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June 28, 2021

Chiquita Brooks-LaSure, MPP

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1752-P

P.O. Box 8013

Baltimore, MD 21244-1850

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program (CMS-1752-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) fiscal year (FY) 2022 Hospital Inpatient Prospective Payment Systems proposed rule published in the *Federal Register* on May 10, 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 surgical care is furnished in the inpatient hospital setting, the College has a vested interest in CMS' Inpatient Prospective Payment System (IPPS) and related hospital quality improvement efforts. 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 IPPS. Our comments below are presented in the order in which they appear in the rule.



PROPOSED CHANGES TO MEDICARE SEVERITY DIAGNOSIS-RELATED GROUP (MS-DRG) CLASSIFICATIONS AND RELATIVE WEIGHTS

Operating Room (O.R.) and Non-O.R. Issues

In this proposed rule, CMS addresses requests submitted by stakeholders regarding changing the designation of specific ICD-10-PCS codes from non-O.R. to O.R. procedures or changing the designation from O.R. procedures to non-O.R. procedures. For each procedure code, the Agency considers whether the procedure would typically require the resources of an operating room; whether it is an extensive or a non-extensive procedure; and to which (if any) MS-DRGs the procedure should be assigned.

ICD-10-PCS Code	Code Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia, open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia, open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia, open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia, open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia, open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia, open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia, open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and fascia, open approach
0J9D0ZZ	Drainage of right upper arm subcutaneous tissue and fascia, open approach
0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and fascia, open approach
0J9J0ZZ	Drainage of right hand subcutaneous tissue and fascia, open approach
0J9K0ZZ	Drainage of left hand subcutaneous tissue and fascia, open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and fascia, open approach

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0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and fascia, open approach
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and fascia, open approach
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and fascia, open approach
0J9Q0ZZ	Drainage of right foot subcutaneous tissue and fascia, open approach
0J9R0ZZ	Drainage of left foot subcutaneous tissue and fascia, open approach

O.R. Procedures to Non-O.R. Procedures

- Open Drainage of Subcutaneous Tissue and Fascia. CMS received a request to designate ICD-10-PCS code 0J9N0ZZ (*Drainage of right lower leg subcutaneous tissue and fascia, open approach*)—which is currently designated as an O.R. procedure—as a non-O.R. procedure. The requestor noted that this procedure consumes resources comparable to related ICD-10-PCS code 0J9N00Z (*Drainage of right lower leg subcutaneous tissue and fascia with drainage device, open approach*) that describes the open drainage of right lower leg subcutaneous tissue and fascia with a drainage device, which is currently designated as a non-O.R. procedure. The requestor stated that these comparable procedures should be recognized similarly for purposes of MS-DRG assignment.

During its review of this issue, CMS identified 21 additional ICD-10-PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia that are clinically similar to ICD-10-PCS code 0J9N0ZZ and are also designated as O.R. procedures. The applicable 22 codes (including 0J9N0ZZ) are listed in the table below.

CMS agreed with the requestor that procedures that describe the open drainage of subcutaneous tissue and fascia consume resources comparable to the related ICD-10-PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia with a drainage device that are currently designated as non-O.R. procedures. The Agency stated that these procedures do not typically require the resources of an O.R. and are not surgical in nature, and therefore proposes to remove ICD-10-PCS code 0J9N0ZZ and the 21 similar procedure codes identified during CMS' review from the FY 2022 ICD-10 MS-DRGs Version 39 Definitions Manual Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index) as O.R. procedures. Under this proposal, these procedures would no longer impact MS-DRG assignment.

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In the FY 2018 IPPS proposed rule, these same 22 ICD-10-PCS codes for open drainage, along with three additional and similar codes, were identified by a commenter as not requiring the resources of an O.R.¹ The list included procedure codes for drainage with or without placement of a drainage device. The Agency stated its agreement in the proposed rule to designate the 25 procedures as non-O.R.

Another commenter opposed changing the designation for 22 of the 25 codes from O.R. to non-O.R. This commenter agreed with the proposal to change the designation for 3 of the 25 procedure codes because such codes specifically described the objective of placing a drainage device. The commenter indicated that the other procedures described by the remaining 22 codes were performed on deeper subcutaneous tissue and fascia, more invasive, and most often performed in the O.R. setting under general anesthesia. The commenter also noted that the 22 procedure codes that did not include a drainage device were assigned when the primary objective of the procedure was to incise through the skin into the subcutaneous tissue and fascia in order to drain and clean out an abscess or hematoma (i.e., fluid collection). Furthermore, the commenter noted that CMS disagreed with a separate recommendation in the FY 2018 IPPS proposed rule to reclassify open extraction of subcutaneous tissue and fascia as non-O.R. procedures, and for the same reasons, the commenter believed that open drainage of subcutaneous tissue and fascia should not be changed from an O.R. procedure to a non-O.R. procedure. In response to the issues raised by this commenter, CMS agreed in the FY 2018 IPPS final rule that it is appropriate to maintain the designation of the 22 procedure codes as O.R. procedures.²

The ACS disagrees that 0J9N0ZZ and the other 21 ICD-10-PCS procedures do not typically require the resources of an O.R. and can be safely performed in non-O.R. settings. We do not believe that the rationale to maintain these 22 codes as O.R. procedures that was presented to CMS in 2017 has changed. The intent of these procedures—which are more complex and resource intensive than the ICD-10-PCS codes describing open drainage with a drainage device (e.g., code 0J9N00Z)—is not to place a drainage device, but instead to incise and drain not only

1 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates [Proposed Rule], 86 F.R. 25070 (2017).

2 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates [Final Rule], 82 F.R. 37990 (2017).

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subcutaneous tissue, but also the fascia in order to reach the infection in the subfascial space. There is no safe way to effectively drain an infection involving the subfascial plane without the resources of an O.R. **Therefore, we do not support CMS’ proposal to redesignate the above 22 ICD-10-PCS codes as non-O.R. procedures for FY 2022 and request that these codes retain an O.R. designation.**

Non-O.R. Procedures to O.R. Procedures

- Percutaneous Revision of Intraluminal Devices. CMS received a request to designate five ICD-10-PCS codes describing the percutaneous revision of intraluminal vascular devices as O.R. procedures. The applicable codes—which are currently designated as non-O.R. procedures—are listed in the table below.

ICD-10-PCS Code	Code Description
02WY3DZ	Revision of intraluminal device in the great vessel, percutaneous approach
03WY3DZ	Revision of intraluminal device in upper artery, percutaneous approach
04WY3DZ	Revision of intraluminal device in lower artery, percutaneous approach
05WY3DZ	Revision of intraluminal device in upper vein, percutaneous approach
06WY3DZ	Revision of intraluminal device in lower vein, percutaneous approach

The requestor stated that the procedure codes that describe the percutaneous revision of intraluminal vascular devices within arteries, veins, and great vessels should be designated as O.R. procedures to compensate for the resources needed to perform these procedures. The requestor also stated procedures to reattach, realign, or otherwise revise intraluminal devices percutaneously require anesthesia, specialized equipment for intravascular visualization, significant skill, and time, therefore, it is important for these codes to be designated with O.R. procedure status.

CMS agreed with the requestor that these five ICD-10-PCS procedure codes typically require the resources of an O.R. The Agency therefore proposes to add code 02WY3DZ as an O.R. procedure assigned to MS-DRGs 270, 271, and 272 (*Other Major Cardiovascular Procedures, with MCC, with CC, and without CC/MCC, respectively*) in MDC 05 (*Diseases and Disorders of the Circulatory System*). CMS also proposes to add codes 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ as O.R. procedures

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assigned to MS-DRGs 252, 253, and 254 (*Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively*) in MDC 05 (*Diseases and Disorders of the Circulatory System*). **The ACS supports CMS’ proposal to designate ICD-10-PCS codes 02WY3DZ, 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ as O.R. procedures with the applicable MS-DRG reassignments as indicated for FY 2022.**

- Open Revision and Removal of Devices from Subcutaneous Tissue and Fascia. CMS received a request to designate six ICD-10-PCS codes describing open revision and removal of neurostimulator generators, monitoring devices, and totally implantable vascular access devices (TIVADs) as O.R. procedures. The applicable codes—which are currently designated as non-O.R. procedures—are listed in the table below.

ICD-10-PCS Code	Code Description
0JPT0MZ	Removal of stimulator generator from trunk subcutaneous tissue and fascia, open approach
0JPT0Z	Removal of monitoring device from trunk subcutaneous tissue and fascia, open approach
0JPT0WZ	Removal of totally implantable vascular access device from trunk subcutaneous tissue and fascia, open approach
0JWT0MZ	Revision of stimulator generator from trunk subcutaneous tissue and fascia, open approach
0JWT0WZ	Revision of totally implantable vascular access device from trunk subcutaneous tissue and fascia, open approach
0JWT03Z	Revision of infusion device in trunk subcutaneous tissue and fascia, open approach

The requestor stated that although removal of these devices is often performed in outpatient surgery, device complications can require removal or revision during inpatient hospitalizations. The requestor indicated it is reasonable for these open procedures to be designated as O.R. procedures to compensate for operating room resources during such inpatient stays.

