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September 17, 2021

Chiquita Brooks-LaSure, MPP

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1753-P

P.O. Box 8010

Baltimore, MD 21244-1850

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals (CMS-1753-P)

Dear Administrator Brooks-LaSure:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2022 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (CMS-1753-P) published in the *Federal Register* on August 4, 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 hospital outpatient departments (HOPDs) and ASCs, the College has a vested interest in CMS' coverage, reimbursement, and quality reporting requirements applicable to these settings. 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 hospital outpatient and ASC payment systems for CY 2022. Our comments below are presented in the order in which they appear in the rule.

PROPOSED UPDATES AFFECTING OPPS PAYMENTS

Proposed Changes to Packaged Items and Services

Under the OPPS, CMS packages payments for multiple interrelated items and services into a single payment, which the Agency believes creates incentives for



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facilities to provide services efficiently and to manage their resources with flexibility. CMS notes that while there are a variety of items that could be used to furnish a service, some of which are more costly than others, packaging encourages facilities to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which, according to the Agency, often occurs if separate payment is provided.

CY 2022 Evaluation of Payments for Opioids and Non-Opioid Alternatives for Pain Management and Comment Solicitation on Extending the Policy to the OPPTS

CMS is required by section 1833(t)(22)(A)(i) of the Social Security Act to review payments under the OPPTS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. In the CY 2019 OPPTS/ASC rule, CMS reported findings from its analysis of utilization patterns for drugs that function as a surgical supply—specifically, Exparel®—in HOPDs and ASCs to determine whether the Agency's packaged payment policy affected the use of this drug. CMS asserted that, if this policy discouraged the use of or impeded access to Exparel®, it would expect to see a significant decline in the utilization of the drug over time. The Agency stated that it had observed such a decrease in Exparel® use in the ASC setting after the drug's pass-through payment status expired in 2014 but did not observe a similar decrease in the HOPD setting. CMS therefore finalized a provision to unpackage and pay separately for the cost of Exparel® in ASCs for CY 2019. The Agency did not make any changes to its payments for non-opioid drugs in the HOPD setting. In the CY 2020 OPPTS/ASC rule, CMS reported findings from a second review of utilization patterns for drugs that function as a surgical supply in HOPDs and ASCs, and indicated that such review did not produce compelling evidence to suggest that revisions to OPPTS payment policies for non-opioid alternatives are necessary.¹

In this rule, CMS states that it has not found conclusive evidence to support the notion that the OPPTS packaging policy, under which non-opioid drugs and biologicals are packaged when they function as a supply in a surgical procedure, has created financial incentives to use opioids instead of evidence-based non-opioid alternatives for pain management. Therefore, CMS proposes to continue its policy to pay separately for non-opioid pain management drugs that function as surgical supplies in the ASC setting, but continue packaging in the HOPD setting, for CY 2022.

¹ 84 F.R. 61176-61180

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The misuse and abuse of prescription opioids has increased dramatically over the last decade, and the ACS appreciates CMS' efforts to identify and eliminate regulatory obstacles that inhibit utilization of non-opioid alternatives for pain management, including those obstacles related to coverage and reimbursement. **We support the Agency's proposal to continue to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in ASCs; however, we continue to urge CMS to expand this policy and allow for unpackaging of non-opioid pain management in all care settings where surgery is performed.** These therapies are often cost-prohibitive for facilities under current Medicare policy because the fees associated with the provision of non-opioid medications—which may be significantly more expensive than opioid therapy—are bundled into the overall payment for “supplies” related to surgical procedures, such that a non-opioid medication is paid at the same fixed Medicare rate as an opioid for postoperative pain management, regardless of the difference in the cost of the two drugs.

Additionally, we believe that the Agency's current method to evaluate utilization of non-opioid alternatives—under which CMS reviews Medicare claims data for certain drugs before and after their pass-through status expired—is too narrow and excludes other factors that may be stronger indicators of the accessibility and use of opioid-sparing therapies by physicians and facilities. We thereby encourage the Agency to investigate other barriers to access to non-opioid postsurgical pain management alternatives beyond pass-through payment status. The ACS suggests that CMS create a new Current Procedural Terminology (CPT) code or modify existing codes to account for the work associated with opioid-sparing therapies furnished by surgeons, which we believe would provide the Agency with reliable claims-based data for a more extensive group of surgeon-administered non-opioid alternatives—including neural blockades and intravenous acetaminophen, among others—and enable CMS to better track utilization and identify access barriers via Medicare billing trends.

