventive care and timely access to surgical care. The root cause of inequities in care is not solved by clinician metrics. It is a much larger social issue.

These advancements in healthcare have also highlighted the lack of resources allotted for safety net hospital systems who care for some of our most underserved communities. When the safety net hospital system was developed decades ago during the period when care was simpler, capitalizing a health care system to meet minimum standards was somewhat attainable. Today, in many cases, safety net systems operate with limited resources and clinicians often are forced to practice "make-do-with-what-you-have" medicine. They experience limitations in infrastructure and budgets that are needed to manage the costs of depreciation, new technology, and so forth, sometimes resulting in understaffing. All these factors can have an impact on patient access to care, oftentimes forcing patients to wait months for screening and prevention or advanced imaging and other essential healthcare services.

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In this RFI, CMS discusses initiatives to bridge the health equity gap in the MIPS track of the QPP.

Improvement Activities

CMS proposes to modify five existing improvement activities (IAs) to shift the focus toward health equity, as well as propose a new improvement activity titled “Create and Implement and Anti-racism Plan,” which focuses on systemic racism as a root cause for differences in health outcomes between socially defined racial groups. CMS explains that the plan should include a clinic-wide review of existing tools and policies—such as value statements or clinical practice guidelines—to ensure that they include and are aligned with a commitment to anti-racism. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps, which may also include development of an organization’s plan to prevent and address racism, improve language access, etc.

The ACS is committed to dismantling systemic racism in surgical care. However, before encouraging individual clinicians and groups to create and implement an anti-racism plan, we support a more strategic approach. The first step might be to understand local economic and racial disparities and create a strategic plan to address health equity. One example of strategic work being done on the systems level is the Health Anchor Network (HAN), a noteworthy initiative which addresses economic and racial inequities through the influence health systems can have on a community. This work includes large and strategic investments in the hospital’s local community, using a health system’s economic power to inclusively and sustainably benefit the local community they serve—including hiring, purchasing, and investing locally. The Health Anchor Network aims to “define the healthcare leadership standard and promote industry collaboration for proactively addressing economic and racial inequities in community conditions that create poor health.”¹⁸ Many large healthcare systems including Kaiser, Rush, and Henry Ford, to name a few, are leading these efforts.

A more general concern that we have with the proposed IA is that the implementation of a system-wide plan (which calls for the development of a value statement, review of policies, improved language access and so on) likely has a greater chance of success if done by department heads or the facility administration, not a single clinician or a group of clinicians. **This an example of how MIPS and MIPS Value Pathways (MVPs) fail to recognize the**

¹⁸ Healthcare Anchor Network. *About the Health Anchor Network*. Retrieved from: <https://healthcareanchor.network/about-the-healthcare-anchor-network/>

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critical importance of how modern surgical care is delivered, including the critical role the facility plays. How would the Agency envision this IA being implemented by surgeons? Instead, **the facility should provide the appropriate resources, infrastructure, and educational opportunities needed to create and implement any type of organizational plan. This could be part of the hospital incentive programs where the hospital attests to having and implementing an organizational plan and the individual clinician or group reports participating in the plan.**

Complex Patient Bonus

CMS proposes to update the complex patient bonus formula in MIPS to make the complex patient bonus more targeted for clinicians caring for high risk and complex patients by giving additional points to clinicians with a higher share of medically and socially complex patients. CMS notes that it intended for this bonus is to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while it continues to work with stakeholders on methods to account for patient risk factors.

While we consider the MIPS complex patient bonus more closely targeting physicians who care for the most complex patients a worthy effort, we have two major concerns with both the clinical risk and social risk indicators. First, using the HCC on CMS administrative claims data alone are insufficient. Clinical data are much more reliable for determining comorbidities and should be used alongside administrative claims data. Second, using dual-eligibility as the sole indicator of social risk does not capture the full scope of patients who might have risk factors that contribute to the complexity of care they need, possibly reducing access for those who do not fit that definition. Only approximately 20 percent of the Medicare population falls within the dual-eligible designation, but we can assume that there are many more patients that have significant condition-specific or social risk factors that contribute to their need for more complex care even though they do not meet the dual-eligible definition. Again, by using the dual eligible designation as the only social indicator, we are concerned access to care may be impacted for those who do not fit that definition. **Identifying patients who will require complex care is a complicated task, therefore the ACS asks that CMS continue to work with stakeholders to design a more inclusive and accurate method to identify patients and provide rewards to clinicians who treat complex patients. We also ask CMS to consider more reliable ways to further reward teams who can demonstrate improvements in care while also serving complex patients, beyond the simple tool of bonus points.**

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CMS also solicits comments specifically on the stratification of quality measure results by race and ethnicity and improving demographic data collection. In our responses to the questions posed in the RFI, we share some findings in surgery and provide insights for how we can begin to close the health equity gap.

1) Future potential stratification of quality measure results by race and ethnicity

Findings in ACS NSQIP

To address disparate outcomes across patient groups, the College analyzed risk-adjusted National Surgical Quality Improvement Program NSQIP data to identify and understand disparities in surgery. In our analysis of risk-adjusted NSQIP data, which includes patient data starting with inpatient admission to 30 days post-discharge, the ACS found that surgical outcomes risk-adjusted for comorbidities did not show statistical differences across race.¹⁹ These findings have led to more research questions, including the need to analyze unadjusted inpatient NSQIP data—will the raw, unadjusted NSQIP data show a preponderance of uncontrolled chronic conditions when stratified by race and ethnicity? Are cancers detected at a later stage in certain groups? In other words, we must shine a light on the problem and avoid risk-adjusting away the differences for purposes of quality improvement and improving health equity. It is important to highlight the chronic conditions of patients who require acute care and the impact those conditions have on outcomes. An uncontrolled diabetic or hypertensive patient will fare worse if they need acute surgical services. We believe this approach aligns with the CMS intent for dealing with complex patients.

Additionally, when we consider the healthcare journey of patients in a safety net system, many of these aspects to support population health are simply not present or inadequately resourced. Safety net care is stretched beyond its limits in acute care. When measured on raw scores for event rates such as Surgical Site Infection (SSI), without risk adjustment, the incidence may appear excessive in this population. These are multifactorial problems that require more research and analysis to better define the problem. We can better serve all patients if we think of doing well across the care continuum—in acute specialty medicine, in chronic prevention, and maintenance of medical conditions. To dramatically improve the care of the safety net population, both acute and primary care must improve care coordination between each other to

¹⁹ This work has not been published in peer-reviewed literature.

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support the much-needed integration of care in this diverse population. We welcome further dialogue with CMS on our findings in NSQIP. **The ACS stands ready to help in the development of standards for aggregation and to work toward the inclusion of SDOH as part of the surgical team's dashboard.**

Expanding Current CMS Stratification Efforts

Currently, CMS is considering expanding the disparity methods to include stratification of the condition/procedure-specific readmissions measures by race and ethnicity. CMS notes the many limitations of stratifying for race and ethnicity because the Agency does not consistently collect self-reported race and ethnicity information for Medicare programs (the gold standard). Instead, CMS utilizes data from the Social Security Administration (SSA) which is less accurate. As part of this work, the Agency is working on efforts to develop consistent data on SDOH. For example, CMS has developed an Inventory of Resources for Standardized Demographic and Language Data Collection and supported the collection of ICD-10 codes for socioeconomic, cultural, and environmental determinants of health. CMS has also supported initiatives to statistically estimate race and ethnicity. ONC has included social, psychological, and behavioral standards in 2015 certified electronic health record technology (CEHRT) (however, this functionality is not included as part of the certified EHR technology required by the Promoting Interoperability performance category). The new release of USCDI v2 includes gender information, social determinants, and sexual orientation.

Because efforts to collect these data are a significant undertaking, CMS believes there is a need to better identify race and ethnicity in the short-term. As a short-term solution, CMS seeks feedback on the application of an algorithm to indirectly estimate race and ethnicity of Medicare Beneficiaries using a combination of other data sources that are predictive of race and ethnicity to permit stratification of measures in the aggregate (hospital or health plan-level), until more accurate forms of self-identified demographic information are available. CMS notes that despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration, there is a small risk of unintentionally introducing measurement bias.

The ACS commends CMS for the resources it has invested in identifying ways to promote health equity and agrees that identifying means to improve the health care of certain populations who have been historically underserved should be a top priority of the agency and the entire US health care system. When we start to think about how to collect and analyze data to determine differences in health outcomes based on race, ethnicity, and

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the role of SDOH, it very quickly becomes a complex and even seemingly endless task. Currently, there is so much noise in the data that we are guessing at the cause; it is hard to know where we should focus. Even if we had well validated data, understanding these relationships would be difficult, but in this case, it is even more complex due to the lack of SDOH data, reliable race and ethnicity data, and the many methodologies available to manipulate the data. We must be more thoughtful in definitions, data needed, and appropriate methodologies. **Therefore, before CMS starts to pick measures and attempts to stratify for race and ethnicity, it is paramount for the Agency to first state the goals that it wishes to accomplish. What will be the hypothesis, scope, and analysis of this work?** Safety net and community hospitals will usually look worse compared to most private hospitals which typically see less complex patients. Is the goal to level the playing field for purposes of accountability? Or is the goal to shine the light on the disparities and to give additional resources to hospitals with sicker and more complex patients?

The current payment system also adds complexity to the scope of this work—clinically dual eligible patients are complex, and from the CMS payment perspective, they are not limited to one payment program (some are FFS, some are managed care, etc.), making it harder to track and provide the necessary support and resources. Before diving into this work, CMS must state their goals and the potential limitations so the public can understand where this work may fall short, including what information the intended goal will and will not provide. Equally important is that CMS be as transparent as possible in this work.

2) Improving demographic data collection

CMS seeks comments on current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity, language preference, tribal membership, and disability status). CMS also seek comments on other efforts we can take within the MIPS program to further bridge the equity gap.

The ACS recommends that CMS consider exploring lessons-learned from Veterans Affairs (VA) data collection efforts regarding access to timely care. The VA tracks wait times for appointment types for a new patient or established patient for various types of specialists and primary care physicians. What additional metrics does the VA track for access? What is the wait time for a colonoscopy? Or a CT or MRI? Wait time for a surgical consult for chronic pain from a hernia or chronic cholecystitis? What about wait time for emergency department admission to a floor bed? These might be important

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data to analyze to help inform CMS data collection efforts and where further research is needed.