CMS did not agree that these procedures warrant an O.R. designation and noted that these procedures are generally performed in the outpatient setting, and when performed during a hospitalization, it is typically in conjunction with another O.R. procedure. Therefore, the Agency proposes to maintain the current non-O.R. designation for the six procedure codes listed above for FY 2022.

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The ACS disagrees with CMS that these procedures do not typically require the resources of an O.R. The Current Procedural Terminology (CPT) codes linked to ICD-10-PCS codes 0JPT0MZ, 0JPT02Z, 0JPT0WZ, 0JWT0MZ, 0JWT0WZ, and 0JWT03Z indicate that such services are performed in an O.R. under anesthesia—no matter if they are furnished on an inpatient or outpatient basis—and we seek clarity from the Agency regarding the relevance of whether these procedures are furnished in conjunction another O.R. procedure during a hospitalization. **We urge the CMS to maintain the O.R. designation for these six ICD-10-PCS procedure codes for FY 2022.**

OTHER DECISIONS AND CHANGES TO THE IPPS FOR OPERATING SYSTEM

Proposed Payments for Indirect and Direct Graduate Medical Education (GME) Costs

Distribution of Additional Residency Positions Under the Provisions of Section 126 of Division CC of the Consolidated Appropriations Act, 2021

The *Consolidated Appropriations Act, 2021* (CCA) amended section 1886(h) of the Social Security Act by requiring the distribution of additional residency positions to qualifying hospitals. For FY 2023, and for each succeeding fiscal year until the aggregate number of full-time equivalent (FTE) residency positions distributed is equal to 1,000, CMS shall initiate separate rounds of applications from hospitals for these additional residency positions.

The ACS welcomed the inclusion of 1,000 new Medicare-funded GME positions under the CAA and is generally supportive of the Agency’s proposal for implementing this provision. Policies to strictly limit Medicare-funded GME positions have contributed to persistent and growing physician shortages in many specialties, including surgery. These shortages can vary regionally and are often more severe in rural areas—for example, a 2020 report prepared by the Health Resources and Services Administration (HRSA) for the Senate Committee on Appropriations found a maldistribution of general surgeons nationwide, with rural areas having only 69 percent of the general surgeons needed to meet demand for care.³ Distribution of the newly funded positions, if done carefully, could be an important first step in addressing these shortages.

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³ U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis. (2020). Report to the Senate Committee on



To be granted an increase in positions under the provision, CMS proposes that a hospital must attest to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased based on any newly awarded positions. The ACS agrees that hospitals should be using newly funded GME positions to increase the overall number of residents they are training, not simply to offset the cost of currently unfunded positions. The intent of Congress when including this provision was to begin to address the current and projected future shortages of physicians.

The CAA requires that no less than 10 percent of the newly created slots be distributed to each of four priority categories: (1) hospitals currently over their caps, (2) rural hospitals, (3) hospitals in states with new medical schools, and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HSPAs). As noted above, regional shortages exist for surgeons and are often worse in rural areas. Because of the nature of surgery, it is not uncommon for surgeons to care for a large number of rural patients in the nearest hospital with the appropriate resources, which often means a hospital in an urban area. The addition of residency positions at rural hospitals and those otherwise treated as being located in rural areas may have a beneficial effect on attracting physicians to practice in these areas after completing their training.

CMS proposes that primary care geographic HPSAs be used in determining which hospitals qualify as "serving areas designated as HPSAs," and that facilities in these HPSAs may apply for additional residency positions for any specialty. While the ACS strongly believes there is a need for a specific shortage designation for access to surgery, given the lack of such a designation currently, primary care geographic HPSAs are likely the most appropriate to use to meet the requirements of the CAA. **However, there are many areas across the country with adequate primary care providers, but a substantial deficit in the number of general surgeons available to treat surgical patients. Therefore, in order to ensure the most appropriate distribution of resources to address workforce issues, ACS urges CMS to work with HRSA, the Department of Health and Human Services (HHS), and Congress to create designations for shortage areas specifically for general surgery.**

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Appropriations in response to *Senate Report 115-289, Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2019.*



Previous Redistribution of Additional Residency Positions

Section 5503 of the Patient Protection and Affordable Care Act (ACA) directed CMS to redistribute 65 percent of teaching hospital's unused direct and indirect GME slots to teaching hospitals. Under this unused slot redistribution program, CMS awarded 726 direct GME slots and 628 indirect GME slots to 58 hospitals in 2011. Of these slots, 70 percent were allocated to hospitals in states with resident-to-population ratios in the lowest quartile, and the remaining 30 percent of slots were allocated to hospitals in rural or health professional shortage areas. Hospitals that received slots under Section 5503 were required to meet certain criteria to avoid forfeiting such slots over the five-year redistribution period from July 1, 2011, through June 30, 2016. **The ACA specified that a hospital must use 75 percent of the awarded slots for residency training in primary care or general surgery.**

In light of growing evidence demonstrating a shortage of general surgeons, the ACS supported the implementation of the unused slot redistribution program and the requirement that 75 percent of the positions attributable to the cap increase be used for primary care or general surgery. While we believe that this 75 percent threshold was intended to bolster the primary care and general surgery workforce as part of healthcare delivery for current and future Medicare beneficiaries, CMS has not provided information on the outcome of this program, such as: the specialties of the training programs that lost unused slots; how many of the redistributed slots were filled; how many of the redistributed slots were awarded to primary care programs compared to how many were awarded to general surgery programs; whether general surgery experienced a net loss or net gain of residency slots; and how CMS monitored hospitals' adoption of the 75 percent threshold.

Now that the five-year redistribution period has ended and given the current implementation of newly funded resident slots, we strongly urge CMS to release its findings regarding awardee hospitals' use of their Section 5503 slots and their compliance with the terms and conditions of the program. We remain concerned with the lack of consistent, unbiased statistics on physician supply and demand and believe that CMS can provide more accurate and actionable workforce data based on this initial round of unused residency slot redistribution. In the interest of transparency and accountability, we ask that CMS make public a comprehensive description of the specialties from which the unused slots were drawn and subsequently redistributed; the number of slots designated as primary care versus general surgery under the 75 percent threshold; how the Agency and its contractors tracked hospitals' participation and enforced the program's statutory and regulatory requirements; and, in the event that it was determined a hospital did

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not satisfy these requirements, how its awarded slots were redistributed to another hospital(s) pursuant to Section 5503. **Such information could be invaluable in informing the distribution of the slots recently provided under the CAA or any future efforts to address pending physician workforce shortages.**

QUALITY, VALUE AND INTEROPERABILITY REPORTING REQUIREMENTS AND RELATED PROVISIONS

ACS General Comments on Quality, Value and Interoperability

As the U.S. health care system begins to transition to Value-Based Health Care (VBHC), 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.

Value is often expressed by payers and other stakeholders as an equation, where quality is the numerator and cost is the denominator (Value = Quality/Cost). And, much of how value-based health care and quality has been defined and implemented by CMS and other payers is dictated by individual payment systems across the Agency. For example, CMS has 24 independent, fragmented quality and value-based initiatives that are unique to specific care settings and payment systems, as illustrated below in Figure 1. This results in a burdensome array of disjointed mandates that provide a fragmented picture of value, do little to incentivize care coordination, and fail to put the patient first.

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Figure 1. CMS Quality and Value-based Payment Programs

CMS 24 Quality and Value-based care payment programs – How to align care across so many payment programs?



For a payment incentive program, it may seem rational to create a numeric equation (Value=Quality/Cost and the 4 weighted categories of MIPS). Instead, we find this has resulted in surgeons chasing payment incentives in the MIPS program, in the Ambulatory Surgery Center (ASC) measures, in the hospital measures, and so forth. Since efforts are not patient-focused, the result is that nowhere in this mix can anyone find quality as a program, quality improvement, or useful metrics to help the surgical care team optimize patient's goals and expectations of care. ACS believes that instead of centering value on the payment system and in the form of an equation, we need to recenter measurement on the unifying goal of care that provides value that matters to the patient. We discuss these distinctions and offer a framework for defining patient-centered value below.

Value Defined for Payment

Under the current fee-for-service (FFS) system, each service and facility has their own system for billing and revenue. This system leads to a piecemeal, fragmented approach to care delivery that does not translate seamlessly when care complexity increases. In less complicated cases where care is typically delivered in one simple office-based visit, the FFS system is efficient and often easily understood by patients. However, when care becomes more complicated, and is delivered by a team across multiple medical specialties and settings over an extended period of time, it becomes much harder for patients to comprehend all the steps and processes of patient care. When that care is also divided into silos for payment and quality measurement, as it is in the current FFS systems,



patients are left with little meaningful information about quality, making it nearly impossible to determine how to assess care based on what matters to them.