PROPOSED SERVICES THAT WOULD BE PAID ONLY AS INPATIENT SERVICES

Proposed Changes to the Inpatient Only (IPO) List

CMS proposes to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list, the Agency proposes to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. **The ACS strongly opposed the elimination of the IPO list for CY 2021, and we thank CMS for acknowledging our objections by proposing to reinstate the**

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list—which serves as an important programmatic safeguard, maintains a common standard of clinical judgment in the Medicare program, and is a valuable tool for ensuring that OPPI payment is only made for services that can safely be performed in the hospital outpatient setting—and to readd the 298 services summarily removed last year for CY 2022.

Topics and Questions Posed for Public Comments

In addition to its proposal to halt the elimination of the IPO list and return services previously removed from the IPO list for CY 2021, CMS seeks feedback from stakeholders on whether the Agency should maintain the longer-term objective of eliminating the IPO list. **The ACS does not support a long-term effort to eliminate the IPO list.** As stated in our previous comments to CMS, we agree with the removal of certain services from the IPO list for which there is evidence that they can safely be furnished in an HOPD or ASC. **However, we are extremely concerned by any broader policy to arbitrarily remove various IPO procedures from the list that do not have sufficient data to support the appropriateness of their performance on an outpatient basis.** We note that, when CMS eliminated the IPO list for CY 2021, it failed to provide any discernible rationale or description of efforts undertaken by the Agency to thoroughly examine each service on the IPO list and provide evidence that all such services can safely be performed in the outpatient setting.

CMS proposes to codify in regulation the five longstanding criteria used to determine whether a procedure or service should be removed from the IPO list. **We urge CMS to finalize the codification of these criteria and to maintain an annual IPO review process to identify procedures that should be removed or added, which offers stakeholders an opportunity to provide input and has historically been an effective mechanism to gather reliable and objective data regarding the safety and efficacy of procedures furnished in the outpatient setting.** We question if, in the absence of regulatory guardrails and clinical evidence to substantiate either (1) elimination of the IPO list in CY 2021, or (2) a longer-term objective of eliminating the IPO list, CMS has considered the potential negative consequences of such policies—several of which are outlined below—for Medicare beneficiaries, as well as for the physicians and hospitals participating in the Medicare program.

Patient Safety and Access

The various procedures on the IPO list have inherent risks, many of which pose a threat to even the healthiest of patients, but particularly to the older and sicker Medicare population. Eliminating the IPO list would make major and complex procedures that typically require extensive inpatient treatment—such as trauma-

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related pelvic, acetabulum, hip and fragility fractures and amputations—payable in the outpatient setting. The ACS does not believe that, even with advancements in medical practice and technology, such complicated procedures can be provided safely in the outpatient setting. We remind CMS that even if a procedure may be performed safely in an outpatient site of service, the risk to the patient does not end when the patient is moved out of the operating room. Instead, the patient may face more risk in the postoperative period, and therefore require the resources and capabilities of an inpatient setting to prevent or manage complications following the procedure.

We are also concerned by the implications that a mass shift of procedures to the outpatient setting would have on the accessibility and affordability of care for Medicare beneficiaries. We wish to highlight that, per CMS rules, the copayment for a single outpatient hospital service cannot be more than the inpatient hospital deductible; however, a patient's total copayment for the cumulative cost of all outpatient services related to a single procedure may be equal to an amount greater than the inpatient hospital deductible.² Therefore, patients treated in the outpatient setting may be subject to increased out-of-pocket costs that exceed the costs incurred had they been treated in the inpatient setting. **The ACS does not support any policies, such as the elimination of the IPO list, that may inappropriately shift cost onto patients and therefore discourage beneficiaries from seeking necessary care.**

Administrative Burden

The elimination of the IPO list would create increased documentation and audit burden for physicians and hospitals, and we question how CMS could eliminate the IPO list without first publishing specific program integrity and reporting guidelines to support provider education and compliance. When the list was eliminated in CY 2021, the Agency failed to specify how utilization reviews would occur for procedures performed on an inpatient basis once they are removed from the IPO list, and it remained unclear how physicians should have indicated that the provision of a service in the inpatient setting was reasonable and necessary, if obtaining prior authorization was required, and when organization determinations would be made by CMS or its contractors. **We do not understand why CMS would ever eliminate a reliable and comprehensive list of services for which site-of-service reviews do not apply, leaving much room for confusion and delays in care as physicians, hospitals, and coding staff are**