Right now, this RFI leaves us with more questions than answers. **Measures to improve health equity for Medicare beneficiaries, including dual eligibles, should focus on how to better define the multifactorial challenges across this diverse patient population. Therefore, we strongly recommend CMS provide a strategic plan that includes a detailed and transparent goal stated for this work, a timeline, and the necessary resources and research needed to achieve the goal, including the collection of self-identified demographic information to identify health disparities more accurately across all patient groups. An extensive deep dive into addressing health equity is required in order to prioritize next steps.**

The Intersect of Data, Digital Tools, SDOH Factors, and Surgical Care

As discussed earlier, there is clear connection between SDOH factors and surgical outcomes. The ability to collect accurate and real-time SDOH data could drastically change care delivery across the phases of care, from preoperative planning to postoperative management. We envision many instances where these data can be used to provide more personalized healthcare services for patients. For example, when a patient is admitted for a surgical procedure, having up to date information about the patient's chronic care management plans and patient generated data that show their average activity levels, heart rate, insulin tracking, etc. could greatly impact the way a surgeon decides how they educate and prepare the patients in the preoperative phase of care. The surgeon might also have access to self-reported information about social risk factors from patient surveys that could assist surgeons in developing more personalized postoperative recovery and follow up plans to ensure optimal recovery.

If the collection of these data were more commonplace, we envision integrating it into clinical workflows through CDS modules available through the physicians EHR and other platforms. Throughout the phases of care, the CDS tools could apply algorithms that evaluate the patient's EHI, including other risk variables, to trigger follow-up reminders and alerts for certain medications or interventions specific to the patient's needs.

To achieve more widespread collection, aggregation, and tracking of SDOH data, improvements in collection methodologies and standardization are necessary across the entire healthcare system. In many instances these data are not widely collected and, when they are, there is variation in how it is identified, classified, and what fields are used in EHRs and other systems.

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While some systems have taken steps to develop and implement internal processes to administer surveys and gather self-reported data from patients, these practices are not widely adopted and there is still much to be done to address the gaps. **The ACS believes that developing standardized data definitions for race, ethnicity, and SDOH is a foundational barrier that, if addressed, would allow stakeholders to gather more complete data sets that can be leveraged for research, quality measurement, and much more.**

Combating Bias Resulting from Use of Digital Health Tools

It is critical to consider bias when designing, training, and using digital health tools. Various forms of bias based on race, ethnicity, gender, sexual orientation, socioeconomic status, and more can be perpetuated through the use of certain advanced digital health tools, especially those using AI/ML. Bias can manifest in digital tools in various ways. For instance, if an AI algorithm is trained with data that fails to include all patient populations for which the tool is used, this would introduce inherent bias. Bias could also be unintentionally written into algorithms, leading to outputs that could have a biased impact on certain populations. The context in which the tool is used should also be considered when trying to avoid bias. If the tool were trained on a certain population for a specific purpose and is applied in a different setting with a different patient population with varying risk factors, this could also result in bias.

While we will be unable to eliminate bias completely, steps can be taken to validate the quality of the data and reduce bias in AI/ML algorithms. **Building a framework through collaboration with stakeholders possessing clinical and technical expertise that guides the development and validation of algorithms can assist in reducing bias if done with a high level of rigor.** The framework could include a checklist with certain steps that developers would have to complete to ensure algorithms have gone through rigorous testing and validation. By following the processes and validation criteria set forth by the framework, developers can ensure that the algorithms are free of significant bias and will output accurate predictions. This type of framework coupled with external validation that utilizes data across various practice settings and demographics, can also be applied periodically following the implementation of the tool, to ensure that as the algorithms take in real-time data, they are still achieving a high-level of accuracy.

In addition to building a framework to validate these algorithms, efforts to expand the data infrastructure to capture validated clinical data—as well as racial, ethnic, and SDOH variables—will support the development of accurate predictive algorithms. **Instead of building databases in silos where some**

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focus on capturing clinical and outcomes data and others capture public health and disparities variables, creating a master database that can integrate all these elements will be beneficial in developing digital tools and using data to better understand variation in outcomes across populations. These databases could integrate data from trusted sources such as patient surveys collected during visits and secure apps on personal devices. Using more expansive data sets will help reduce the gaps in data that are used to develop predictive models, therefore allowing the models to “learn” how to aggregate greater variations in data elements.

We also strongly recommend that in future RFIs on this topic, CMS solicit information on the necessary efforts from hospitals and clinicians to implement a coordinated strategic plan to address health equity such as: the development of standards, data collection methods, ways to address the digital divide, staff training to ensure that patients are comfortable answering all demographic questions, education on what do with the stratified data to inform quality improvement cycles, and more.

TRANSFORMING MIPS: MIPS VALUE PATHWAYS

In previous rulemaking, CMS finalized the implementation of a new participation pathway: the MIPS Value Pathways. CMS believes that MVPs will improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to facilitate the transition to Alternative Payment Models (APMs). MVPs aim to provide a cohesive participation experience for physicians by standardizing performance measurement around a specialty, medical condition, or public health priority and creating alignment across performance categories to decrease the siloed nature of the traditional MIPS program. In this rule, CMS proposes to incrementally implement MVPs, beginning with the CY 2023 MIPS performance year with an initial group of seven MVPs. The ACS’ comments to the MVP principles and CMS’ implementation plans are provided below.

As the QPP and other Medicare programs transition toward Value-Based Health Care (VBHC), the ACS believes it is important to define value based on what matters to the patient. Patient-centered value is about the judgment applied by a patient and their family for care that meets their goals at an affordable price. A patient’s interpretation about their care is relative to their personal values for quality, safety, access, inclusiveness, price, trustworthiness, appropriateness and so forth. Transparently reporting on how a patient values care for a specific condition would then become a useful tool for other patients who are seeking a reasonable place for their care. The ACS believes the intent of the law is more than to purchase care based on value. We believe it is to

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inform patients about the value of the care they receive, and that this will serve as a means for driving quality improvement.

While the MVP pathway aims to move the needle on more meaningful value-based care, it is only the first step, and it must not be the last. The path forward must move to more patient centric, condition-centric value assessments that cross over payment systems and link the elements of the care team together in a coordinated manner. To do this, the next step will be the transition toward modern quality improvement followed by the transition towards team-based, value-based reimbursement models with shared accountability and ultimately bundled care for conditions, or Episodes of Care (EOC). EOCs are patient-centric and aligned with value-based payment models including alignment with the hospital, ASCs, SNF care, home health and so on from preoperative to postoperative care to include the full episode. EOCs represent a move that unites the elements of FFS payment into team-based fiscal alignment. It is also possible to use EOCs inside other payment models such as large risk-bearing entities, including accountable care organizations (ACOs), which may rely on population-based payments per member per month (PMPM). **To best facilitate this first step in transition, we urge CMS to begin implementing MVPs focused on defining value based on what matters to the patient. To start, CMS should identify what information is critical for a patient when looking for a clinician who best fits their needs for their medical condition(s).**

To the ACS, it seems that CMS assesses the effectiveness of their quality payment programs based on the types of measures used, the burden of measurement, and the level of participation in a payment program. These seem to be secondary aspects of a quality program. **The ACS wonders if a patient-centric measure of effectiveness would serve our quality initiatives. One way to do this is to consider how CMS Care Compare can provide the information that patients need to identify a clinician with the information reported through MVPs.** Is CMS' Care Compare site currently useful in guiding care for patients? Is it an instrument used to incentivize care improvement or is it just the outgrowth of an incentive payment system with extracted metrics which lack utility for the end users? Perhaps a meaningful way to highlight the value of the CMS Care Compare site is to consider the journey by creating a patient persona. How would an individual patient find the information useful?

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Patient Persona on Care Compare



A patient with critical aortic stenosis (AS) who lives in NY, NY, visited the CMS Care Compare hospital site and found several hospitals with high star ratings and great patient survey reports. He wondered, what do these ratings mean for patients with AS?

The Care Compare ratings gave him a general sense of hospital quality and safety by showing how some patients that were treated for unknown conditions in an unknown sample felt about their care. But the reports did little to help him in understanding the serious decisions he needed to consider for his health and his particular condition. He went back to the Care Compare site to see what he could find under the physician section. Which specialty should he explore? Cardiology? Cardiac Surgery? He picked the cardiologist since he would like to avoid an open-heart operation. His search turned up 300 cardiologists within 10 miles of his location. The report gave no specifics related to his condition. To learn more about a cardiologist, he would have to select one and ‘click’ on a name to get more details about this physician. He randomly selected a cardiologist for review whose office seemed to be nearby to a major medical center. The site reported this cardiologist participated in Medicare. What performance information did the compare site reveal? It reported that the cardiologist met the standards for using electronic medical record technology. He felt no more educated about where to get specialty advice about his AS after visiting the Care Compare site and was very frustrated. He still had no sense of where or how to get the assistance except to keep scrolling through 300 cardiologists hoping to find more information.

He then spoke with his PCP who referred him to someone she trusted. He wondered how she came to this judgment but had no other way to assess the care except for her advice. Perhaps he would check with others to see if ‘word of mouth’ referrals agreed with his PCP?

Patient-centric Measures of Effectiveness

This patient’s experience shows us that building a quality program based on incentive payment program metrics makes it difficult to provide patients or care teams with meaningful information. Even worse—for clinicians looking to improve quality, Care Compare uses a different benchmark for public reports than they do for MIPS incentive payments, and now CMS is proposing to rely on a third and different indicator of quality measures under the proposed MVP enhanced feedback reports for confidential performance feedback reporting to clinicians. This is confusing to the provider in terms of understanding what

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goal post they should be aiming for. While it is reasonable that clinicians may rely on different metrics for quality improvement efforts than are posted for patient decision making, there should never be contradictory information such as two different performance rates for Surgical Site Infection (SSI), for example.

Another example for consideration is tracking something like avoidance of SSI for breast cancer (episode-specific) which might be useful for driving quality improvement (QI) efforts for a clinical team, but the patient might be more interested in metrics such as resumption of activities of daily living, meeting body image goals, or involvement in the decisions of their care.²⁰

MIPS cost data reported on Care Compare are another potential source of confusion. If you consider all the various cost measures being used and the different methodologies implemented, it will be a “noisy” environment. Total cost per beneficiary is too blunt an instrument and draws little actionable attention. Acumen’s methodology is a gross misrepresentation of true price and seeks to represent a narrowed view of cost by only accounting for that which is assuredly appropriate and uniquely clinician-attributable rather than what is more plausible, realistic, and patient-centric. In addition, related law now calls for hospital price transparency and advanced explanation of benefit (EOB) reporting.

The ACS believes it is essential to create consistent standards in price transparency which best reflect true patient costs. We again think it is a useful exercise to measure the effectiveness of cost measures from the perspective of the patient persona. Does the clinician under the patient’s consideration participate in care models where the entire episode of care provides the affordability that patients can understand and decide to accept or reject?

Patients want to know two major factors: where to get the best care and what care will cost them. Clinicians do not have the information to give them because MIPS quality does not align with cost and cost measures are too narrowly defined to reflect true costs to patients. **Logically for a value expression ($V=Q/\$$), measurement of the price of care and quality should align based on a single standard so that information provided to patients to make informed decisions on their care is consistent across all aspects of care.** With all the metrics for cost and quality, what source should they trust? Is any of this information meaningful or actionable?