Not only does the fragmented system cause frustration and confusion for patients, but similar frustrations are also felt by surgical teams. Single metrics used across the 24 CMS quality programs do not reflect modern, team-based care delivery—in fact, they measure the surgeon, hospital, anesthesiologist, pathologist, etc. separately from one another. It is likely that many physicians are required to comply with multiple programs, first at the physician-level, and if employed, also as part of their healthcare facility. The quality teams are working within misaligned systems that are focused on single metrics for purposes of compliance, instead of investing in programs built on verified standards of true high-quality care. We have heard many examples of this from ACS Fellows where hospital administrators are requiring physicians to adjust the way they deliver patient care simply to avoid payment penalties. One example is that hospitals have created quality protocols to remove foley catheters in an attempt to meet the CAUTI metrics. This policy leads to frequent premature removal of urinary catheters only to have them replaced within 24 hours from urinary retention. Some surgeons have reported patients experiencing 3 to 5 days of repeat catheterizations since each day the nurses remove a catheter only to have it reinserted. In some cases, changes to physician workflows in the electronic health records (EHR) and other structures and care processes are being implemented to meet these metrics. When this begins to happen, the potential for unintended consequences and patient harm increases.

Value Defined for Patients

ACS views “Quality as a Program” not as a few unrelated measures such as those in CMS payment programs. **“Quality as a Program” is a framework that defines value from the patients’ perspective, it builds the teams and infrastructure needed to deliver on patient goals, and it aligns facilities and teams to organize around the patient as they move throughout the healthcare system.** The framework for quality as a program in surgery appreciates the comprehensiveness of surgical care—it includes structure, process, and outcomes to drive cycles of improvement. These elements are all part of a verification program. This results in the team organizing around the patient with shared accountability and breaks down the current silos that show a fragmented picture of quality. Within quality programs, verification of standards, infrastructure, and data provide surgeons and the surgical teams with the resources and environment needed to deliver optimal care and assist in reaching quality goals.

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From the ACS perspective, we have observed a transformation of healthcare from silos of care into team-based episodes of care that seek to optimize patient’s expectations for their individual care journey. This transformation may be the result of the combination of many factors such as: policies focused on value-based care, interoperability and the digital era in healthcare, the increasing percentage of employed physicians, complexity of care, physician burnout, implementation of Advanced Payment Models (APMs) and other payment models, the role of risk-adjusted clinical data registries, various IOM reports on quality, and other factors. The College has also focused on work that has further fostered this transformation toward patient-centered care, including defining quality as a program with shared accountability for the entire episode of care. These factors are leading to an appreciation of the team within a care model, as well as the resources and shared knowledge needed to provide care. Clinicians are making efforts to improve care based on their commitment to professionalism. Instead of staying in the siloed care, they are changing the care model to center around the patient and have begun to perform new roles within the team.

To achieve this means building on the right structure, with the right processes for the team. It means tracking quality as a program, requires transparency for payment systems in an incentive-based payment system, and more. All these changes are preparing teams for novel payment models, including episode based/bundled care—yet, the business model has not kept pace. Trying to squeeze this transformation into the current FFS payment program with fractured metrics of care is counter-productive to this transformation and the focus on payer policies and regulations distracts from the work that is already taking shape.

In our decades of experience running quality programs, we believe quality includes the following key components, also illustrated in Figure 2:

1. Quality verification program which verifies surgery across all departments, providing the resources, structures, leadership and cultural commitment to provide the foundation for driving high quality
2. Clinical accreditation programs which verify care for a condition such as Bariatric, Cancer, Trauma, Geriatric Surgery etc.
3. High-value process measures such as Enhanced Recovery After Surgery (ERAS) protocols
4. Clinical Outcomes to measure event rates (Surgical Site Infection (SSI), Reoperation)

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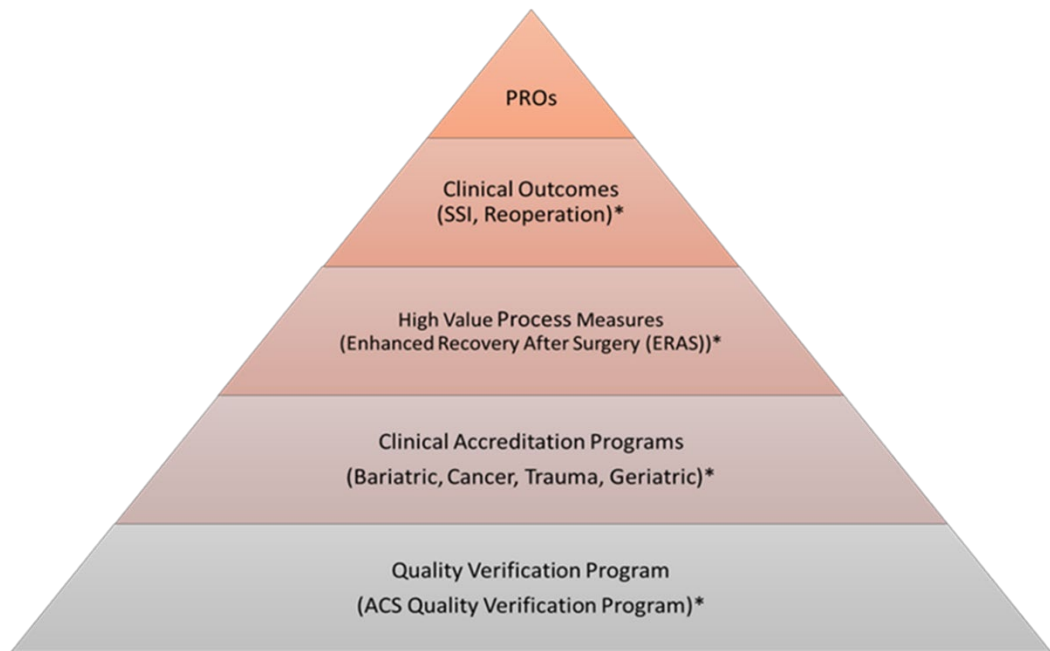
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5. Patient-Reported Outcomes (PROs) to include the patients voice in determining the successful outcome of the intervention from the patient's perspective.

Figure 2: Key Components of a Surgical Quality Program



*Indicates example

One incredibly important distinction that we cannot overstate is that CMS must first consider what constitutes a quality program for a condition, so hospitals and surgical teams have what is needed to deliver optimal care—critical to this is programmatic alignment across hospital and physician programs. Only after that framework is developed for a condition should CMS, along with medical specialties and other stakeholders, consider how to incentivize the full program as part of a payment program.

Squeezing metrics into a series of payment programs designed for FFS might have been the way to initiate the transition to quality. However, it is now time to realize that the alternative payment models are more likely to serve as a vehicle to move quality from its silos into a program that is more ideal for delivering care. If an alternative payment model is not available, then another consideration is to use Center for Medicare and Medicaid Innovation (CMMI)

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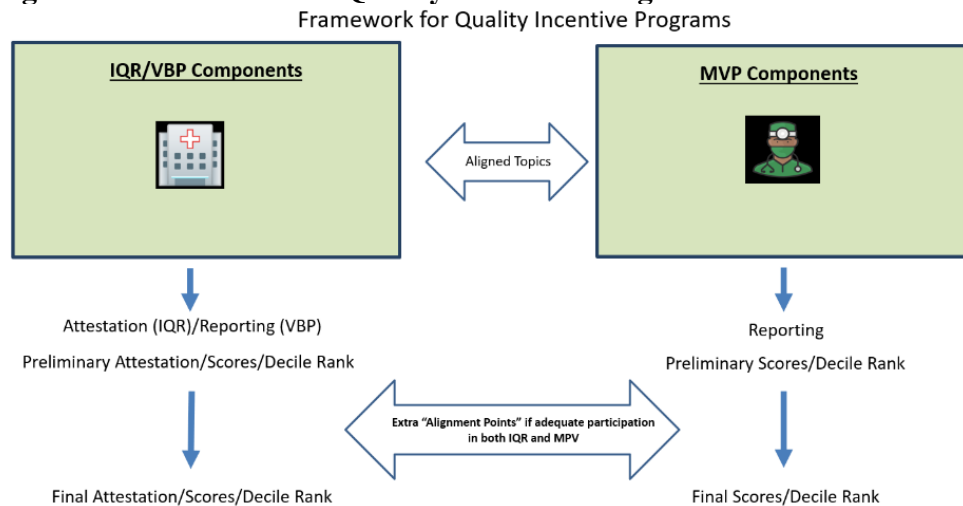


to implement a pilot that reconfigures the quality metrics found in FFS into a quality program that spans across the multiple FFS barriers and creates payment incentives that have clinical alignment with quality goals. In order to incentivize a comprehensive surgical quality program we assert that the payment program should:

1. Address the comprehensive patient journey and patient goals across the five phases of surgical care
2. Link clinicians and facilities to create shared accountability
3. Include structure, processes and the tools needed for performing QI across the surgical team
4. Reflect proper alignment, structure, processes, and outcomes
5. Incentives for physicians and hospitals/facilities should rely on interrelated quality measures
6. CMS programs should reward those willing to make a special effort toward programmatic alignment

The ACS recommends that CMS explore ways to develop quality programs that can be aligned in this way. **CMS can start by 1) developing quality programs aligned around a defined condition; 2) evaluating the measures within the 24 current CMS programs to determine which key measures should be utilized to create a quality program; 3) add critical structural measures; and 4) invest in the development of PROs.** Not only would this offer a more meaningful measurement framework for hospitals and physicians, it would also significantly decrease the burden associated with reporting data across multiple programs. Figure 3 below illustrates what alignment could look like across the Inpatient Quality Reporting (IQR) program and MIPS.