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² Centers for Medicare & Medicaid Services. (2020). *Inpatient or outpatient status affects your costs*. What Medicare Covers. Retrieved from <https://www.medicare.gov/what-medicare-covers/what-part-a-covers/inpatient-or-outpatient-hospital-status>



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stripped of clear guidelines for proving the medical necessity of inpatient care.

We are also concerned that other payors, including Medicare Advantage plans, would use the lack of the IPO list as a means to inappropriately force patients into the outpatient setting for cost-only reasons, regardless of the decisions made between the patients and their surgeons. In the CY 2021 OP/ASC rule, CMS itself stated that stakeholders have informed the Agency that removing a service from the IPO list creates expectations that the service must be furnished in the outpatient setting “regardless of the clinical judgment of the physician or needs of the patient.” We were disappointed that CMS disregarded this stakeholder feedback and eliminated the IPO list for CY 2021 without instituting any safeguards against inappropriate behavior forcing procedures into the outpatient setting.

We reiterate that we do not believe that CMS has applied a serious clinical review of the services on the IPO list and seek clarification from the Agency about the general purpose for its potential longer-term objective of eliminating the IPO list. High-quality surgical care involves much more than providing services at the lowest possible cost, and CMS should not eliminate the IPO list as a mechanism to allow any procedure to be performed as an outpatient service without evidence of patient safety. As noted above, complications can occur with any surgical procedure, particularly during the post-operative period. For many services on the IPO list, such complications will be best identified early and treated promptly in the inpatient hospital setting. We believe that CMS would greatly benefit from coordinating with the surgical community to identify which specific procedures on the existing IPO list may be safely provided in an outpatient setting, instead of simply selecting a subset of codes for removal without first seeking input from the relevant specialty societies. We urge the Agency to adhere to the notice-and-comment rulemaking process and officially propose any changes to OP/ASC payment rules with an adequate explanation of such proposals—including objective data analyses, clear coding and billing rules, protections for patient safety and care quality, and other details—before finalizing any policy as significant as the elimination of the IPO list.

PROPOSED NONRECURRING POLICY CHANGES

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years

Medical Review of Inpatient Hospital Admissions for Procedures Removed from the Inpatient Only List for CY 2022 and Subsequent Years

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As finalized in the CY 2021 OPPI/ASC, procedures removed from the IPO list after January 1, 2021 were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC-QIO) referrals to Recovery Audit Contractors (RACs) for noncompliance with the 2-Midnight rule, and RAC reviews for “patient status.” Because CMS now proposes to halt the elimination of the IPO list and add 298 services that were removed back to the IPO list, the Agency believes that there will no longer be an unprecedented volume of procedures removed from the IPO list at once, and thus the indefinite exemption may no longer be warranted.

Accordingly, CMS proposes to rescind the indefinite exemption and instead apply a two-year exemption from 2-Midnight medical review activities for services removed from the IPO list on or after January 1, 2021. **The ACS supports CMS’ proposed two-year exemption from 2-Midnight medical reviews, as we believe that such exemption would allow sufficient time for physicians to become more familiar with appropriate coding, billing, and documentation requirements for procedures removed from the IPO list, develop patient selection criteria to identify which patients are appropriate candidates for outpatient procedures, and to develop related policy protocols.**

Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 amends section 1833(a) of the Social Security Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test.³ Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance), results in the beneficiary having to pay coinsurance. The reduced coinsurance will be phased in beginning January 1, 2022.

We thank CMS and Congress for addressing surprise medical bills related to colorectal cancer screening and diagnostic services, and support the elimination of coinsurance for such services to reduce out-of-pocket costs for Medicare beneficiaries. We encourage the Agency to consider how to address additional cost-sharing issues that may arise as new colorectal cancer screening

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³ Pub. L. No. 116- 260



technologies (e.g., Cologuard) continue to emerge and increase in Medicare utilization relative to flexible sigmoidoscopies and screening colonoscopies.