In summary, MIPS or MVP, it does not matter which, currently fall short of the mark for informing the AS patient or helping care teams understand price,

²⁰ Sage, J., Witowski, M., Opelka, F. (2021). Expressing value in health care. *Bulletin of the American College of Surgeons*. 106(7), 24-33. <https://bulletin.facs.org/2021/07/expressing-value-in-health-care/>.



quality, safety, and overall outcome attainment for a specific condition or procedure. What other options does CMS have? What if the patient was able to find a CMS Care Compare site that was organized by condition, represented as episodes of care with measures that are meaningful to patients, and drive QI cycles for clinicians? It is important to focus on the presentation of data to the end users as well as the underlying metrics themselves. However, if we are not measuring the right metrics in the right way, it does not matter how we present the data. **As illustrated in the patient persona example, the ACS is concerned that unless MVPs are a step in the progression to patient level measures for a condition, MVPs seem to be more of the same set of MIPS metrics reorganized into categories. If we make the same mistakes with MVPs, we cannot expect a different outcome than we have seen with MIPS.**

Failed Hypothesis for Driving Quality Improvements

ASC believes CMS must rethink the quality measure framework. For nearly a decade, the quality measure enterprise has operated with the hypothesis that if we use performance metrics in payment incentive programs with adequate levels of participation, accountability in public reports and clinical feedback would be enough to establish a culture of quality improvement. However, this hypothesis has fallen short of the mark; it has not achieved what we have tried to achieve in driving high quality. We believe there are two primary reasons for this:

1. It is hard to develop reliable and valid quality metrics given the intricacy of care and due to the complex science of quality measurement. It has proven very difficult to make a measure generalizable on the national level that is also useable, feasible, and at the same time will move the needle in quality on a large scale.
2. For clinicians and patients, most of the MIPS metrics are not usable in terms of what happens in day-to-day delivery of care across the various care settings each patient faces when undergoing surgery, making the measures void of meaning and actionability. The result of this is that clinicians have essentially participated by choosing the path of least resistance that results in the lowest negative payment implications. As illustrated in the patient persona, this method has not resulted quality measures that are helpful to inform patients and hardly drive real improvements in care, except in very small specific areas.

Simply put, incentivizing payment using limited, unaligned performance measures is failing to achieve the intended goals. **Measures are not**

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meaningful unless patients find the measures to be informative and useful for their care and that care teams respond in kind by building QI into their culture; measures should be judged based on the impact they have on QI to achieve value-based care. Additionally, when it comes to quality, payment incentives are an important lever, but not the only lever. Transparency has the effect of accountability and influences other factors such as market share. Balancing all the behavior incentives such as personal professionalism, market forces, revenues and compensation rewards are all arrows in the quiver for driving quality improvement.

We Need a New Hypothesis

The ACS sees a path forward for CMS and other payors to achieve the goals of providing patients with the necessary information about where to get care that suits their clinical needs and how to establish its affordability. For more than half a century, the ACS has viewed quality in the context of programs that are evidence-based and demonstrate improvements in care, while measurements are key components of such programs. Based this work, the ACS asserts we must consider a new hypothesis for the quality measure enterprise. **To drive real improvements in care we must appreciate and incentivize all the components of a comprehensive quality program— high value process, structure, resources, data, event rate monitoring, patient reported outcomes.**

Solution: Incentivize a Comprehensive Quality Program

The College’s solution to a comprehensive quality program is based on the ACS Quality Model—it informs the patient and brings together a team to drive quality improvement with standards, as illustrated in the Four Guiding Principles of Continuous Quality Improvement:

Four Guiding Principles of Continuous Quality Improvement

1	2	3	4
STANDARDS	RIGHT INFRASTRUCTURE	RIGOROUS DATA	VERIFICATION
<ul style="list-style-type: none"> Individualized by patient Backed by research 	<ul style="list-style-type: none"> Staffing levels Specialists Equipment Checklists 	<ul style="list-style-type: none"> From medical charts Backed by research Post-discharge tracking Continuously updated 	<ul style="list-style-type: none"> External peer-review Creates public assurance



The ACS Quality Model has a history of aligning facility and providers for seamless, continuous reliable standardized care. The program includes such attributes as demonstrable commitment to surgical quality from the C-suite; appointment of a surgical quality officer and surgical quality committee; establishment of a hospital safety culture; a formal case review process; standard surgeon onboarding, credentialing, and privileging policies; data systems organized to find problems (such as complications and inefficiencies) and fix them; and so on. There is evidence in the peer reviewed literature that patients have better outcomes if they are treated in a verified center. For example, in one study, the overall risk of death was 25 percent lower when care was provided at a trauma center than when it was provided at a non-trauma center.²¹ Again, it is so much more than just holding clinicians accountable to specific quality measures.

The ACS Clinical Programs are based off the ACS Quality Model and rely on having the right structure and processes in place to achieve positive outcomes and assure safe care for surgical episodes of care. ACS Clinical Programs set the standards for clinical care and these programs are where condition- or specialty-specific (such as Bariatric, Trauma, Geriatrics) standards are added. Layering on top of clinical accreditation are appropriate and adequate processes that 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—the model used in the ACS NSQIP®—followed by outcomes reporting by the patient, or PROs. Population health measures, as a required component to MVPs, should report community-wide on how the team is doing in a domain of care—such as for cancer—looking at prevention, early detection, long term survival and so on. In other words, indicators that are domain-specific to signal to the care team how they are doing in their community. **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 thereby allowing for patients, clinicians, facilities, and payors to assess more completely the quality of care.**

Based on our experience in running quality programs, we assert that the goal for MVP should be to incentivize a comprehensive quality program that provides information that patients need to make decisions about care and the information, resources, and structures clinicians need to drive quality improvement transition toward measures that meaningfully inform true quality improvement cycles.

²¹ MacKenzie, EJ., Rivara, FP., Jurkovich, GJ., et al. (2006) A national evaluation of the effect of trauma-center care on mortality. *New England Journal of Medicine*, 354(4), 366-78.
<https://pubmed.ncbi.nlm.nih.gov/16436768/>

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MVPs should be developing a pathway to reporting information that matters to the patient seeking care based on conditions or episodes. This information should not be siloed based on individual clinicians or facilities, but instead should link clinicians and facilities to create care coordination with shared accountability:

1. **PROMs**: Did patients report good/excellent outcomes for an episode of care?

This can be represented by episode-specific patient reported outcomes, indicating whether goals of care were met.

2. **Verification or Accreditation**: Does the care team have what they need to deliver optimal care for that condition?

This can be represented by a verification program or similar quality program that ensures the care delivered has met structure and process standards within a clinical domain to measure outcomes, safety records and enter into improvement cycles.

3. **Event Rate Reporting**: Is the care safe for that condition?

This can be represented by event rates for quality and safety assurance pertinent to the episode. Reporting reoperation for breast cancer which has low readmissions rates compared to patients with open heart surgery for a valve replacement should not be used as an apples-to-apples comparison across breast surgeons and cardiac surgeons.

4. **Price Data**: What can the patient expect the overall cost to be for the episode?

The ACS applauds ongoing efforts to provide price transparency for an episode of care (EOC), but these efforts should align with episodic cost measures. It is important to establish what is meant by an episode and these definitions should be standard. Rarely does complex medical care involve a single transaction. When care is simple and limited to a transaction or two, cost is typically not a problem. More complex care involves multiple transactions over a period of time, and, to a patient, these costs can be painfully additive. By reporting on standard episodes, it is possible to avoid confusion to patients and for providers. The information becomes more actionable for everyone. In addition, price transparency is becoming part of different payment programs in commercial, federal, and by state systems. The ACS feels efforts are necessary to create consistency across all federal programs for through use of common episode structure. Other Agency efforts to provide direct contracting or price transparency are generating interests in EOCs or bundles.

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We believe that patients, as a natural extension, will want to understand the quality of care for their personal condition that aligns with the episode price. When a patient wishes to become more knowledgeable about their care, they look for episodes which appear to cover their condition and to understand the care journey as they enter into it. They look for services related to her/his condition in her/his locale. To create a website that has this information would be invaluable. For example, episodes can be categorized into large domains like cardiac, musculoskeletal, or cancer episodes. Patients would look for the cardiac episode domain and drill down to find their condition. If aortic stenosis (AS) was considered as a condition within the cardiac care domain of episodes (Clinical Affinity Groups – CAGs), a patient could appreciate institutions which reported their outcomes, volumes of patients treated with this condition, quality ratings for general cardiac episodes, and any specifics for AS if volumes were adequate and worth reporting. The patient would be able to know whether the care site met general cardiac care standards, as well as cardiac surgical care standards. Perhaps if the specific cardiac domain is not reporting highly specified standards, the delivery system may be able to reflect whether the site meets the standards for geriatric surgical care. Some institutions may be certified in both complex cardiac care and geriatric surgical care. The dates for each verification review attestation to how current the sites were in meeting the standards, within 1 to 3 years, could be available. The cardiac standards would also specify services, their quality and safety record for those services, volumes and patient reported outcomes. Price transparency would provide general overall costs for the average or typical service.

In conclusion, the ACS approach is to move to Episode of Care built on a value expression ($V=Q/S$) and placed in contractual arrangements for a team-based, risk bearing entity that relies on value-based revenue. The value-based incentive payment could be based on elements a payor would extract from the ACS quality model (verification, event rates, and PROs) and implement in scoring for their payment incentive programs. In this model, the team members in a risk-bearing entity would have shared accountability, working together to deliver care as optimally as possible. In addition, this episode approach would be consistent with the price transparency law for the episode.

MVP Transition

CMS requests comment on innovative ideas to help achieve desired MVP results of improving value, reducing burden, helping patients compare clinician performance to inform patient choice in selecting clinicians, and reducing barriers to movement into APMs. CMS notes that the Agency is interested in targeting a focused episode of care as well as MVPs that measure the patient

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journey and care experience. CMS is also interested in how MVPs could measure the value of multi-disciplinary team-based care.

As discussed above, the ACS asserts that it is critical to keep in focus that MVPs are a means to an end and not an end in itself; the MVP “pathway” is the first step toward value-based care. As CMS transitions to MVPs, the Agency must consider how the program can drive real quality improvement which will require QI to be the focus for quality. In our experience running quality programs, it has become clear that no matter how “good” someone considers quality measures, the key is using the measures to improve.

The next step in the transition will be the move toward modern quality improvement followed by the shift towards team-based value-based reimbursement models with shared accountability and ultimately bundled care for conditions, or Episodes of Care (EOC). EOCs are patient-centric, aligned with value-based payment models and include all aspects of care from preop to postop. **Quality should set up quality improvement, and quality improvement efforts should reflect new efforts to enhance quality—a virtuous cycle. MVP IAs should be a program to educate care teams to track compliance and performance in PROs, and then demonstrating a data-driven quality improvement activity. The ACS believes CMS should define a roadmap that ultimately leads to quality that informs patients, drives surgical teams to excel, and uses business incentives from the payor to reward those who achieve and are exemplar.** We understand that when applying the principles the ACS has espoused, there may be statutory constraints that require CMS to be creative in how to combine quality and IA into some aspect of shared scoring.