Figure 3. Framework for Quality Incentive Programs





When aligning across a condition (or “topic”) the facility would attest in IQR to providing the resources/infrastructure/educational opportunities to deliver on patient goals. In order to incentivize this alignment across clinician and hospital programs, it will be critical to offer alignment points or other benefits initially. Attesting that these key elements are provided by the facility provides the surgical team with what is needed to deliver optimal care. The surgical team can then report measures to reflect the comprehensiveness of the quality program, with an emphasis on PROs to determine whether care met patient goals.

Defining value based on what matters to the patient can also play a critical role in the system’s ability to transform to become more accessible, affordable, transparent, and equitable. Looking across the delivery systems and payment programs to measure outcomes with data is representative of populations who have historically been underserved will uncover disparities in care and is the first step in addressing health equity.

To address disparate outcomes across patient groups the College analyzed risk-adjusted ACS National Surgical Quality Improvement Program (ACS NSQIP) data to identify and understand these differences in surgery. ACS found that surgical outcomes risk-adjusted for comorbidities did not show statistical differences across race or ethnicity. These initial findings suggest that if patients access a delivery system and we risk adjust for their co-morbidities, the outcomes of care are essentially the same. These findings present more questions than answers and solidify the need for further research to truly understand the relationships between race and ethnicity, social determinants of health (SDOH), comorbidities, and surgical outcomes.

This also raises questions about the methodologies used to measure and evaluate these factors, such as are we risk-adjusting away important aspects of care, and what other approaches should be explored? Disparities in surgical care may be related to problems in access, early detection, prevention and chronic maintenance, which are often influenced by SDOH. When patients present for surgical care at a late stage of disease or uncontrolled comorbidities, their outcomes may be worsened by their underlying conditions, as well as delays in their diagnosis. As such, ACS strongly encourages further research into measures which would bring light to the true causes of disparities. Efforts that define timely access, preventive measures, early detection, and better chronic care maintenance will likely also improve overall outcomes of care.

As the COVID-19 pandemic has further demonstrated, there is a critical need for better measures of inherent disparities to bring attention and investment to

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under-resourced areas and populations, and then the payment system must change so that it is accountable for the results of every individual. Patient-centered VBHC provides an opportunity to improve communication with a more diverse set of patients and build trust within communities that have previously been excluded. Redirecting the wasted funds into improved access and adequate resources would encourage delivery systems to come to the aid of underserve patients.

HOSPITAL READMISSIONS REDUCTION PROGRAM

The Hospital Readmissions Reduction Program (HRRP) requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. The reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG).

Proposed Flexibility for Changes that Affect Quality Measures during a Performance Period in the Hospital Readmissions Reduction Program

In this proposed rule, CMS states that they have identified the need for flexibility in their quality reporting programs to account for the impact of circumstances beyond participating facilities' or practitioners' control. The Agency cites the COVID-19 public health emergency (PHE) as an example of an external factor that would impact quality measurement. To account for these external factors and the impact they have had on medical practice, CMS states that the measures in their quality programs need to be reevaluated to determine whether measure specifications need to be updated to account for lessons learned during the PHE.

To address the impact of the COVID-19 PHE on quality measurement scores, CMS proposes to adopt a cross-program measure suppression policy for the duration of the COVID-19 PHE. The measure suppression policy will enable CMS to suppress the use of quality measures via adjustments to the programs' scoring methodologies if they determine that circumstances related to the COVID-19 PHE have affected those measures by distorting measurement scores. This would result in skewed payment incentives and inequitable payments. CMS proposes to adopt the following Measure Suppression Factors that would guide its determinations of whether to suppress measures for one or more years that overlap with the PHE for COVID-19. These factors would apply to the HRRP, Hospital Value-based Purchasing (VBP) Program, Hospital Acquired Condition (HAC) Reduction Program, Skilled Nursing Facility

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(SNF) Value-based Purchasing Program, and End-Stage Renal Disease (ESRD) Quality Incentive Program:

1. Significant deviation in national performance on the measure during the PHE for COVID-19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
2. Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID-19.
3. Rapid or unprecedented changes in: (i) clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or (ii) the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.
4. Significant national shortages or rapid or unprecedented changes in: (i) healthcare personnel; (ii) medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix.

Hospitals would still receive confidential feedback reports under the HRRP and Hospital VBP Program, to inform their quality improvement activities and make them aware of any changes in performance rates observed by CMS. CMS also states that they will continue to publicly report data for the suppressed measures with appropriate caveats that acknowledge the limitations of the data due to the PHE.

The ACS is supportive of CMS' efforts to adjust reporting requirements and offer flexibilities across the various hospital quality and value-based reporting programs to account for the impact of the COVID-19 PHE. We believe that hospitals should not be penalized as they continue to recover from the impact of the COVID-19 PHE while restructuring and reassessing workflows. We agree that scoring measures that are tied to hospital reimbursement would lead to invalid and inequitable results for these programs during this time. While we appreciate these efforts, we ask that CMS consider the future of these programs and how these flexibilities will impact future benchmarking, while also considering how the response to the pandemic has changed care delivery. Even as we move into a "post-COVID" era, it will be important to know if patient care and quality outcomes have returned to pre-COVID times or have improved. Given this, we suggest

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that CMS determine how it will benchmark in the future. This might require the development of new benchmarks for these measures or the use of benchmarks from FY 2019-2020.

***Proposals to Address the Impact of COVID-19 on Current HRRP Measures
Technical Measure Specification Update to Exclude COVID-19 Diagnosed
Patients from All Other Condition/Procedure-Specific Readmission
Measures Beginning with FY 2023***

In addition to suppressing measures that will be significantly impacted by the PHE, CMS proposes to update the specifications for measures that are less severely impacted by excluding certain ICD-10 codes that represent patients with a secondary diagnosis of COVID-19 from the measure denominators, beginning with the FY 2023 program year. These measures include:

- Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505)
- Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515)
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891)
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure Hospitalization (NQF #0330)
- Hospital-Level 30-Day, All-Cause Risk Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551)

The ACS worries that excluding patients with a secondary diagnosis will prevent hospitals and clinicians from understanding any possible relationships between COVID-19 and the conditions reviewed by these measures. **Since we are still in the early stages of realizing the full impact of COVID-19 post-pandemic on specific conditions, if possible, it would be more informative for CMS to provide hospitals with data in confidential feedback reports that includes the entire cohort for each measure, cohort with a COVID diagnosis, and cohort excluding patients with a COVID-19 diagnosis.** Only the latter should be tied to reimbursement.

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Request for Public Comment on Possible Future Stratification of Results by Race and Ethnicity for Condition/Procedure-Specific Readmission Measures

In the *Closing the Health Equity Gap in CMS Hospital Quality Programs* RFI which starts on page 28, we provide additional comments on the stratification of race and ethnicity in CMS quality programs.

In response to CMS' request for comment on the stratification of condition/procedure specific readmission measures based on race and ethnicity, we have long questioned the meaningfulness and actionability of the CMS readmission measures. The fallacy with this measure is that patients are readmitted because they received poor care; however, this measure does not help identify what the problem might be due to the inherent bias, in other words, what is the true cause of the readmission? We also question how CMS will accurately identify race and ethnicity given the many limitations, including that the Agency does not consistently collect self-reported race and ethnicity information for Medicare programs, and instead utilizes data from the Social Security Administration (SSA), which is not very accurate. Further dividing measures results based on race and ethnic will only further confuse the measure, especially given the low reliability of these data.

HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM

Retention and Removal of Quality Measures

Proposed Removal of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (NQF #0531) Beginning with the FY 2023 Program Year

CMS proposes to remove the *CMS Patient Safety and Adverse Events Composite (CMS PSI 90)* from the Hospital VBP Program under removal Factor 8—the costs associated with the measure outweigh the benefit of its use in the program. The Agency states that because CMS PSI 90 will be retained the HAC Reduction Program, removing the measure from the Hospital VBP Program will reduce the clinician costs associated with tracking duplicative measures across programs. **The ACS supports the removal of this measure and agrees that limiting duplicative measures across the hospital quality and value-based purchasing programs will reduce burden on physicians and hospitals.** As mentioned in the “General Comments” section, we believe that CMS should not only be working to remove duplicability across the hospital programs, but they should also begin considering pathways for programmatic alignment across hospital and physician programs. Without efforts to align quality and payment across the care team, the current

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measurement system serves as a distraction and strains or burdens efforts to build a quality program. The quality teams working within misaligned systems end up chasing metrics for payment reporting rather than building metrics for quality improvement.

Updates to the Specifications of Four Condition-Specific Mortality Measures and One Procedure-Specific Complication Measure Beginning with the FY 2023 Program Year to Exclude Patients Diagnosed with COVID-19

In addition to suppressing measures that will be significantly impacted by the PHE, CMS proposes to update the specifications for measures that are less severely impacted by excluding patients with either principal or secondary diagnosis of COVID-19 from the measure denominators, beginning with the FY 2023 program year. These measures include:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229)
- Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550)

As discussed in our comments in the HRRP, ACS worries that excluding patients with a primary or secondary diagnosis will prevent us from understanding potential relationships between COVID-19 and the conditions reviewed in the mortality measures. **Since we are still in the early stages of realizing the full impact of COVID-19 post-pandemic on specific conditions, we believe, if possible, it would be more informative for CMS to provide hospitals with data in confidential feedback reports that for each measure includes the entire cohort, the cohort with a COVID-19 diagnosis, and the cohort excluding patients with a COVID-19 diagnosis.** Again, only the latter should be tied to reimbursement.

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Scoring Methodology and Data Requirements

For the FY 2022 program year, CMS proposes to suppress all the measures in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction Domains for the FY 2022 VBP program year since circumstances caused by the COVID-19 PHE have affected those measures significantly. CMS would calculate measure rates for all measures, but would only calculate achievement and improvement scores, as well as a domain score for the measures in the Clinical Outcomes Domain, which CMS is not proposing to suppress. Since the Clinical Domain is only weighted at 25 percent of the Total Performance Score (TPS) and no other domains will receive scores for FY 2022, CMS also proposes to not award TPSs to any hospital for the FY 2022 program year, because no hospital would receive a TPS for FY 2022. The net result of these payment adjustments would be neutral for hospitals.

ACS appreciates that this proposal recognizes that payment adjustments based on TPSs calculated using the current scoring methodology would not provide a representative score of a hospital's overall performance in providing quality of care during a pandemic. However, **if finalized, we ask that CMS take into account the impact this policy will have on facility-based scoring under the MIPS for PY 2021.** Under MIPS, clinicians who practice predominantly in facilities have the opportunity to receive scores in the MIPS quality and cost performance categories based on the appropriate Fiscal Year score for the Hospital VBP Program earned by their assigned facility. This policy is designed to reduce the reporting burden for these clinicians, who are dually impacted by federal quality mandates imposed on both facilities and clinicians. Under current regulations, CMS is scheduled to use FY 2022 TPSs for purposes of determining MIPS facility-based scores for performance year 2021. **If CMS finalizes its policy to not provide facilities with a FY 2022 TPS, we request that it also adopt policies that allow it to continue to apply facility-based scoring under MIPS in 2021 or otherwise offer protections to facility-based clinicians who intended to rely on their facility's score this year and might not have collected any MIPS data over the last six months.** Many surgeons have come to rely on the facility-based scoring mechanism to achieve scores in the quality and cost performance categories within MIPS because it significantly reduces the burdens associated with having to report separately to both the hospital and physician-level programs. These clinicians should not be penalized for failing to report MIPS data for 2021.

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Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs – Request for Information

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 previous sections, the ACS believes that the current structure of CMS programs forces physicians to chase metrics, instead of implementing quality programs that 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 are of little value to patients for assessing value and to physicians for driving quality improvement cycles. Creating a digital framework to aggregate data for these single metrics will only make it easier and less burdensome to collect data for measures that do not drive meaningful quality improvement or appreciate the comprehensive patient journey and patient goals. Instead, we suggest focusing this transition on utilizing digital tools to enhance more comprehensive quality improvement programs.

Quality improvement using digital services should focus on supporting a digital services landscape that goes beyond only aggregating quality metrics. It should meet four general aspects to leverage digital services through open standards-based platforms that enhance knowledge sharing around care. These open platforms are needed and could leverage the information sharing and care coordination found in Health Information Exchanges (HIEs). To realize the full potential of open platforms, we need to ensure they are not faced with undue burden from proprietary vendors. The four aspects for a digital services platform should:

1. Support the use of clinical decision support (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 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.

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4. Support quality metrics payors seek for their payment incentive programs in a patient centered manner.

Furthermore, digital tools that enhance quality programs or enable payor metrics should be engineered with an architecture that deploys open source, standards-based infrastructure, such as Fast Healthcare Interoperability Resources (FHIR), HL7 V2 messaging, etc. These should be implementable on open standards platforms that are scalable and not constrained by the EHR vendors and their conformance with standards, such as each release of FHIR. Such solutions are emerging quickly. For example, the Amazon Health Lake provides engineering in its digital services for this architecture.⁴

Additionally, we add a note of caution to CMS regarding implementation of digital services. Many EHR vendors are anxious to add in various digital tools insisted upon by CMS—but 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 ideas with regards to digital services. It is not enough to reduce clinical burden of data aggregation if the fiscal burden of a constrained, proprietary vendor action consumes more and more of the precious healthcare resources. CMS should be considerate of all aspects of implementation.

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,
- electronic health records,
- instruments (such as, medical devices and wearable devices),
- patient portals or applications,
- HIEs, and
- registries, etc.

4 Amazon HealthLake. <https://aws.amazon.com/healthlake/>



To support a “quality program” framework, described in ACS “General Comments” on page 10, 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. In regard to the data sources that can be used to gather electronic health information (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.⁵ 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 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 on the physicians’ EHR to track quality goals, easily access relevant patient information, SDOH metrics, and ensure successful completion of care plans. In 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.

Area #1: Leverage and advance standards for digital data and obtain 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

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⁵ Business Process Management for Healthcare. *About BPM+ Health*. <https://www.bpm-plus.org/about-us.htm>



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 continue to be developed. CMS and ONC should work to create pathways for bi-directional data exchange with EHRs. In many cases, establishing an agreement with EHR vendors that enable bi-directional exchange or access to their proprietary platforms can be extremely costly and unsustainable for hospitals and physicians.

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 would be useful to quality measurement, such as Operative Reports using SDC, clinical protocols, ERAS, and clinical CDS tools.**

Area #2: Redesign our 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, payers, CMS, and others and calculate measure scores, and produce reports. The ACS believes that this is an extremely important step in redesigning digital quality measures and enhancing "quality as a program". **Transitioning to self-contained tools that can track patients across the care continuum by gathering and analyzing data for quality metrics, PROs, as well as assess conformance with the care plan will be highly valuable for both patients and physicians.**

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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 additionally 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, payers, the care team, etc. Platforms such as this can use secure APIs to bi-directionally exchange data with HIEs, taking advantage of the longitudinal data captured in an HIE. The data is then sent to a data lake where the data is aggregated and can be shared back to the platform where physicians can view the analyzed data in a dashboard.

Area #4: Work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate

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 payers. 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.

As previously mentioned, the ACS is a strong advocate for alignment across CMS 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.

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Closing the Health Equity Gap in CMS Hospital Quality Programs— Request for Information

It is well established that SDOH have an impact on quality of care. Lack of access, limits on resources, lack of preventive care, poor early detection, and limited chronic care maintenance are some of the factors that contribute to care inequities, which can result in worse overall outcomes in surgical care. 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 these outcomes. To further this effort, the Agency requests information on how to revise CMS programs to improve the reporting of health disparities to provide comprehensive and actionable information for hospitals, providers, and patients. CMS solicits comments specifically on the stratification of quality measure results by race and ethnicity, improving demographic data collection, and the possible development of a Hospital Equity Score to synthesize results across multiple social risk factors.