ACS STRATEGIC COMMENTS ON QUALITY, VALUE, AND INTEROPERABILITY

As the U.S. health care system begins to transition to Value-Based Health Care (VBHC), the ACS believes it is important to define value based on what matters to the patient. Patient-centered value is about the judgment applied by a patient and their family for care that meets their goals at an affordable price. A patient’s interpretation about their care is relative to their personal values for quality, safety, access, inclusiveness, price, trustworthiness, appropriateness and so forth.

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). 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, making it difficult to incentivize care coordination and fails to put the patient first.

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?



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For a payment incentive program, it may seem rational to create a numeric equation ($\text{Value} = \text{Quality} / \text{Cost}$ and the 4 weighted categories of Merit Incentive-based Payment System [MIPS] for example). Instead, we find this has resulted in surgeons chasing payment incentives in the MIPS program, and separately in the outpatient and ASC measures, inpatient hospital measures, and so forth. Since efforts are not patient-focused, this results in an inability to find quality as a program, quality improvement, or useful metrics to help the surgical care team optimize patient's goals and expectations of care.

The ACS measures success of a quality incentive payment program from two perspectives: (1) Do the quality measures form a summary on Care Compare that helps patients find where to get safe and affordable care? and (2) Do the quality measures provide incentives for building care teams focused on quality improvement for the most common episodes of care they provide? Subtle distinctions are present when we think of quality metrics or quality as a program for patients. We discuss these distinctions and offer a framework for defining patient-centered value below.

Challenges with Value Defined for Payment

Under the current fee-for-service (FFS) system, each service and facility have their own structure for billing and revenue. This payment business model 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, thus 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, facility, 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. Often the metrics being aggregated across the various payment approaches do not reflect the same patient types and are not complementary. The quality teams are working within misaligned systems that

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are focused on single metrics for purposes of compliance, instead of investing in programs built on verified standards around a family of patients to produce true high-quality care. We have heard many examples of this from ACS Fellows where their employers are requiring physicians to adjust the way they deliver patient care simply to avoid payment penalties. One example is that facilities have created quality protocols to remove foley catheters in an attempt to meet the catheter-associated urinary tract infections (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 three to five 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) as well as 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.

Opportunities with Defining Value for Patients

The 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, and builds the teams and infrastructure needed to deliver on patient goals. This framework also aligns facilities and teams to organize around the patient as they move throughout the healthcare system.** 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 and results in the team organizing around the patient with shared accountability by breaking 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 the environment needed to deliver optimal care and assist in reaching quality goals.

The ACS has observed a transformation of healthcare from silos of care into team-based episodes of care (EOCs) 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 Institute of Medicine (IOM) reports on quality, and more. 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

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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 used in payment has not kept pace with the evolution of the care model into complex teams working across a care journey. Trying to squeeze this care journey accountability transformation into the current silos scattered across a FFS payment program with fractured metrics of care is counter-productive to this transformation. This results in a greater focus on payer policies and regulations while real quality is taking a backseat, detracting 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, or similar quality 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)
5. Patient-Reported Outcomes (PROs) to include the patient's voice in determining the successful outcome of the intervention from the patient's perspective

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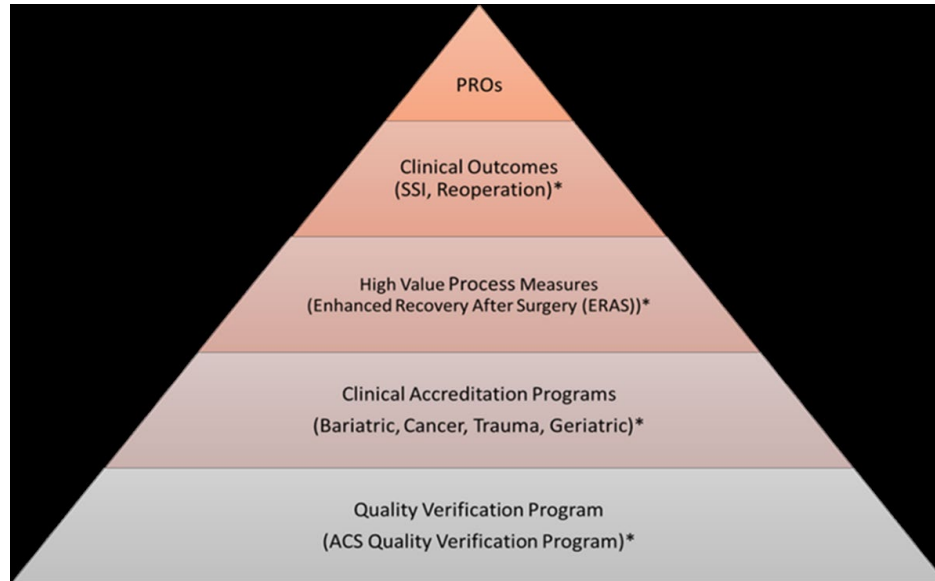
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Figure 2: Key Components of a Surgical Quality Program