MVP Implementation

The College envisions the implementation of MVPs as individuals working on a portfolio of domains (trauma, cancer, complex GI, cardiac, etc.) in the clinical area they treat, tracking event-rates relevant to the episodes within their domain, episode-specific PROs, and meeting the standards of care within that clinical domain, as described. And, as part of the measures included in an MVP, it is more helpful to have measures that target the episode, not system measures (such as readmissions), to help patients understand and choose care as it relates to their condition. **We also recommend that CMS develop a prioritized list of episodes to build since it is not possible to build out every possible episode. In developing criteria, CMS must remain focused on the patient using CMS Care Compare when seeking information for their condition.** Implementation across many specialties will require more creative

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management from CMS. The goal must remain centered on the highest rewards for actions that best inform patients and drive care teams to improve.

CMS' goal should be to reach a point in their quality programs where they are trusted enough that a member of Congress could visit their Care Compare website and find what they need to inform their family members where to optimally find stroke care, cancer care, trauma services, total joint replacement, etc. Those results would establish the team member options, their overall quality relative to the patient's condition, the volume of services compared to the region, and the expected total episode price along with regional and national estimates for comparison.

MVP and Subgroup Implementation Timeline

CMS proposes to delay the implementation and availability of the proposed MVPs, until the 2023 performance period/2025 MIPS payment year. CMS also proposes voluntary reporting of MVPs to prepare stakeholders through the transition plan for MIPS before potentially retiring traditional MIPS and requiring all MIPS eligible clinicians (ECs) to participate through an MVP (or the APM Performance Pathway (APP)).

The College agrees that a delay in the implementation of the proposed MVPs is appropriate given the clear need for more strategic planning to avoid a repeat of the failures in the MIPS program. We encourage CMS to develop a transparent process to engage stakeholders to help innovate MVPs for patient-centric value and help decide what MVPs to prioritize from the patient perspective. Additional time will also be needed to consider alignment of measures across CMS programs, including MVP/MIPS measures and CMS facility measures.

Transparency is critical during this process to ensure that the MVPs are appropriate and meaningful to all members of the healthcare team for the condition or episode. CMS should establish a formal process to ensure transparency and early involvement of all relevant specialty societies in the development of MVPs. CMS should also adopt a formal criterion to ensure that MVP development is clinician-led. Furthermore, CMS should provide clear and timely feedback about why a candidate MVP submission might not have been proposed for implementation.

Lastly, a delay will give practices time to reorganize how the care teams report MVPs within their TIN. For example, institutions who have traditionally reported through the CMS Web Interface will need to consider reporting via sub-groups which will require administrative reorganization, possible changes

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to the practice's business model, as well as investment in new technology to capture the appropriate data across the care team. If MVPs are truly a move toward value-based care, practices may also change workflows for more integrated patient and formal processes for quality improvement. **To this end, the ACS supports voluntary participation in MVPs for the foreseeable future, and at least until there is a well-established inventory of MVPs for clinicians to report.**

Subgroup Composition

To align with the MVP guiding principles finalized in the CY 2021 PFS final rule, CMS proposes to establish subgroup reporting as an option for MVP Participants and those individuals and entities who choose to report the APP. Within this section, CMS proposes: (1) definition of subgroup reporting, single specialty group, multispecialty group, and special status designation; (2) subgroup eligibility requirements; and (3) application of the low-volume threshold and special status designations for subgroups.

CMS proposes to define a subgroup as “a subset of a group which contains at least one MIPS EC and is identified by a combination of the group TIN, the subgroup identifier, and each MIPS EC's NPI.” The group would be responsible for identifying their affiliated subgroups, and the subgroups would submit data on the MVPs that are relevant to the MIPS ECs within the subgroup. CMS also proposes that clinicians in the subgroup would receive their final score based on the subgroup's combined performance. CMS considered other limitations for subgroup composition but is not proposing any additional criteria at this time.

Critical to the transition toward Episodes of Care (EOC) is the incentive for care teams to organize around a patient to treat their condition with shared accountability. Therefore, it is important that CMS ensure the MVP implementation of subgroups does not unintentionally isolate specialties or discourage coordinated and team-based approaches to care across clinician types. **We seek clarity on how CMS will prevent this given how CMS plans to benchmark performance. As described in detail in the MIPS Transformation section, the ACS believes the path to team-based integrated care is organized around the patient (not the services in a payment system) by determining what matters to the patient alongside what the clinical team must track to deliver on patient goals and ensure patient safety.** This requires episode-specific patient-reported outcomes, indicating whether goals of care were met, tracking event rates pertinent to the episode to ensure patient safety, and ensuring that the team has what they need to deliver optimal care for an outcome which can be achieved through

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verification of care for the condition that ensures the care delivered has met structure and process standards within a clinical domain.

To achieve patient-centric value, individual clinicians participate in the care for a patient in the context of an episode. For example, a surgical patient may receive care from a PCP, surgeon, anesthesiologist, medical specialist, radiologist, and a pathologist. These clinicians have their distinct roles in the context of team-based care, and together share accountability for the cost and quality of that episode for that patient. **To this end, we encourage MVP subgroups to be organized similar to Clinical Affinity Groups (CAG), which are sets of clinicians who regularly participate together in episodes of a given type, medical or surgical, and thus form the normative standards of care for those episodes.** CAGs are designed to make sense to clinicians by providing specific and meaningful clinical contexts (episodes) that are needed to make inferences about quality and cost. Most, if not all, team members for any individual episode of care would be members of a particular CAG (or subgroup), though not all CAG members would be on the team for a specific episode. Individual clinicians should work on a portfolio of domains in the clinical area they treat.

MVP Requirements

MVP Development Criteria and Maintenance

Within the rule, CMS addresses multiple topics and puts forth the following proposals that focus on the development of MVPs.

Requirement of Outcomes or High Priority Measures

To align with the proposal in this rule to require MVP Participants to report one outcome measure or high priority measure (if an outcome measure is not available), CMS proposes that beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, MVPs must include at least one outcome measure that is relevant to the MVP topic so that MVP Participants are measured on outcomes that are meaningful to the care they provide. In addition, beginning with the CY 2022 MIPS performance period, each MVP that is applicable to more than one clinician specialty should include at least one outcome measure that is relevant to each clinician specialty included. CMS also proposes to allow the inclusion of outcomes-based administrative claims measures within the quality component of an MVP.

Beginning with the CY 2022 MIPS performance period when outcome measures are not available, each MVP must include at least one high priority

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measure that is relevant to the MVP topic. In addition, beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, each MVP must include at least one high priority measure that is relevant to each clinician specialty included. CMS defines high priority measures to include outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measures.

As stated throughout our comments, the ACS views quality as a program that incorporates interrelated structure, processes and key outcomes that drive quality improvement cycles. A critical element in developing a quality program that drives improvements in care is ensuring that the proper metrics are selected. These metrics should be consistent with the care processes and support the goals for care determined by the patient and their physician. **In a quality improvement cycle, the metrics used should give physicians information that they can use to directly inform improvements in care processes, and if this connection cannot be made, then the “right” metrics are not being gathered.**

While we acknowledge the importance of gathering outcomes data, without selecting the proper measures and aligning those metrics with the other elements of a quality program, the data is informational, rather than actionable. Therefore, **we ask that CMS reconsider how they are implementing MVPs, and more specifically selecting the measures they are using to evaluate physicians’ performance. The measures CMS has selected and are requiring within MVPs may allow for the administration of payment incentives for individuals, but lack the ability to inform patients, create clinical alignment, and support quality improvement cycles.**

Encouragement to Include Patient-Centered Measures

CMS is not proposing any revisions to this previously finalized criterion that considers the inclusion of (to the extent feasible) patient-reported outcome measures (PROMs), patient experience measures, and/or patient satisfaction measures. However, CMS requests comment on whether there are other aspects of patient measurement that should be considered as a part of the patient-centered measures definition.

As discussed in previous sections, value in health care must focus on what matters to the patient, with the goal for all stakeholders to deliver care based on what the patient values. Therefore, **MVP measures, including those reported on CMS Care Compare, must consider a framework and a visual representation in attempt to express a patient’s perspective on the value of**

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health care they receive relative to their goals and expectations. This must illustrate the multidimensional nature of value for patients by appreciating that patients individually value different elements of care.

A patient's value assessment relies heavily on PROMs appropriate for the condition. PROMs 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. Dimensions that are critical for inclusion in the “numerator” of a value relationship ($V=Q/\$$) will vary based on the condition—for example, the numerator for colon cancer will be different from what is needed for breast cancer, a knee replacement, mental health conditions, and so on.

PROMs indicate whether the operation or intervention was successful based on why the patient sought care and whether the treatment was able to deliver results on the goals of care. PROMs may include such factors as whether the patient was able to regain function, if the treatment relieved their pain, if they were able to return to normal activities, and so on. PROMs also can be used for digital symptom monitoring, as they have been shown to be effective at improving symptom control, quality of life, survival, and less frequent emergency department visits (demonstrated in cancer patients).^{22, 23}

Also critical for a patient-centric approach is to incentivize the use of episode-based PROMs in the CMS facility programs that are aligned with MVPs. One way to consider alignment of PROMs at the clinician and facility level is to measure whether the facility has the infrastructure to measure a specific PROM for a condition, and then the clinician can be measured based on a quality improvement plan to follow up on the responses to the same PROM.

Patient experience measures should reflect whether patients felt they were treated respectfully, whether they felt their voice was heard and personal goals understood, and if they experienced a trusting relationship with the care team

Health Equity Measures in MVPs—RFI

CMS acknowledges a lack of health equity measures, which the Agency intends to prioritize through future cycles on measure development. CMS also

²² Basch, E., Deal, AM., Dueck, AC., et al. (2017). Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. *JAMA*, 318(2), 197-198.

²³ Basch, E., Deal, AM., Kris, MG., et al. (2019). Symptom monitoring with patient-reported outcomes during routine cancer treatment: A randomized controlled trial. *Journal of Clinical Oncology*, 37(6), 528.



explains that they believe there is potential to address health equity, specifically all seven MVPs proposed in this rule, including improvement activities related to health equity. CMS solicits information on whether there should be specialty-specific health equity measures.

The ACS commends CMS for the resources it has invested in identifying ways to promote health equity. The College agrees that identifying means to improve the health care of certain populations who have been historically underserved should be a top priority of the agency and the entire US health care system. When we start to think about how to collect and analyze data to determine differences in health outcomes based on race, ethnicity, and the role of SDOH, it very quickly becomes a complex and even seemingly endless task. Currently, there is so much noise in the data that we are guessing at the cause; it is hard to know where we should focus. **Therefore, the ACS believes an extensive deep dive into addressing health equity is required in order to prioritize next steps across all CMS programs, including MIPS/MVPs.** To start, measures to improve health equity for Medicare beneficiaries should focus on how to better define the multifactorial challenges across the diverse Medicare patient population. **We strongly recommend CMS provide a strategic plan that includes a detailed and transparent goal stated for this work, a timeline, and the necessary resources and research needed to achieve the goal, including the collection of self-identified demographic information to identify health disparities more accurately across all patient groups. Part of this plan might include priority areas where there are demonstrated disparities in care, such as access to bariatric surgery.**^{24, 25}

To begin thinking strategically about health equity measures, we recommend CMS consider the following types of measures:

Measures of Inclusivity

The ACS strongly supports the development of PROs and patient experience measures to gather feedback directly from the patient without interpretation of the patient's response by a clinician or anyone else. CMS should prioritize measures that focus on patients' feeling of inclusivity. **Inclusivity measures are a much-needed area of development in health care and could encompass a patient's experience of receiving care that is sensitive to culture, beliefs, language, race, and personal circumstances along with feelings of trust, communication, autonomy, and more.** Developing and

²⁴ Gould, KM., Zeymo A., Chan, KS., et al. (2019). Bariatric surgery among vulnerable populations: The effect of the Affordable Care Act's Medicaid expansion. *Surgery*. 166(5), 820-828.