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 with little meaningful, relevant, and understandable data available for 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.^{6,7}

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6 Haider AH, Scott VK, Rehman KA, et al. *Racial disparities in surgical care and outcomes in the United States: a comprehensive review of patient, provider, and systemic factors.* J Am Coll Surg. 2013;216(3):482-92.e12. doi:10.1016/j.jamcollsurg.2012.11.014

7 de Jager E, Levine AA, Udyavar NR, et al. *Disparities in Surgical Access: A Systematic Literature Review, Conceptual Model, and Evidence Map.* J Am Coll Surg. 2019;228(3):276-298. doi:10.1016/j.jamcollsurg.2018.12.028



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 NSQIP data to identify and understand these differences in surgery. In our analysis of risk-adjusted NSQIP data, which includes patient data starting with inpatient admission to 30 days post discharge, we have not found statistically significant differences across race and ethnicity.⁸ 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.

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

⁸ This work has not been published in the peer review literature.

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Expanding Current CMS Stratification Efforts

Currently, CMS is considering stratification of race and ethnicity in quality measure results. The Agency has two methods of reporting hospital quality data stratified by social risk factors—the Within-Hospital disparity method and the Across-Hospital method. The Within-Hospital disparity method is meant to promote quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their *clinical risk factors*. The Across-Hospital method is meant to be complementary and assesses hospitals' outcome rates for *dual-eligible* patients only, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. In 2020, CMS provided hospitals, through confidential Hospital Stratified Reports (HSRs), the results of each of the six condition/procedure specific readmission measures stratified using dual eligibility which showed worse outcomes for dual eligible beneficiaries.

In addition to the already available stratification of dual-eligible patients, CMS solicits feedback in expanding the disparity methods to include stratification of the condition/procedure specific readmission 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 not very accurate. Since accurately identifying better race and ethnicity data are a significant undertaking, CMS seeks feedback on the application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual-eligibility) for hospital-level disparity reporting, 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 the role of SDOH, it very quickly becomes a complex and even seemingly endless task. Currently,

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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. 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.

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 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.

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SDOH related considerations in Digital Health

Estimates vary, but anywhere from 21 million to 42 million Americans lack access to a broadband internet connection.⁹ Roughly a quarter of adults with household incomes lower than \$30,000 do not have access to a smartphone.¹⁰ As healthcare access, delivery, quality, and patient engagement continue to lean on technological innovations, there is a gap between individuals who have access to technologies and the digital literacy to use them and those who do not. For example, during the pandemic, use of telehealth increased sharply, yet adoption was not equal across different populations. When considering how to address inequities in care, CMS must also consider how lack of broadband access, smart devices, and digital literacy may impact patients access to care and how they receive their medical information.

It is also important to keep the impact of the digital divide front of mind when evaluating methods to collect race, ethnicity, and other SDOH data. 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. Therefore, CMS should consider ways to ensure that all patients are accounted for. There is also a need for development of structured formats based in open health IT standards to ensure that race, ethnicity, and SDOH data are consistently captured across clinical systems, such as EHRs and registries. Today, there is variation in how these data are identified, classified, and the fields that are used in EHRs and other systems to collect this information. Developing standardized data definitions for race, ethnicity, and SDOH will allow stakeholders to gather more complete data sets that can be used as the foundation for research, quality measurement, and much more.

In addition, 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 Artificial Intelligence(AI)/Machine Learning(ML). Bias can manifest in various ways such as the data on which the algorithm is trained could fail to include all patient populations for which the digital health tool is used; the algorithm itself could be written in a flawed manner that results in a biased impact on certain

9 Johnson, S.R., *The digital divide becomes a new social determinant of health*. Modern Healthcare; 2021. <https://www.modernhealthcare.com/technology/digital-divide-becomes-new-social-determinant-health>

10 Vogels, E.A., *Digital divide persists even as Americans with lower incomes make gains in tech adoption*. Pew Research Center; 2021. <https://www.pewresearch.org/fact-tank/2021/06/22/digital-divide-persists-even-as-americans-with-lower-incomes-make-gains-in-tech-adoption/>

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populations; or the context of the use of the digital health tool could result in a biased outcome.¹¹ It is critical that bias be considered in the design, training, and use of digital health tools. The results of the use of such tools should also be monitored for unanticipated bias and corrected if bias is found.

Part of this work should also ensure that identifying SDOH patient data does not lump minority groups together and label them as one group, but instead that the stated goal is to identify the uniqueness and diversity of beneficiaries and understand how improve their health and deliver value by giving hospitals and institutions that serve them the proper support. **When measuring outcomes stratified by race and ethnicity at the facility level, CMS should provide resources and support to hospitals where disparities are identified, instead of reducing updates which leave them with even fewer resources.**

Quality Measure Recommendations

CMS seeks recommendations for other types of quality measures or measurement domains, in addition to readmission measures, to prioritize when stratifying by dual eligibility, race and ethnicity, and disability. 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 implementing patient-reported metrics of inclusion in the care process is also an important step in addressing systemic bias in health care delivery.

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; and timely and appropriate care will lead to overall better patient outcomes.

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11 Brodwin, E, Ross, C. *Promise and peril: How artificial intelligence is transforming health care*. STAT e-book; 2020.



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.

2) Improving demographic data collection

CMS seeks comments on the possibility of hospital collection of standardized demographic information for the purposes of potentially incorporating into measure specifications to permit more robust equity measurement.

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

3) The potential creation of a Hospital Equity Score to synthesize results across multiple social risk factors

CMS is considering creating a Hospital Equity Score that could summarize hospital performance across multiple social risk factors (initially dual eligibility and race and ethnicity), summarize hospital performance across the two disparity methods (i.e., the Within-Hospital Disparity Method and the Across-Hospital Disparity Method), and potentially multiple measures. Upon development of this methodology, and prior to any potential future public reporting, CMS intends to initially provide results of the Hospital Equity Score in confidential HSRs. CMS seeks feedback on the creation and confidential reporting of a Hospital Equity Score to synthesize results across multiple social risk factors and disparity measures, including race/ethnicity and dual eligibility, as well as interventions hospitals could institute to improve a low hospital equity score.

The creation of a Hospital Equity Score is intriguing, but we seek further information on how it would be used—what is the goal? Would it be used for resource reallocation or accountability? If it would be used for accountability purposes than this concept is extremely premature. As discussed above, better

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data and further research is needed to identify the issues—currently there is so much noise in the data that we are unsure of the causes; it is even hard to know where we should focus data collection efforts because the data is so unreliable. If used for resource reallocation, this could be a means or incentive to get more care to vulnerable patients. An equity score that identifies access problems and resource needs would lead to reallocations for closing a gap—but that means more measures would have to assure that the funding reallocations were used for an approved attempt to remedy the problem. We also must be sure that these methods do not unintentionally exacerbate the systemic inequities in care. The first step should be an intensive effort to gather better data (including self-reported) to accurately identify actionable targets to improve health equity. This should be the first part of a strategic plan (mentioned above) with a structured timeline for deliverables.

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM

Under the Hospital IQR program, hospitals must meet the requirements for reporting specific quality information to receive the full market basket update for that year, and hospitals that do not will receive a two-percentage point reduction in that year's inpatient hospital payment update factor.

Proposal to Adopt New Measures for the Hospital IQR Program Measure Set

Proposed Maternal Morbidity Structural Measure Beginning with a Shortened Reporting Period from October 1, 2021 Through December 31, 2021, Affecting the FY 2023 Payment Determination Followed By Annual Reporting Periods for Subsequent Years

In the proposed rule, CMS discusses the prevalence of maternal morbidity in the United States and describes one of the main factors contributing to the increase in maternal morbidity and mortality as inconsistent obstetric practices. They cite that many hospitals lack standardized protocols to address obstetric emergencies and complications that arise during pregnancy and childbirth. Therefore, CMS proposes to adopt the *Maternal Morbidity Structural Measure* (Maternal Morbidity Measure), beginning with a shortened reporting period running from October 1, 2021 through December 31, 2021, affecting the FY 2023 payment determination, to help address the maternal health crisis. The structural measure is designed to determine hospital participation in a state or national Perinatal Quality Improvement (QI) Collaborative initiative and implementation of patient safety practices/bundles within that QI initiative. Hospitals would report this measure by attesting to a two-part question once a year.

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In the past, the ACS has advocated for the incorporation of structural measures in CMS quality programs. We believe the intent and direction of the perinatal quality improvement initiative is a manifestation of the ACS Quality Model. The ACS Quality Model begins with selecting a condition, procedure, or episode of care. In this instance, it is maternity care. The ACS model lays out the structural elements in a series of domains which link the entire care team into a working unit that focuses on the patient, their expectations, preventable harms, and ultimate outcomes. When developed properly, structural measures can be highly effective in standardizing care practices, eliminating gaps in care, and promoting safer and higher quality care. As mentioned, the ACS believes that quality is a program, not a collection of single metrics. High-fidelity quality programs include the right structure, process and key outcomes that value the infrastructure, resources, and processes needed to deliver optimal care and improvement. A quality program developed around a high-risk condition, such as maternal morbidity and mortality, should be developed first by defining the patient care journey and next by selecting condition-specific elements that are verified by clinical experts to create a program. Hospitals can then be virtually and externally evaluated and accredited if they meet the necessary standards for delivering optimal, high-quality patient care. The ACS applies this process for developing quality programs for several surgical specialties that have proven effective in driving cultures of quality improvement in hundreds of hospitals across the country. We believe that CMS should consider how to acknowledge participation in these types of verification and accreditation in both hospital and physician quality reporting programs for continuous, reliable, and standardized maternity care.

Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure

CMS proposes to adopt the *Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure*, beginning with a voluntary reporting period from July 1, 2022 through June 30, 2023, followed by mandatory reporting July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination. This measure uses claims data to define the measure cohort and a combination of EHR and claims data for risk adjustment. Similar to the Hybrid Hospital-Wide Readmission Measure with Claims and EHR Data, adopted in the IQR program in the FY 2020 IPPS/LTCH PPS final rule, a set of core clinical data elements will be extracted from the EHR. The data elements are values for a set of vital signs and common laboratory tests that will be used, in addition to claims data for risk adjustment of patients' severity of illness.

With this measure concept, we believe that CMS is taking a step in the right direction. By using data from the EHR to enhance clinically enriched claims

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data you can strengthen the aggregation of the quality measure, but the proper metrics must be selected to achieve this. Incorporating clinical data from the EHR, or other sources, adds an additional layer of complexity to the measure science because the selected data elements must be correct to achieve reliable and valid measure outputs. In the ACS' many years of experience implementing clinical data registries, we have found that not only the selection of the proper data elements, but also oversight over the data entry process is essential in ensuring the aggregation of reliable data. In the future, we believe there will be digital services that will be able to achieve this level of specificity, but these technologies still require testing to ensure validity and reliability.

Future Considerations within the IQR

Potential Future Development and Inclusion of a 30-Day, All-Cause Mortality Measure for Patients Admitted with COVID-19 Infection

To continue learning about the impact of the COVID-19 infection on measure outcomes, and how the PHE influenced hospitals' ability to care for patients, CMS is considering the future inclusion of a new hospital-level measure, *all-cause mortality for Medicare beneficiaries admitted with COVID-19 infection (COVID-19 mortality measure)*. As mentioned in earlier sections, we believe that there is still much to understand about the impact of the COVID-19 PHE on the broader healthcare system, as well as the relationship between a COVID-19 diagnosis and outcomes in patients with other health conditions. **We believe that developing condition-specific measures will be helpful in understanding these relationships, but research is still needed to develop methodologies that establish the connection between a COVID-19 diagnosis and other primary conditions.**

Potential Future Inclusion of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

In past years, the ACS has advocated for the use of condition-specific functional patient-reported outcome measures (PROMs) in CMS programs, because they can more accurately measure the success of the procedures based on outcomes that are important to the patients, while also supplying the clinical team with information essential to the patient's recovery. Measuring PROMs gives the patient the opportunity to determine whether their care goals have been met, share their post-surgical experience, and provide meaningful, actionable data for the surgical team. PROMs tailored to a condition or episode allow clinicians to better understand the elements of care their patients value

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most and empower patients to work with care teams to communicate goals and engage in shared decision making prior to and during care. Continuing the use of PROMs in CMS programs will reflect a transition to a more patient-centric program by assessing outcomes that matter most to patients. Also critical for a patient-centric approach is to include this measure in the clinician programs, such as MIPS and/or MIPS Value Pathways (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, and then the clinician can be measured based on a quality improvement plan to follow up on the responses to the same PROM.

CMS requests stakeholder comment on the potential future inclusion of a PROM following elective total hip and/or knee arthroplasty (THA/TKA). **The ACS supports the inclusion of this measure. Using joint-specific PROMs to measure hip or knee pain and functioning following a THA and TKA procedure are highly effective in measuring a patient's post-operative goals.** THA and TKA procedures are unique from some other surgical procedures (such as cancer surgeries) because the improvements in a patient's joint-function and the presence of pain can be clearly tracked through the pre-operative and post-operative phases of care. Utilizing PROMs that focus solely on patients' post-operative goals and outcomes becomes more complicated when measuring outcomes in other specialties such as oncological care, where improvement metrics are influenced by many other factors that are unique to the specific patient's condition. In these other instances, there are not always metrics that can be applied to all patients that undergo these treatments. In these cases, PROMs may be more focused on the patient's experience while receiving treatment. It is the ACS' hope that condition-specific functional PROMs will become more commonplace in other surgical specialties, as they are appreciated by both the patient and the surgical team in assessing value.

Potential Future Reporting of a Structural Measure to Assess the Degree of Hospital Leadership Engagement in Health Equity Performance Data

To improve public transparency, CMS seeks feedback on appropriate measures regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities. ACS believes that this is critically important for hospitals to measure, monitor, and improve access for underserved patients, including individuals with intellectual and developmental disabilities.

As discussed in previous sections, based on ACS's analysis of NSQIP risk-adjusted clinical data, we see little difference in patient 30-day surgical outcomes once patients are admitted to the hospital. One key takeaway is that

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these data include patients who were able to access hospitals and receive surgical care. But this also raises more questions than we have answers for, highlighting the need for further study. What about members of the community who never made it to the surgeon, or those who made it to the surgeon but with a delay in diagnosis such as stage IV cancer or other potentially preventable advanced disease? Insured status and having care managed by primary care physicians are two factors that can increase equitable access to surgical care. An initial indicator to track community access is to look at the hospital demographic compared to the community demographic for race, ethnicity, and disability status. Another consideration is to track newly insured or insured patients and what percentage of those patients are assigned to a Patient-centered Medical Home (PCMH). Assignment to a medical home will provide some level of assurance that a patient's chronic care is being well-managed, and they will have access to timely and appropriate surgical care if needed.

To inform these efforts, the Health Anchor Network (HAN) is 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. 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.”¹² Many large healthcare systems including Kaiser, Rush, and Henry Ford, to name a few, are leading these efforts.

There are also efforts in Socially Responsible Surgery working to integrate surgery and public health to address the social barriers that have the potential to decrease access to surgery and lead to worse surgical outcomes in underserved patient populations. These efforts are in nascent stages but may present considerations for how to address SDOH in surgical care, including research and training opportunities.¹³

Stratification of the Hospital-Wide All-Cause Unplanned Readmission Measure

CMS seeks comment on the idea of stratifying the performance results of the Hospital-Wide All-Cause Unplanned Readmission (HWR claims only)

12 Healthcare Anchor Network, <https://healthcareanchor.network/about-the-healthcare-anchor-network/>.

13 Robinson TD, Oliveira TM, Timmes TR, Mills JM, Starr N, Fleming M, Janeway M, Haddad D, Sidhwa F, Macht RD, Kauffman DF, Dechert TA. Socially Responsible Surgery: Building Recognition and Coalition. *Front Surg*. 2017 Apr 5;4:11. doi: 10.3389/fsurg.2017.00011. PMID: 28424776; PMCID: PMC5380666.

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measure (NQF# 1789) by dual eligibility and indirectly estimated race and ethnicity. CMS also seeks comment on the idea of stratifying said performance results by disability status and seek suggestions for appropriate measures of disability status that could be derived from administrative data or self-reporting for this purpose.

In response to CMS' request for comment on the stratification of condition/procedure specific readmission measures based on race and ethnicity, we have long questioned the meaningfulness and actionability of the CMS readmission measures. The fallacy with readmission measures is that patients are readmitted because they received poor care; however, this measure does not help identify what the problem might be due to the inherent bias, in other words, what is the true cause of the readmission? To further complicate these issues, we also question how CMS will accurately identify race and ethnicity given the many current limitations of the current data, as described by CMS in the Closing the Health Equity Gap in CMS Hospital Quality Programs RFI. Given the data that CMS currently has to stratify for race and ethnicity, there is too much noise making it impossible to identify disparities, especially the cause of how this relates to readmissions. To ensure that we do not do more harm than good, we need much better data to even know where to go directionally.

In light of this request for comment, it is important to recall that the HWR measure in the HRRP can result in increased penalties for safety net hospitals, which serve marginalized populations.¹⁴ These are hospitals that need greater assistance to support their local population, not penalties based on readmission measures fraught with bias.

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

CMS proposes to maintain the *Query of Prescription Drug Monitoring Program (PDMP)* measure as an optional measure under the Electronic Prescribing objective. CMS also proposes to increase the amount of bonus points available for reporting this measure from 5 points to 10 points to incentivize clinicians to perform queries of PDMPs. The Agency cites stakeholders' past concerns about the lack of PDMP integration in EHR workflows and wide variation of PDMP implementation across states.