*Indicates example

One incredibly important distinction that we cannot overstate is that CMS must first consider what constitutes a quality program for a condition, or the associated episodes of care within the condition, so facilities and surgical teams have what is needed to deliver optimal care. Programmatic alignment across facility and physician programs is critical to achieve this. 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.

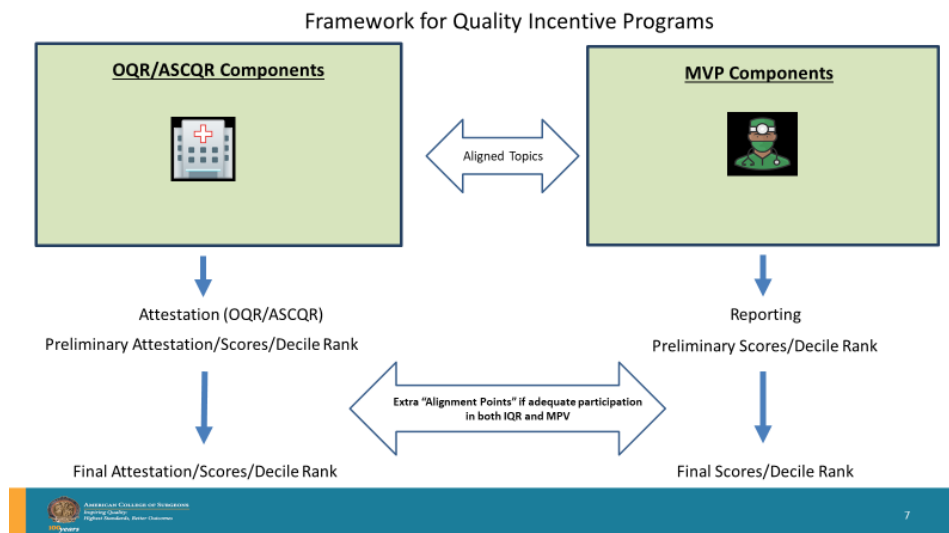
Squeezing metrics into a series of payment programs designed for FFS might have been the way to initiate the transition to quality. However, it is now time to realize that to implement APMs as a vehicle to move quality from its current silos to a program that is more ideal for delivering care, we need to consider the roadmap from FFS to measuring quality from a patient's perspective in their EOC. While awaiting the APMs focused on EOCs, perhaps the maturity model for this transition should begin in the Center for Medicare and Medicaid Innovation (CMMI). CMMI would be an excellent resource for implementing 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. There are many challenges to work through for an implementation that would serve all stakeholders and meet statutory requirements. In order to incentivize a comprehensive surgical quality program, we assert that the payment program should begin by:



1. Addressing the comprehensive patient journey and patient goals across the five phases of surgical care
2. Linking clinicians and facilities to create shared accountability
3. Include structure, processes and the tools needed for performing quality improvement (QI) across the surgical team
4. Reflecting proper alignment, structure, processes, and outcomes
5. Offering incentives for physicians and hospitals/facilities that rely on interrelated quality measures
6. Rewarding 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) adding critical structural measures; and 4) investing in the development of PROs.** Not only would this offer a more meaningful measurement framework for facilities and physicians, but 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 Outpatient Quality Reporting (OQR) program and MIPS.

Figure 3. Framework for Quality Incentive Programs



When aligning across a condition (or “topic”) the facility would attest in the OQR or Ambulatory Surgical Center Quality Reporting (ASCQR) program to providing the resources/infrastructure/educational opportunities to deliver on patient goals. To incentivize this alignment across clinician and facility programs, it will



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initially be critical to offer alignment points or other benefits. 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 ultimately uncover disparities in care and is the first step in addressing health equity.