²⁵ Hoffman AB, Myneni AA, Orom H, et al. (2020). Disparity in access to bariatric surgery among African-American men. *Surgical Endoscopy*. 34(6), 2630-2637.



implementing patient-reported metrics of inclusion in the care process is also an important step in addressing systemic bias in health care delivery.

Measures of Access

Another area for consideration is measures that focus on access to surgical care. These types of measures can provide information on whether patients gained timely access to a surgeon when/if they needed surgery. This could be a set of measures that track whether the system was able to ensure a timely access and referral to surgical care. This can incentivize better care coordination between chronic and acute care to improve health equity. Timely and appropriate care can lead to overall better patient outcomes.

Measures of Patient Risk

We would also seek measures that assess the patient's preoperative risks and expected outcomes based on their overall preop care for chronic conditions which affect surgical outcomes (DM, COPD, CHF, and so forth). Acute surgical care in poorly managed chronically ill patients may lead to suboptimal outcomes and increase costs. Patients with unmanaged diabetes may present with HbA1c in excess of 8.0 for elective surgery. This poor glucose control makes a patient high risk. In a safety net system, it is not uncommon for preoperative diabetes referrals to primary care or medical specialties to be three to six months later. Delays in care may be intolerable for patients with severe acute conditions requiring urgent surgical care, such as cancer care. Similarly, there are often delays in preoperative advanced imaging when CT or MR scans cannot be scheduled for preoperative staging. The impact is that surgical planning differs compared to institutions that have ready access to all preoperative services typically required for care.

Establishing a Portfolio of MVPs

CMS proposes seven MVPs that will be available for voluntary reporting beginning with the CY 2023 reporting period/2025 payment period. The proposed MVPs focus on the following topics: Rheumatology, Stroke Care, Ischemic Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair, and Anesthesia. Transparency is critical to ensure that the MVPs are appropriate and meaningful to all members of the healthcare team for the condition or episode. For example, organized neurosurgery was not consulted during the development of the Stroke MVP despite the contributions of neurosurgeons to the treatment of stroke patients in the acute care setting. **CMS should establish a formal process to ensure transparency and early involvement of all relevant specialty societies in**

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the development of MVPs. The process may involve defining the care pathway for a patient with episodes of care that are contained within the seven clinical affinity groups defined by CMS. It may also mean understanding the roles and contributions of the appropriate clinical experts for the episodes. For example, osteoarthritis and joint replacement episodes involve PCPs, rheumatologists, orthopedic surgeons, radiologists, and physical therapy/rehabilitation medicine. Additionally, **CMS should adopt a formal criterion to ensure that MVP development is clinician-led and incorporates inputs from other appropriate stakeholders.** Lastly, CMS should provide clear and timely feedback about why a candidate MVP submission might not have been proposed for implementation.

The ACS also recommends that CMS develop a transparent process to prioritize what MVP episodes need to be built since it is not possible to build out all episodes. In developing criterion, CMS must remain focused on the patient in Care Compare seeking information for their condition to help facilitate value assessment.

Proposed MVP Reporting Requirements

Each proposed MVP includes an inventory of quality measures, improvement activities, cost measures, and population health measures that CMS believes are relevant to the MVP's specific focus area. MVP participants have less reporting requirements than clinicians reporting in traditional MIPS, which aligns with CMS' efforts to implement MVPs as a pathway to reduce reporting burden. As such, MVP participants are required to select and report on four quality measures, including one outcome measure (or a high-priority measure if an outcome measure is not available). To meet the reporting requirements for IA in a MVP, participants must report one of the following: two medium-weighted activities one high-weighted activity; or participate in a certified or recognized patient-centered medical home or comparable specialty practice.

Proposed Improvement Activity Requirements in MVPs

CMS proposes that MVP Participants who report an MVP, must report one of the following: two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice.

The ACS believes that the quality and improvement elements of an MVP should be interrelated, instead of two disconnected categories. Quality measures should be developed to support improvement efforts, but in many cases, we have lost focus of this and use measures as separate standalone

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metrics. From the ACS perspective, quality metrics are a foundational element of a quality improvement program, but the goal is to gather data through the quality measures to drive improvements in patient care. Improvement activities should simultaneously and seamlessly embody the improvement cycle that is driven by quality measures. If quality data is provided to physicians or groups but they are unable to facilitate improvements in care based on those metrics, then the measures are not effective. **Therefore, the ACS continues to advocate for cohesion between quality measurement and improvement cycles. We believe that driving true improvements in care requires the successful implementation of all elements of a quality program—including structure, process, and outcomes—that ultimately inform improvement. We have heard from many program participants who met the quality program standards and had access to high fidelity risk adjusted clinical data that they did not know what to do with the data to improve.** In response to this feedback, the ACS developed the Surgical Quality Improvement Course an introductory (basic) course on quality improvement. The course focuses on practitioners performing or overseeing improvement efforts including surgeons, trainees, and residency program directors, to name a few. The ACS basic course is broadly applicable to surgery and teaches key quality improvement concepts and the quality improvement process—including how to start a QI project, data measurement, and analysis. The course also offers tools for current state and root cause investigation and data analysis, change management for QI, measuring patient safety, and building a QI team and fostering a culture of quality improvement. In addition, the College will offer an advanced course, which focuses specifically on ACS Quality Programs, such as a Commission on Cancer course using the National Cancer Database (NCDB) data, for example.

Proposed Reporting Requirements for the Foundational Layer: Promoting Interoperability

In the CY 2021 PFS final rule, CMS stated that an MVP must include the full set of PI measures and that MVP participants are required to meet PI category reporting requirements that are consistent with what is established under traditional MIPS. In addition, CMS proposes to require that an MVP participant that is part of a subgroup would be scored based on their affiliated group's performance for the PI category. From the ACS' perspective, CMS' decision to maintain the same rules and measures for the PI portion of an MVP is an example of how MVPs are merely a reshuffling of the traditional MIPS categories. As we have stated in previous comments, we believe **the PI category should be restructured to enable interoperability beyond EHRs. To truly promote interoperability, CMS must incentivize the use of enhanced digital health IT capability.** Having functionalities for digitally

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enhanced data aggregation should be a minimum standard for health IT in the MVP program. EHR requirements should support meeting national standards that enable the bidirectional movement of health data across the digital environment. In this environment, APIs can flourish to deliver performance measures, inform patients, and to share knowledge with registries and other smart devices.

Quality improvement using digital services should focus on supporting a digital services landscape that goes beyond simply aggregating quality metrics. Instead, it should leverage digital services through open standards-based platforms that can enhance knowledge sharing around care and enable the following services:

1. Support the use of **clinical decision support** to make clinical guidelines and pathways available as a digital service through platforms that are not constrained by proprietary efforts from EHRs.
2. Support the ability to **gather cohort data for outcomes** reporting, for conformance with standards-based care.
3. Support **research and clinical trials** for expanding sample sizes in randomized clinical trials (RCTs) and observational studies.
4. Support **quality metrics payors** seek for their payment incentive programs in a patient centered manner.

Proposed Reporting Requirements for the Foundational Layer: Population Health Measure

In the CY 2021 PFS final rule, CMS discusses the inclusion of population health measures calculated from administrative claims-based data as a part of the foundational layer of MVPs. CMS proposes to codify that a population health measure is a quality measure that indicates the quality of a population's or cohort's overall health and well-being, such as access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services.

Instead of requiring physicians to report on generic population health measures, the ACS asserts that the measures should be focused on the domain of care that is most relevant to the care the physician provides. The measures should report community-wide on how the team is impacting the specific domain of care. For example, an MVP focused on trauma surgery should include a population health measure that focuses on what the group is doing to help reduce violent acts in their community, or an

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MVP for cancer care could look at prevention, early detection, long-term survival, etc.

Scoring MVP Performance

CMS proposes to score MVPs with the same scoring policies finalized in traditional MIPS. This means that MVP participants will be scored based on their performance on measures and activities in the four MIPS performance categories; the performance standards for each performance categories; calculation of achievement and improvement scores; and calculation of final scores.

Scoring Quality and IA

As discussed thematically throughout our comments, the transition toward value centered on the patient must shift focus from the individual accountability of traditional MIPS toward the team-based nature of care. To transition toward value, MVPs should be developing a pathway to reporting information that matters to the patient seeking care based on conditions or episodes. The ACS Quality Model leads this work and when translated to MVPs should consider how to weigh the various comments into an aligned Quality and IA score as described by general concepts in the remarks below:

- **Highest Weight**
PROMs: These measures are assigned the highest value since these are most aligned with the patients' goals and expectations. For their initial implementation in an MVP, these may be general PROMs applied broadly across clinical domains. As these measures mature over time in future years, we would expect the or PROMS that may be more episode-specific when available (e.g., PROMS for joint replacement). Data for PROMs can be collected through clinical data registries or other data sources.
- **Mid Weight**
Verification or Accreditation for a Condition: Patients seem to be aware when the care environment demonstrates that it is part of a well-structured clinical care programs with clearly aligned, smooth business processes. The ACS verification programs ensure the care delivered has met structure and process standards within a clinical domain and the accreditation includes that the program reviewed involves measured outcomes, safety records, and pathways to enter improvement cycles. A structural measure could be modeled after the Hospital Inpatient Quality Reporting Program (IQR) Maternal Morbidity Structural

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Measure attestation measure, in alignment with facility quality efforts.²⁶

As another alternative for scoring verification measures beyond attestation, CMS could model a measure after the Bundled Payments for Care Improvement Advanced (BPCI-A) measure, Bariatric Surgery Standards for Successful Programs.²⁷ In this example, verification could be scored based on credit for how clinical teams meet standards:

- 0 Points: The hospital does not meet the criteria as enumerated by the specific standards.
 - 1 Point: The hospital meets the criteria as enumerated by the specific standard
 - 2 Points: The hospital exceeds the criteria as enumerated by the specific standard by demonstrating (for example, but not limited to) more meetings, more quality improvement projects, etc.
 - 3 Points: The hospital is considered exemplary against the criteria as enumerated by the specific standards by demonstrating (for example, but not limited to) more meetings with a specific percentage of attendance by particular personnel, more quality improvement projects which are shared outside of the organization, etc.
- Lowest Weight
Event Rate Reporting: Event reporting is an important statement of quality and safety but tends to be less commonly applied. These should be more generally applied, but also include event rates that are specific to the episode when available.