Because there are still many technical and operational concerns around how to optimize a query of PDMP, CMS states that it does not feel that this measure

¹⁴ Zuckerman, R. et al., Effect of a Hospital-wide Measure on the Readmissions Reduction Program. N Engl J Med 2017; Oct. 19, 2017. 377:1551-1558 DOI: 10.1056/NEJMsa1701791.



should be required. Yet, through recent updates to requirements for certified health IT, standards development activities around PDMPs, and other projects that can more tangibly inform future policy changes, CMS believes that there is a clearer trajectory towards potentially requiring the *Query of PDMP measure* in the future. In the proposed rule, CMS describes a number of recent efforts to improve interoperability between EHRs and PDMPs, including forthcoming requirements to incorporate HL7 FHIR-based APIs and NCPDP SCRIPT standards for electronic prescribing in Certified Electronic Health Record Technology (CEHRT).

As stated in our past comments, 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.

Provide Patients Electronic Access to Their Health Information Under the Provider to Patient Exchange Objective

CMS is proposing to modify the *Provide Patients Electronic Access to Their Health Information* measure to require eligible hospitals and Critical Access Hospitals (CAHs) to ensure that the patient (or patient-authorized representative) has indefinite access to their patient information using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT. The proposed requirement would apply beginning with the EHR reporting period in CY 2022 and would include all patient health information from encounters on or after January 1, 2016, to align with the date of service start date finalized in the Patient Access and Interoperability final rule. The ACS continues to support efforts that give patients increased access to and control of their personal health information and feels that aligning these look-back dates for

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patient information will be helpful as hospitals and physicians implement these changes in their practices.

Health Information Exchange Objective: Engagement in Bi-directional Exchange Through Health Information Exchange (HIE)

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

To incentivize participation HIEs that support bi-directional data exchange, CMS proposes to add the new *HIE Bi-Directional Exchange* measure as an optional alternative to the two-existing measures: *the Support Electronic Referral Loops by Sending Health Information* measure and the *Support Electronic Referral Loops by Receiving and Reconciling Health Information* measure. Therefore, hospitals may report either the two existing measures OR may choose to report the new measure which would be worth 40 points and reported by attesting to the following statements:

- Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department, and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- Participating in an HIE that is capable of exchanging information across a broad network or unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.
- Using the functions of CEHRT to support bi-directional exchange with an HIE.

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

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

Modifications to the Public Health and Clinical Data Exchange Objective

CMS is proposing to require four of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the EHR reporting period in CY 2022: Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting. In addition, CMS proposes to retain

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the Public Health Registry and Clinical Data Registry Reporting measures and make them optional and eligible for bonus points beginning with the EHR reporting period in CY 2022. Currently, Hospitals are required to attest to any two of the six measures under the Public Health and Clinical Data Exchange Objective. CMS believes that increasing the reporting requirements from two to four measures would allow public health agencies to better monitor and assess future health threats and the long-term COVID-19 pandemic recovery.

The ACS thanks CMS for maintaining the Clinical Data Registry Reporting measure within this objective and offering bonus points for those who report this measure. 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 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 conduct 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 that would require eligible hospitals and CAHs to attest to having completed an annual assessment of SAFER Guides beginning with the EHR reporting period in CY 2022. 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 Medicare Promoting Interoperability Program.

We feel 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 hospital, specifically the items in the High Priority Practices Checklist. **The ACS suggests that CMS and ONC consider developing an update to 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 patient safety threats that stem from increased interoperability and new technologies.

Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT

Beginning with the CY 2022 EHR reporting period, CMS proposes to no longer require attestation statements 2 and 3 as part of the Promoting Interoperability Program’s prevention of information blocking requirement.

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Considering the new information blocking regulations finalized in the ONC 21st Century Cures Act final rule—that define information blocking and identify reasonable and necessary activities that do not constitute information blocking—the Agency believes that statement 2 and 3 are no longer necessary. Statement 2 requires attestation to a series of statements regarding the use of certified technology and a designated manner for implementing certified technology. CMS believes that the reasonable and necessary activities established under the ONC 21st Century Cures Act final rule (i.e., the exceptions to information blocking) now provide more specific direction to providers when responding to a request for EHI than the general “technical, legal, and other practical constraints,” which are currently targeted by statement 3. **While the ACS agrees that it is acceptable to remove these attestations in light of the recently finalized 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 proper oversight these challenges will persist. As the health care system continues to implement pathways for standards-based bi-directional exchange of electronic health 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 limit the exchange of EHI due to excessive constraints.

Scoring Methodology for the EHR Reporting Period in CY 2022

Currently hospitals and CAHs must earn a minimum of 50 points on the measures and objectives in the PI program to be considered a meaningful EHR user. CMS cites that a majority of participating hospitals and CAHs have successfully met the minimum threshold of 50 points. As such, CMS proposes to increase the minimum required score for the measures and objectives from 50 points to 60 points (out of 100 points). **The ACS asks that CMS broaden the focus of this program beyond EHRs and to recognize those who have implemented advanced digital health tools. These advanced digital health tools present endless opportunities to increase the delivery of high-value care through functions such as better patient tracking, care management, care coordination, etc.**

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PROPOSED CHANGES FOR HOSPITALS AND OTHER PROVIDERS AND SUPPLIERS

Organ Acquisition Payment—Proposed Policy Changes

CMS proposes a series of changes related to organ transplantation, including provisions that, if finalized, would formalize current cost-reporting guidance in regulations; limit Medicare payment for donor hospitals that are not Transplant Centers; limit Medicare payment for certain costs related to living donors; deny Medicare payment for the transportation of donors; and deny Medicare payment for organs transplanted under a research protocol. **The ACS believes that any changes to the national system of organ transplantation must be accompanied by in-depth and thorough impact analysis and direct input from transplant stakeholders—however, it appears that the Agency failed to meet these standards when developing transplant-related proposals included in this rule.** Surgeons and other stakeholders in the transplant community are eager to work with CMS to conduct the proper analyses and identify solutions that do not upend the transplant system. **We echo the below concerns raised by the American Society of Transplant Surgeons regarding the Agency’s proposed transplant provisions.**

For over three decades, the Medicare program cost apportionment rules have assumed that organs procured by a Donor Transplant Center and transplanted at a different Recipient Transplant Center are transplanted into a Medicare recipient. The current methodology was initially adopted both because the CMS recognized that there was no established system for tracing the insurance status of organ recipients and because the Agency recognized the need for an incentive for Transplant Center hospitals to maintain active organ procurement programs. Under this proposed rule, CMS would require Donor Transplant Centers to ascertain the insurance status of all recipients of organs sent to other Transplant Centers and to count only certain (and not all) organs transplanted into Medicare recipients. Such cost apportionment changes—which eliminates incentives to strengthen organ procurement programs—would significantly disrupt the organ recovery efforts of Transplant Centers across the country. As such, CMS’ proposals have the potential to jeopardize organ availability, reduce access to transplantation, and increase the number of patients who die while waiting for a transplant.

These changes would also impose administrative responsibilities on Donor Transplant Centers and on Medicare contractors that would be extremely difficult to fulfill. Under the Agency’s cost reporting proposals, Donor Transplant Centers would be required to provide, and Medicare Administrative Contractors (MACs) would be required to audit, evidence of the Medicare

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status of each deceased organ recipient transplanted at another Transplant Center. There is no established system or process for Donor Transplant Centers to obtain this information from Recipient Transplant Centers, and implementation of the new rules would entail substantial new administrative burdens both for Transplant Centers and the MACs that audit them. Undoubtedly, adding such administrative burdens for Transplant Centers will take resources away from timely patient care and facilitation of organ transplantation.

Moreover, it is unclear whether Donor Transplant Centers could fulfill these responsibilities regardless of the administrative costs they were willing and able to expend. Under these proposed changes, a Donor Transplant Center would need to obtain a copy of the Recipient Transplant Center's contract with each recipient's primary payor to determine whether amounts not paid by that payor could be billed to Medicare as a secondary payor; however, commercial payors universally preclude Transplant Centers from disclosing contract terms. Since Medicare serves as a secondary payor for a significant proportion of kidney transplant patients—and, when Medicare serves as a recipient's primary payor, eligibility is often determined retroactively outside the time period covered by the proposed cost report requirement—these impossible-to-fulfill administrative requirements have the potential to result in significant underpayment of Medicare's portion of organ acquisition costs. This proposed rule does not consider the possible impact on Medicare costs of the potential reduction in access to kidney transplantation and the concomitant increase in Medicare spending for dialysis or for the consequent harm to a disproportionate number of minority and underserved groups.

We strongly believe that these and other potential repercussions on organ availability, access to transplantation, and cost, should be examined thoroughly in coordination with the appropriate stakeholders before CMS determines whether to implement so significant a change in payment for organ acquisition costs. As such, we urge CMS to pause implementation of its proposed transplant provisions for FY 2022.

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

Sincerely,

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