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 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.

PROPOSED REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

Modifications to Previously Adopted Measures

Proposal to Require OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning with Voluntary Reporting for the CY 2023 Reporting Period and Mandatory Reporting Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination and for Subsequent Years

Beginning with the CY 2024 reporting period, CMS proposes to restart the OP-37a-e measure by requiring the measure in the Hospital OQR Program. CMS previously adopted the measures to assess patient experience, but subsequently delayed their implementation due to lack of sufficient operational and implementation data. CMS proposes voluntary data collection and reporting beginning in 2023, and mandatory data collection and reporting beginning with CY 2024.

Gathering patient experience data is a critical part of quality improvement efforts and understanding how care aligns with patient goals. **ACS seeks further**

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information on the effect the CAHPS surveys have on care delivery and quality improvement. While we have heard from physicians that administering and collecting the CAHPS survey data is burdensome from the operational perspective, we wonder if the surveys may have a positive, indirect effect on the way physicians communicate with patients. An evaluation of the effectiveness of the CAHPS surveys would help CMS better understand who is benefitting from the information learned from the surveys and if the survey data is informing improvements in care delivery. It would also inform CMS of what is missing from CAHPS, or if there are other tools that could provide more nuanced condition or procedure-specific information that would offer more value to patients. **Therefore, the ACS recommends that CMS continually review these types of tools to ensure that they are providing the most valuable information to patients, physicians, and payers.**

We also expect that patient experience and patient reported outcome measures (PROMs) will evolve. The initial measures tend to be broad in nature and represent a blunt instrument. As the measure science matures, we envision measures becoming more condition-centric by describing how the care delivered met the patient's goals and their expectations for the quality of life for their condition. It may be that future measures are highly specified for a condition while being broadly expressed for meeting the patient's needs.

Hospital OQR Program Measures and Topics for Future Considerations

Request for Comment on Measures That Address Quality in Hospital Outpatient Setting of Procedures that Transitioned from Inpatient Setting

Considering the CMS proposal to halt the elimination of the IPO list for CY 2022, CMS seeks comment on the potential future adoption of measures that would allow better tracking of quality of care for services that transition from the IPO list and become eligible for payment in the outpatient setting. It is critical that CMS examines ways to evaluate the quality of these services as they move to different care settings to ensure that there is not a decrease in quality or safety. This is particularly important since the current criteria employed by CMS for determining whether procedures on the list should be removed (and thus payable under the OPSS) do not account for the impact that change would have on quality of care. Also important to consider is determining where procedures can be performed goes beyond the cost of delivering care. **Physicians should always have the autonomy to determine the care setting that will support the best outcomes for patients.** Every patient is different, and a patient's ability to recover at home will not always be the same. For example, in some cases, a procedure, such as a hernia repair, may be safely performed as an outpatient

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procedure, but a more complex patient will need more postoperative monitoring and may not have the same ability to recover at home.

The ACS also recommends that CMS create a strategy for transitioning procedures from the inpatient to the outpatient setting to ensure they can be safely performed. For example, when surgeons transitioned from performing open to laparoscopic cholecystectomy, they did not make an automatic leap from the inpatient setting to the ASC. They went through a series of phases where patient experiences, safety, and overall outcomes were tracked. First, surgeons cautiously moved to a shortened hospital stay, then to overnight stay in the ASC, and finally to a 23-hour stay. Within each of these steps there was a series of intentional safety checks to ensure that there were no unintended consequences caused by making a dramatic shift in the site of care. In addition, CMS must acknowledge that when a procedure moves from the inpatient to the outpatient setting, more care coordination in the preoperative and postoperative phases is required. The inpatient setting is more supportive of end-to-end patient care. **To ensure that patients continue to receive coordinated and integrated care, we recommend CMS develop a regulatory oversight and quality tracking process that ensures patients are receiving the same end-to-end care as the procedures move to the new environment.**

In addition, we remind CMS that as more procedures transition to ASCs, this will impact hospital revenue streams and business models. Hospitals typically must cross subsidize services to fund their various departments. As more services move to the ASC setting, we recommend that CMS consider repricing the remaining underfunded inpatient procedures. In conclusion, it is paramount that physicians always have the autonomy to make decisions that support the best patient outcomes, but we acknowledge that the business model may need to be rebalanced to provide the best care for the community.