Improvement Activity credit can be met based on the attestation of the development of a QI cycle using clinical data. These activities can be scored on a graduated scale based on their applied settings and their impact on PROMs or event rate reduction. More work is needed to define meaningful IA activities, settings, and roles played by the various actors within and across the episode. Facilities need to be engaged with activities and facilitate meetings with key staff who work with the clinical physician leads in defining the problem, the improvement activity, the data tracking, and outcomes reporting. These are elements of the verification/accreditation programs which would require periodic external review.

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²⁶ CMS Maternal Morbidity Structural Measure. Retrieved from:

<https://www.cms.gov/files/document/maternal-morbidity-structural-measure-specifications.pdf>.

²⁷ BPCI Advanced Model Year 4 Quality Measures Factsheet. *Bariatric Surgery Standards for Successful Programs Measure*. Retrieved from: <https://innovation.cms.gov/media/document/bpci-advanced-alt-fs-my4-bariatric>.



Enhanced Performance Feedback in MVPs

CMS proposes to include comparative feedback within the annual performance feedback it provides MVP participants. The additional feedback will give MVP participants information on how their performance compares to similar clinicians who report on the same MVP.

The ACS appreciates CMS' efforts to provide physicians with more specific feedback about their performance in MVPs. However, we believe that the indicators CMS uses to show a physician's "quality" are confusing and lack meaningful metrics that drive improvements in care. The various feedback CMS provides through Care Compare, the annual performance feedback reports, and this newly proposed comparison among MVPs makes it difficult for physicians to determine where they should be focusing their efforts in the program.

CMS also asks stakeholders to elaborate on what they consider "actionable" information. This question is similar to questions the ACS receives from Fellows who participate in ACS Quality Programs. Everyone always intends to do their best, but when quality metrics reveal differences, it can be difficult to find a meaningful and actionable improvement activity.

As described, we believe that actionable information provides value to both the patient and the care team. It can be used to help patients make decisions about their care, as well as inform and educate clinicians on ways to continue to improve care and deliver value to patients. **Instead of offering physicians feedback on generic quality measures, we believe that CMS needs to focus on the care model, improvement cycles, the roles of the various actors, and the services delivered during an episode of care.** When a practice takes part in a certified quality program, they can assess the practice's infrastructure; how the care team's processes align to meet standards of care within a clinical domain; and gather interrelated, accurate, clinical, risk-adjusted outcomes data and PROs to highlight areas where further improvements are needed. With this information you can compare groups within the same specialties or compare clinicians based on the services they provide to assess their failure points and drive toward actionable fixes. If publicly reported, this information can also be useful for patients as they search for physicians. Patients would be able to search for physicians within a certain clinical domain or who delivers an episode of care and learn that the care team has efficient processes that comply with standards of care, receives a high patient experience score based on PROs, and delivers safe care through outcomes reporting.

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APM PERFORMANCE PATHWAY

In the CY 2021 PFS final rule, CMS finalized the APM Performance Pathway (APP). The APP was designed to provide a predictable and consistent reporting option for MIPS ECs who participate in a MIPS APM. Similar to MVPs, the APP includes a single, predetermined measure set clinicians can report on at the individual, group, or APM entity level. Participation in the APP is optional for all MIPS APM participants, however, all Medicare Shared Savings Program ACOs were required to report to the APP beginning with the 2021 performance period.

ACS applauds CMS for sunsetting elements of MIPS that have not driven quality improvement, but as mentioned in previous sections, we do not think the pathways that CMS is proposing to replace traditional MIPS—such as MVPs and the APP—are the solution. **As implemented, the APP is not a meaningful or relevant glidepath for surgical specialists in APMs because it focuses on primary care, similar to the CMS Web Interface measures. From the surgical perspective, the goal should be a framework that supports a comprehensive approach to quality that aligns with modern surgical care delivery and drives meaningful quality improvement efforts for surgical specialists in APMs.**

MIPS PERFORMANCE CATEGORY MEASURES AND ACTIVITIES

Quality Performance Category

Data Submission Criteria

When reporting traditional MIPS, a MIPS EC, group, or virtual group must submit data on at least six measures, including at least one outcome measure. This can be achieved by reporting Qualified Clinical Data Registry (QCDR) measures, MIPS clinical quality measures (MIPS CQMs), electronic CQMs (eCQMs), or Medicare Part B claims measures. CMS also developed administrative claims measures that are automatically evaluated and calculated (in addition to the six measures) for individual MIPS ECs, groups, and virtual groups if the case minimum of the measure is met. Beginning with the 2023 MIPS performance period, under the MVP proposal, CMS would allow an outcomes-based administrative claims measure to be selected when a MIPS EC registers for an MVP to fulfill the MVP outcome measure requirement.

CMS is also considering whether or how to allow and utilize outcome-based administrative claims measures to fulfill the outcome measure requirement within traditional MIPS. CMS seeks feedback on how it could automatically calculate an outcome-based administrative claims measure and apply it as one

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of the minimum six required measures, and if this would be an advantage for stakeholders as they participate in traditional MIPS.

The ACS thanks CMS for considering how to better utilize administrative claims-based measures. The ACS has continuously advocated that CMS measures should be collected, analyzed, and aggregated within a given domain or clinical service line by a single source for consistency in data interpretation. However, this has proved to be very difficult given how the MIPS measure system has been implemented, with multiple sources reporting the same measure inconsistently. **Most of the current MIPS measures do not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation; often using multiple data sources—including self-reported data—resulting in noisy metrics that are often not trusted by the physician community. Therefore, ACS supports the utilization of administrative claims measures as the single source for aggregation on a case-by-case basis and only for measures that have demonstrated reliability with claims data and are actionable in driving quality improvement cycles.**

Importantly, if CMS is the owner or “sole source” of the data for certain measures, it will be critical that there is transparency and consistency with the data definitions, appropriate inclusion/exclusion criteria, that data analytics are understood and standardized, that there is consistency in data ascertainment methods, and CMS is transparent in how data are normalized. By applying the appropriate measure science, CMS could create more reliable and valid comparisons in MIPS if the appropriate claims-based measures are chosen, compared to many of the current MIPS measures that are noisy.

As CMS develops these measures, the Agency should seek expert advice on the appropriate measures to report as part of an episode. Many outcome measures will require administrative claims data to be supplemented with clinical data for statistically valid results. The Agency should also seek expert advice to ensure that the data are meaningful and actionable for surgical practice and patients. For example, a measure that tracks readmission rates following a surgical procedure must include the proper exclusion/inclusion criteria. If a patient is admitted to the hospital for a motor vehicle accident unrelated to the patients’ previous surgical procedure, this should not be included in the measure’s numerator.

Group and Virtual Groups Reporting via the CMS Web Interface

In the CY 2021 Physician Fee Schedule Final Rule, CMS finalized the removal of the CMS Web Interface as an available collection and submission type

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under MIPS beginning with the CY 2022 MIPS performance period. In response to stakeholder comments and concerns about the difficulty of making this transition in light of the COVID-19 PHE, CMS proposed to extend the availability of the CMS Web Interface as a collection and submission type for the 2022 MIPS performance period and sunset the reporting mechanism beginning with the 2023 performance period. **In the past, ACS has raised concerns about how the measures required for groups reporting through the Web Interface could not effectively measure quality improvement in surgical care. However, we appreciate that CMS has listened to stakeholder concerns and is giving groups additional time to make the necessary updates to their reporting processes.**

Selection of MIPS Quality Measures

Each year CMS updates the quality measure set in the MIPS program by adding new measures, removing measures, and modifying the specifications of other measures. For 2022 MIPS performance period, CMS proposes a measure set of 195 MIPS quality measures. Below are comments to the General Surgery Specialty Measure Set:

General Surgery Specialty Measure Set

Beginning with the CY 2022 performance year, CMS proposes to remove two measures, *Selection of Prophylactic Antibiotic—first- OR second-generation cephalosporin* and *Perioperative care: VTE Prophylaxis*, from the general surgery specialty measure set. **As ACS has stated in previous sections, measuring stand-alone metrics have not been effective in achieving the goal of informing quality improvement cycles and driving real improvements in care. Therefore, we support a transition toward measures that do move toward that goal.** However, we caution CMS that removing some measures will make it more difficult for some groups—including surgical specialties—to succeed in the program. Given this, we recommend maintaining these measures until CMS has a clear plan for how they will replace them to give surgeons who are still required to report via traditional MIPS enough reporting options to avoid a MIPS-related penalty.

Cost Performance Category

Addition of Episode-based Measures

CMS proposes the addition of five new episode-based measures to the Cost performance category beginning with the 2022 performance period. The five proposed episode-based measures include:

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- Melanoma Resection;
- Colon and Rectal Resection;
- Sepsis;
- Asthma/Chronic Obstructive Pulmonary Disease (COPD); and
- Diabetes.

In prior comments to CMS, ACS has advocated for the need to measure cost and quality over the same episode of care 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 allows for comparisons with others who may be more efficient.

The ACS nominated three surgeons who took part in the colon and rectal resection measure development subcommittee. Based on ACS Fellows' experience during Wave 3 of measure development, the Acumen process for developing these measures is not structured to form measures that truly measure cost or offer actionable results. During the development process, subcommittees are required to follow a single, basic framework, regardless of condition or patient population. **We do not believe that physician cost, quality, and overall value can be evaluated using a one-size-fits-all approach. Procedures and patient populations are vastly different and cannot always be evaluated for appropriateness in the same manner.**

Another ongoing problem with the Acumen cost measure development process is that it relies exclusively on claims data. The limitations of administrative data interfere with risk stratification, subgrouping, and defining accurate and appropriate inclusion and exclusion criteria. Many have also had concerns about applying the CMS-Hierarchical Condition Categories (HCCs) risk adjustment methodology to these episode-based cost measures. The CMS-HCCs were not designed to risk-adjust narrowly defined patient cohorts, such as episode groups.

In addition, this approach to developing cost measures fails to account for the impact that cost reduction may have on patient outcomes or other measures of quality. It is virtually impossible for clinicians to evaluate, provide meaningful feedback on, and find significance in cost performance data when it is presented with no consideration of quality. While we acknowledge that CMS is working towards aligning cost measures with relevant quality measures through MVPs, the measures' set forth by CMS do not offer actionable information that can be used to incentivize reduction of costs.

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Finally, the current process lacks transparency. Until recently, CMS did not publicly release performance benchmarks for this performance category. Historically, this information has only been available through confidential feedback reports. Without current information, it is difficult for physicians to gauge how they might be scored in this performance category.

Proposed Process for Cost Measure Development by Stakeholders

CMS proposes to establish a process, beginning in CY 2022, for the development of cost measures by stakeholders, outside of the current development process. The process is intended to ensure that the cost performance category has consistency across measures, aligns with CMS priorities, and is consistent with the Meaningful Measures Framework.