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

CMS requests comment on the potential future adoption of a respecified version of a patient-reported outcome-based performance measure (PRO-PM) for two procedures—elective primary THA and TKA, which were removed from the IPO list effective with CY 2020 and CY 2018, respectively. The measure reports the hospital-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare beneficiaries aged 65 years and older. The ACS is supportive of CMS' continuing efforts to incorporate PROMs into federal quality incentive programs. The ACS has extensive experience developing

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and implementing quality programs in various surgical domains using the ACS Quality Model. As discussed in previous sections, the ACS Quality Model incorporates PROs, verification standards, and event rate reporting, with the largest emphasis on PROs. Given this, as CMS thinks about the most effective way to adopt PROMs, **we recommend they first develop a strategy that allows for multi-stakeholder input throughout PRO development and considers the data collection methodologies, functionalities that allow rapid real-time feedback, and continuous innovation cycles. The strategy should also ensure that the PROs are focusing on the interests of the patient, clinician, and payer.**

From the ACS perspective, the current focus should be on developing PROs that can be broadly applied across the surgical domain and can advance to become more specified to conditions, such as cancer, then further advanced for highly specified conditions, such as breast or colon cancer. Multi-stakeholder efforts are required to transition from general to specific PROs. Stakeholder groups, such as specialty societies, can be helpful in maintaining PROs as they can leverage their data from clinical data registries or other data sources to aggregate and test PROs. These groups will also be critical in driving innovation in PRO development. There are also opportunities to incorporate equity and inclusion variables in PROs. This should be considered as these measures are piloted and tested. To understand how these measures perform across various patient populations, it is important that they be piloted and tested in various care settings, such as hospital outpatient centers, rural community hospitals, urban health centers, safety net hospitals, and academic health systems.

The foundational goal in developing and implementing PROs should be to get a point where we can provide patients with valuable information as they make decisions about their care, including choosing a clinician. Patients should be able to search by condition and learn more specific information about the care they might receive from the physician and the facility. Patients want more information than they are given now through star ratings and the Care Compare site. **To offer more valuable information for patients, the ACS advocates for the development and adoption of reliable and valid PROs focused on patient goals for their care.**

Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program

Low patient socioeconomic status (SES) has demonstrated adverse impacts on surgical care. Limits on resources, lack of preventive care, poor early detection, and limited chronic care maintenance are some of the factors that contribute to surgical care inequities. Part of CMS' strategy to address health inequities is to:

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improve data collection, consider ways to measure and report on equity to better identify and understand health disparities, develop and disseminate solutions to achieve health equity, and implement sustainable actions to achieve health equity. The ACS commends CMS on the issues and questions raised in this RFI and is committed to closing the health equity gap. As the American College of Surgeons, we witness the many dimensions of inequities in surgical care and seek to use all our resources to help the nation overcome the barriers of inequities.

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

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

In this RFI, CMS discusses initiatives to bridge the health equity gap.

1) Introduction and Expansion of the CMS Disparity Methods to Hospital OQR Program Setting

Findings in ACS National Surgical Quality Improvement Program (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.⁴ These findings have led to more research questions, including the need to analyze unadjusted inpatient NSQIP data—will the raw, unadjusted NSQIP data show a preponderance of uncontrolled chronic conditions when stratified by race and ethnicity? Are cancers detected at a later stage in certain groups? In other words, we must shine a light on the problem and avoid risk-adjusting away the differences for purposes of quality improvement and improving health equity. It is important to highlight the chronic conditions of patients who require acute care and the impact those conditions have on outcomes. An uncontrolled diabetic or hypertensive patient will fare worse if they need acute surgical services. We believe this approach aligns with the CMS intent for improving care for complex patients.

Additionally, when we consider the healthcare journey of patients in a safety net system, many of these aspects to support population health are simply not present or inadequately resourced. Safety net care is stretched beyond its limits in acute care. When measured on raw scores for event rates such as SSSI, 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. **The ACS stands ready to help in the development of standards for aggregation and to work toward the inclusion of the social determinants of health (SDOH) as part of the surgical team’s dashboard.**

Currently, CMS is considering expanding how they provide feedback on quality measures in the hospital outpatient setting to include the results influenced by disparities by stratifying measures for race and ethnicity. 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, thereby allowing for a comparison among

⁴ This work has not been published in peer-reviewed literature.