The Measure Prioritization Criteria include:

- *Clinical coherence of measure concept (to ensure valid comparisons across clinicians).*
- *Impact and importance to MIPS (including cost coverage, clinician coverage, and patient coverage).*
- *Opportunity for performance improvement.*
- *Alignment with quality measures and improvement activities to ensure meaningful assessments of value.*

To ensure that cost measures developed by stakeholders meet the same standards as cost measures currently used in MIPS, CMS proposes to apply the following standards when considering stakeholder developed measures:

- *Measures must assign services that accurately capture the role of attributed clinicians.*
- *Measures must have clear, ex ante attribution to clinicians.*
- *Measures must be based on episode definitions that have clinical face validity and are consistent with practice standards.*
- *Measures' construction methodology must be readily understandable to clinicians.*
- *Measures must hold clinicians accountable for only the costs they can reasonably influence.*
- *Measures must convey clear information on how clinicians can alter their practice to improve measured performance.*
- *Measures must demonstrate variation to help distinguish quality of care across individual clinicians.*

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- *Measure specifications must allow for consistent calculation and reproducibility using Medicare claims data.*

The ACS welcomes the opportunity to develop and submit new cost measures for MVPs. However, as proposed in the *Standards for Measure Construction and the Measure Prioritization Criteria*, the opportunities to develop new measures will be constrained to largely mirror the structure and scope of the existing, ineffective episode-based cost measures. This will likely lead to measures very similar in nature to episode-based cost measures currently developed for the MIPS program. This may be intentional, but the lack of flexibility in approach to the measurement of the price paid for care will preclude innovative approaches which could be beneficial not only to MVPs but also in price transparency efforts and in alternative payment models. The existing MIPS cost measures are very narrowly defined, limiting their value for incentivizing reduction in cost within MIPS and for other purposes outside of the MIPS program.

Logically, and for the sake of efficiency, measurement of the price of care should align with existing and developing price transparency regulations so that information provided to patients to make informed decisions on their care is equivalent to feedback received by physicians for improvement purposes. Specifically, episode-based cost measures and information required by price transparency regulations should use common episode definitions. The alternative is a state of confusion for both physicians seeking to reduce cost and for patients seeking cost-efficient care.

As an example, consider a surgeon who, based upon the MIPS cost measure for colon and rectal resection, has an average cost performance score in MIPS. However, under the price transparency requirements, their costs appear 20 percent greater than the regional average because a broader array of items and services are considered. This inconsistency will lead to mistrust of information and unclear targets to reduce cost. Furthermore, this example can be expanded beyond the Medicare program where the same procedure performed by the same surgeon might not be in network for the prevailing insurer at the hospital where it is performed; meaning the costs would appear even higher in a good faith estimate for a typical patient under the requirements being proposed for the No Surprises Act.

If we intend to identify and reduce the cost of unnecessary, duplicative, or unwarranted aspects of care and to inform patients about the overall cost of care through price transparency, we should seek solutions that complement each other. There is no connection between the way we measure price for payment incentive purposes and the way we are proposing to measure

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it for transparency purposes. This is a missed opportunity that requires greater flexibility to allow for more comprehensive episode definitions that look at care from the perspective of the patient, rather than simply at charges under the direct control of a single physician. Measures that recognize the team-based nature of care with shared accountability are more appropriate if we expect to optimize the total care expenditure. CMS MIPS cost measures seek to constrain charges to what is substantially in the direct influence of a physician. The judgment applied to determine what is in the control of a specific physician is statistically ‘noisy’ at best because care delivery is typically team-based in modern healthcare.

Team-based episodes would be necessarily broader, with accountability shared among all of those who have influence over the care of the patient, the ultimate outcome, and cost of their care. If such a standard were adopted by the Medicare program, it would likely also be adopted in the private sector, allowing for more meaningful comparisons regardless of payor. For example, ACS is currently using price information derived from such episodes in our ACS THRIVE efforts (<https://www.facs.org/quality-programs/acs-thrive>).

Using a standard episode definition to measure the price paid by Medicare patients and beneficiaries for transparency purposes and then using the same standard for payment purposes—such as in the cost category of MIPS or in alternative payment models—would provide valuable, actionable information to physicians, payors, and patients alike. The ACS price transparency efforts define an episode of care, such as colectomy for colon cancer. The price covers the services that are considered appropriate based on inputs from the teams of clinicians who treat such patients. In addition to the appropriate services, the episode definition database also includes all plausible services that may be associated with this episode. The plausible services are where the warranted versus unwarranted services reside. ACS also further defines the services assigned to an episode into pre-facility, in-facility, and post-facility price mappings. These reports allow for regional comparisons based on volume of services and mean or median overall price. In addition, the clinical teams can assess their pre-facility, in-facility, and post-facility differences to better understand the opportunity for reducing wasteful expenditures.

The approach taken by the ACS is used for other commercial activities. It is more reliable because it is clinically derived and attributes the best faith estimate of real or true costs to the episode of care. This approach is highly consistent with the Congressional intent behind price transparency and no surprise billing.

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Improvement Activities Performance Category

The IA performance category is included in MIPS with the intent of measuring provider engagement in activities that improve clinical practice. This performance category is reported via attestation and is worth 15 percent of the MIPS EC's final score.

The ACS believes that CMS has missed the mark in measuring clinicians' commitment to activities that drive real improvements in care. The IA category is undervalued and underappreciated in the current program because the category is designed for the sake of payment rather than the implementation of processes that use quality data to drive improvement. From the ACS perspective, quality metrics are a foundational element of a quality improvement program, but the overarching goal is to gather actionable data through the quality measures to drive improvements in patient care. **To this end, the ACS advocates for a program that allows for more cohesion between quality measurement and improvement cycles. The Improvement Activities category should simultaneously and seamlessly embody the improvement cycle that is driven by quality measures; if quality data is provided to physicians or groups but they are unable to facilitate improvements in care based on those metrics, then the measures are not effective.** The ACS acknowledges that CMS may be restricted by how the MACRA law defines the IA category, but we believe that to fully achieve the intent of the law, driving improvements in care requires the successful implementation of all elements of a quality program including structure, process, and outcomes that ultimately inform improvement.

To support ACS Quality Program participants, the ACS recently developed the Surgical Quality Improvement Course. The development of this course was in response to quality program participants who met the program standards and had access to high fidelity, risk-adjusted clinical data but they did not know what actions to take to improve. The surgical QI course aims to provide a quality improvement educational course for practitioners performing or overseeing improvement efforts including surgeons, trainees, and residency program directors to name a few. This course is part of the all-encompassing quality program. The ACS currently offers a basic course, which is broadly applicable to surgery, that teaches the key quality improvement concepts, the quality improvement process—including how to start a QI project, data measurement and analysis, including tools for current state and root cause investigation and data analysis, change management for QI, measuring patient safety, building a QI team, and fostering a culture of quality improvement. The College is also currently developing advanced courses which focus specifically

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on ACS Quality Programs, such as a Commission on Cancer course using National Cancer Database (NCDB) data, for example.

Improvement Activities Inventory

CMS proposes to modify five existing improvement activities to shift the focus toward health equity, as well as propose a new improvement activity titled “Create and Implement an Anti-racism Plan,” which focuses on systemic racism as a root cause for differences in health outcomes between socially defined racial groups. CMS explains that the plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps, which may also include development of an organization’s plan to prevent and address racism and/or improve language access etc.

The ACS is committed to dismantling systemic racism in surgical care. We think the first step in addressing systemic racism might be to understand local economic and racial disparities and create a strategic plan to address health equity. One example of strategic work being done on the systems level is the Health Anchor Network (HAN), a noteworthy initiative which addresses economic and racial inequities through the influence health systems can have on a community. This work includes large and strategic investments in the hospital’s local community, using a health system’s economic power to inclusively and sustainably benefit the local community they serve—including hiring, purchasing, and investing locally. The HAN aims to “define the healthcare leadership standard and promote industry collaboration for proactively addressing economic and racial inequities in community conditions that create poor health.” Many large healthcare systems including Kaiser, Rush, and Henry Ford, to name a few, are leading these efforts.

In response to the specific IA proposal, we are concerned that the implementation of a system-wide plan which calls for the development of a value statement, review of policies, improved language access and so on has a greater chance of success if done by department heads or the facility administration—not a single clinician or group. This is an example of how MIPS and MVPs fail to recognize the critical importance of how modern surgical care is delivered, including the critical role the facility plays. How would the Agency envision this IA being implemented by individual clinicians such as surgeons? Instead, the facility should provide the appropriate resources, infrastructure, and educational opportunities needed to create and

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implement any type of organizational plan. This could be part of the hospital incentive programs where the hospital attests to having and implementing an organizational plan and the individual clinician or group reports participating in the plan.

Promoting Interoperability Performance Category

The Promoting Interoperability (PI) performance category is one of the four required MIPS performance categories that is used to determine a MIPS final score for MIPS ECs. CMS has described the PI category as a way to promote patient engagement and electronic exchange of information using CEHRT. As the ACS has stated in the past, we urge CMS to look beyond EHRs as they continue to score physicians under this category. Technology is advancing into healthcare at a rapid pace. There is 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 of digital services that will decrease burden, and help clinicians deliver improved patient care.

Instead of measuring the functionality of EHRs, CMS could consider how to measure the key aspects of shared knowledge. Measures could be built around the major elements of clinical informatics, which are defined by the American Medical Informatics Association (AMIA)

The ACS also 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.

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

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CMS proposes to maintain the Electronic Prescribing Objective's Query of PDMP measure as an optional measure under the Electronic Prescribing objective. CMS also proposes to continue offering 10 bonus points for this measure for the CY 2022 performance period/2024 MIPS payment year to incentivize clinicians to perform queries of PDMPs. The Agency cites stakeholder 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 the PDMP, CMS states that it does not feel that this measure should be required.

As stated in our past comments, the ACS agrees that this measure should not be required. Without the ability to seamlessly exchange data between EHRs and PDMPs, it is challenging to electronically report due to the additional documentation and verification with an external system. This 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.

CMS also seeks feedback on whether this measure should be a required measure under the PI performance category in the future. Currently, there is wide variation in the sophistication of functionalities for each state's PDMP. Each state also has their own standards for their PDMP which has resulted in limited data sharing across state lines. **The ACS does not support that this measure be required until CMS can ensure that there is widespread uniformity in PDMPs across the country.**

Proposed Changes to the Provide Patients Electronic Access to their Health Information Measure Under the Provider Patient Exchange Objective

The *Provide Patients Electronic Access to their Health Information* measure under the Provider Patient Exchange Objective requires that for at least one unique patient seen by the MIPS EC:

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1. The patient is provided timely access to view online, download, and transmit his or her health information; and
2. The MIPS EC ensures the patient's health information is available for the patient to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS EC's CEHRT.

CMS proposes to revise this measure to require MIPS ECs to ensure that the patient's health information is available to the patient to access indefinitely using the application of their choice. The current measure does not specify how long clinicians are required to make patient data available or ensure that the patient data remains available to the patient should the clinician switch EHR vendors. The proposed requirement would begin with the 2022 performance period and include all patient health information from encounters on or after January 1, 2016.

The ACS is generally supportive of giving patients more access to and control of their electronic health information. However, **we ask that CMS provide more clarity on how they plan to define the "indefinite" period in which a provider would be required to make patient health information available.** Currently, practices must comply with the time periods for record retention as described in federal and state law. In this proposal, it is unclear how long a practice would have to continue storing patient records after their practice closes or the patient transfers to a different physician, for example. If a practice is required to maintain electronic records indefinitely, they would still have to maintain costly data storage space even after the practice's doors have closed. **Given this, the ACS recommends that CMS should not finalize this proposal, and should provide further clarity before imposing these requirements. If CMS chooses to go forward with implementing this measure, we suggest that CMS delay the inclusion of this measure until clinicians are required to begin utilizing EHRs certified to the 2015 Edition Cures Update to report in the PI category.** We believe that the functionalities required by the updated version of CEHRT will further enhance practices' ability to seamlessly transfer EHI between different systems.

Modifications to the Public Health and Clinical Data Exchange Objective

Currently, a MIPS EC must submit a yes/no response for two different public health agencies or clinical data registries for any of the five measures associated with the Public Health and Clinical Data Exchange objective to earn 10 points for the objective. Beginning with the CY 2022 performance period, CMS proposes to require two of the measures associated with this objective:

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- Immunization Registry Reporting; and
- Electronic Case Reporting.

CMS believes these two measures would allow public health agencies to be better prepared for future health threats and a long-term COVID-19 pandemic recovery through vaccine update and case surveillance.

In addition, CMS proposes that beginning with the CY 2022 performance period, a MIPS EC would receive 10 points for reporting a “yes” response for each of the two required measures. CMS also proposes to retain the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures as optional measures and available for bonus points. A MIPS EC may earn five bonus points if they report a “yes” response for any one of these three bonus measures.

The ACS supports CMS’ efforts to help public health organizations better prepare future public health emergencies and the long-term effects of the COVID-19 pandemic through the *Immunization Registry Reporting* and *Electronic Case Reporting* measures. We also thank CMS for maintaining the Clinical Data Registry Reporting measure within this objective and offering bonus points for those who report to clinical data registries. Many clinical data registries have implemented mechanisms to gather data about the impact of COVID-19 and will be good sources of information when determining how different clinical specialties were ultimately impacted by the COVID-19 pandemic.

SAFER Guides

The Safety Assurance Factors for EHR Resilience Guides (SAFER) guides were developed by ONC in 2014 and updated in 2016. The guides assist hospitals in conducting self-assessments to optimize the safety and safe use of EHRs in three main areas: foundational guides, infrastructure guides, and clinical process guides. CMS proposes to add a new measure to the Protect Patient Health Information objective, beginning with the CY 2022 performance period. The new measure would require MIPS ECs to attest to having completed an annual self-assessment using the High Priority Practices Guide at any point during the calendar year with a yes/no attestation statement. In CY 2022, this measure would be required, but it would not be scored, and that reporting “yes” or “no” will not affect the total score for the Promoting Interoperability performance category.

The ACS feels that the SAFER guides are comprehensive, but in some cases several of the assessments contain information that should be the responsibility of the vendor to meet and complete, rather than the

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hospital; specifically, the items in the High Priority Practices Checklist. Then, instead of requiring individual clinicians to complete these assessments, the ACS recommends that CMS should require the health IT vendor complete the assessment when they complete the implementation of the health IT. This should be done on a regular basis to ensure the systems continue to meet the safety requirements of these guidelines as the health IT software undergoes regular system updates. In addition, the ACS suggests that CMS and ONC consider reviewing and updating the SAFER guides as they have not been updated since 2016. The digital health landscape is constantly transforming, and these guides should be updated to ensure that they include possible patient safety threats that could stem from increased interoperability and new technologies.

Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT

Beginning with the CY 2022 performance period, CMS proposes to no longer require attestation statements B and C of the existing Information Blocking attestations. CMS believes that the below statements can be removed in light of the information blocking regulations finalized in the ONC 21st Century Cures Act final rule.

- Statement B: Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers, including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.
- Statement C: Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers and other persons, regardless of the requestor's affiliation or technology vendor.

While the ACS agrees that it is acceptable to remove these attestations in light of the recently implemented 21st Century Cures Act final rule information blocking regulations, we want to highlight the importance of the information blocking issue. The ACS remains concerned that without

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the proper oversight, challenges with information blocking will persist. As the health care system continues to implement pathways for standards-based bidirectional exchange of EHI, health IT vendors have created proprietary platforms that place a major financial burden on physicians, clinical data registries, and those developing digital health platforms, such as specialty societies. For example, if a specialty society develops a digital health platform that supports clinical data registries and quality programs, they would be required to enter expensive financial agreements with EHRs' proprietary platforms to access EHI and integrate those data into their systems. Placing monopolistic barriers on “read” and “write” capabilities should be considered data blocking as such barriers will restrict the interoperability needs for advance knowledge management. **We request that CMS respond with details on what the Agency is doing, along with ONC, to address this issue.**

Reweighting the PI Category for MIPS eligible clinicians in small practices

In past years, MIPS ECs in small practices (a TIN consisting of 15 or fewer ECs) could qualify for reweighting of the PI category through an application-based significant hardship exception. Beginning with the CY 2022 performance period, CMS proposes to no longer require an application for clinicians and practices seeking to qualify for a small practice hardship exception and reweighting. Instead, in the event that no data is submitted for any of the measures for the PI category by or on behalf of a MIPS EC in a small practice, CMS would assign a weight of 0% to the PI category and redistribute its weight to another performance category. **The ACS supports this proposal. Automatically reweighting the PI performance category for small practices will reduce unnecessary administrative requirements and support small practices as they work to meet the performance threshold and avoid a negative payment adjustment.**

Performance Category Scores

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

CMS proposes multiple updates to the quality measure scoring policies beginning with the CY 2022 performance year. In past years, quality measures that have benchmarks, meet the case minimum requirements, and meet the data completeness requirements were given a 3-point floor. CMS also gave physicians three quality measure points if they reported quality measures that do not have a benchmark or do not meet the case minimum requirement. CMS proposes to remove these scoring floors for both types of quality measure beginning with the CY 2022 performance period. This means that for measures

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with benchmarks that meet the case minimum and data completeness requirements, physicians will receive 1 to 10 points towards their quality category score. In addition, should these policies be finalized, physicians who report measures that do not have benchmarks or meet the case minimum would receive zero points towards their quality category score, unless they are part of a small practice, who will still receive three points for these measures.

In the proposed rule, CMS also states that they do not want to discourage physicians from reporting new measures, so they are proposing a 5-point floor for quality measures that are new to the program for all collection types for their first two years in the program. How CMS proposes to score these measures is included below:

- New measures that can be reliably scored against a benchmark because they meet the data completeness requirement, can have a performance period benchmark calculated, and meet case minimum requirements will be scored from 5 to 10 measure achievement points.
- New measures that cannot be reliably scored against a benchmark because they lack a benchmark or do not meet case minimum but meet the data completeness requirement will receive a score of five.
- New measures that cannot be scored because they do not meet the data completeness requirement will receive a score of zero for clinicians other than small practices, while small practices will continue to receive three points.

In general, the ACS is supportive of efforts to incentivize the use of new quality measures in MIPS. We believe this will allow for greater utilization of innovative measures that show evidence of driving improvements in care. We also ask CMS to consider how they will evaluate the measures that have been in the program for multiple years and have not had a benchmark. While some of these measures may not be the “right” measures for a quality improvement program and should not be incentivized or maintained, there may be measures that might provide valuable information, but have gone unreported because of low scoring potential. Keeping this in mind, we ask that CMS, with stakeholder input, also incentivize reporting for existing measures if their outputs are proven to drive improvement.

Calculating the Final Score

Complex Patient Bonus

The complex patient bonus was introduced in the CY 2018 QPP final rule. Initially the complex patient bonus would add up to five bonus points to a

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MIPS EC's final score, and the bonus is determined through a calculation that accounts for medical risk through the HCC risk score, and social risk by measuring the proportion of patients that are dually eligible for Medicare and Medicaid. CMS has stated that they intended for the complex patient bonus to be a short-term strategy to address the impact that patient complexity might have on MIPS scoring while they worked with stakeholders to establish a methodology that better captures patient risk factors. For the CY 2022 performance period, CMS proposes to revise the complex patient bonus formula so the complex patient bonus better targets clinicians who treat a higher caseload of complex and high-risk patients. CMS makes five separate proposals to revise the complex patient bonus beginning in CY 2022, these proposals are as follows:

- The complex patient bonus will be added to the final score for the MIPS payment year provided that the MIPS participant(s) submits data for at least one MIPS performance category during the applicable performance period.
- The complex patient bonus is limited to MIPS ECs, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median.
- For MIPS ECs, groups, and subgroups, the complex patient bonus components—medical complexity and social complexity—are calculated for the specific risk indicators. The components are then added together for one overall complex patient bonus. CMS will also use a standardized score for each risk indicator to determine how far the risk score is from the mean.
- For APM entities and virtual groups, the complex patient bonus components—medical complexity and social complexity—are calculated for the specific risk indicators. The components are then added together for one overall complex patient bonus. CMS will also use a standardized score for each risk indicator to determine how far the risk score is from the mean.
- The complex patient bonus cannot exceed 10.0 and cannot be below 0.0

The ACS supports the goal of improving care of complex patients and appreciates CMS' efforts to acknowledge physicians who care for more complex patients. Over time these patients will likely require more resources from the system, and it is important to appropriately align incentives so that teams who demonstrate improved care of complex patients are rewarded. This is critical to improve access to care for complex patients.

While we consider the MIPS complex patient bonus more closely targeting physicians who care for the most complex patients a worthy effort, we have

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two major concerns with both the clinical risk and social risk indicators. Using the HCC on CMS administrative claims data alone is insufficient. Clinical data is much more reliable for determining comorbidities and should be used alongside administrative claims data. Additionally, using dual-eligibility as the sole indicator of social risk does not capture the full scope of patients who might have risk factors that contribute to the complexity of care they need, possibly reducing access for those who do not fit that definition. Only approximately 20 percent of the Medicare population falls within the dual-eligible designation, but we can assume that there are many more patients that have significant condition-specific or social risk factors that contribute to their need for more complex care even though they do not meet the dual-eligible definition. Again, by using the dual-eligible designation as the only social indicator, we are concerned access to care may be impacted for those who do not fit that definition. **Identifying patients who will require complex care is a complicated task in itself, as we have outlined in our responses to the “Closing the Health Equity Gap” RFI, therefore the ACS asks that CMS continue to work with stakeholders to design a more inclusive and accurate method to provide rewards to clinicians who treat complex patients. We also ask CMS to consider more reliable ways to further reward teams who can demonstrate improvements in care while also serving complex patients, beyond the simple tool of bonus points.**

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

Sincerely,

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