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hospitals on their performance caring for their patients with social risk factors. These methods were first confidentially reported in the inpatient setting in 2019 for the Pneumonia Readmission (NQF#0506) and Pneumonia Mortality (NQF#0468) measures, stratified dual eligibility for Medicare and Medicaid. Confidential reporting for hospitals has since expanded to include additional measures. CMS requests comment on the idea of stratifying the performance results of the following six OQR measures:

- MRI Lumbar Spine for Low Back Pain (OP-8)
- Abdomen CT – Use of Contrast Material (OP-10)
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP-13)
- Facility 7-Day Risk-Standardization Hospital Visit Rate after Outpatient Colonoscopy (OP-32)
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35); and
- Hospital Visits after Hospital Outpatient Surgery (OP-36).

The first three measures listed—*MRI Lumbar Spine for Low Back Pain (OP-8)*; *Abdomen CT – Use of Contrast Material (OP-10)*; and *Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP-13)*—are designed to track appropriateness of care. The following three measures—*Facility 7-Day Risk-Standardization Hospital Visit Rate after Outpatient Colonoscopy (OP-32)*; *Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35)*; and *Hospital Visits after Hospital Outpatient Surgery (OP-36)*—focus on event rates.

To start, the ACS seeks clarity on what CMS hopes to achieve by stratifying these measures for race and ethnicity. What will be the hypothesis, scope, and analysis of this work? In assessing appropriateness by race and ethnicity, are there concerns about disparities that would reflect differences in available services based on race and ethnicity? In assessing care safety using event rates, does CMS expect to assess for disparities related to endoscopy, chemotherapy, or outpatient surgery? Measure selection should have a strategic direction so that the results will inform and direct corrective actions. Perhaps the goal is to shine the light on the disparities and to give additional resources to facilities with sicker and more complex patients. In general, facilities with a preponderance of underinsured, such as those represented by dual eligibility, will typically look worse when compared to most private facilities that typically see less complex patients.

Understanding the goals for the knowledge gained would help in determining the proper utility of these measures. 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. If for

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accountability, risk adjustment methodologies are crucial. If for defining a resource need, it is less about risk adjustment and more about resource adequacy.

While sharing this information with facilities might give them some understanding of how many dual-eligible patients they treat and their outcomes, there are still elements of the stratification and data collection methodologies that need to be improved to provide meaningful feedback. Caring for some dual-eligible patients will require more resources and care management support to overcome the complex mix of comorbidities. While appropriateness measures often suggest areas of overuse, these measures may also help indicate where there is underuse in the dual-eligible population. Identifying this cohort for underuse can help inform future research questions to address factors such as mental health, housing, and transportation. Timely and appropriate care will lead to overall better patient outcomes. Therefore, a greater impact could be made to improve care for these patients if resource needs are identified and action can be taken to fill observed gaps in care.

CMS must also remember that many factors might contribute to an adverse outcome, and the adverse event may not be related to receiving poor care. These measures may not help to identify the true cause of the visit to the ED or hospital following an outpatient procedure. We question how CMS will accurately identify race and ethnicity given the many limitations of the current data. 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. There is too much noise in the data that CMS currently uses to stratify for race and ethnicity, making it impossible to draw trustworthy conclusions and identify disparities, especially how they relate to adverse events. The results may yield nothing more than a guess as to the cause for any noted variations. This confounds where to focus in on problem identification. 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 to ensure that we do not do more harm than good, we need much better data to determine the best way to begin this work.

2) *Additional Social Risk Factors*

CMS notes the many limitations of stratifying for race and ethnicity because the Agency does not consistently collect self-reported race and ethnicity information for Medicare programs (the gold standard). Instead, CMS utilizes data from the Social Security Administration (SSA) which is less accurate. Therefore, the

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Agency is working on efforts to develop consistent data on SDOH. For example, CMS has developed an Inventory of Resources for Standardized Demographic and Language Data Collection and supported the collection of ICD-10 codes for socioeconomic, cultural, and environmental determinants of health. CMS has also supported initiatives to statistically estimate race and ethnicity. Office of the National Coordinator for Health IT (ONC) has included social psychological and behavioral standards in 2015 certified electronic health record technology (CEHRT)—however, this functionality is not included as part of the certified EHR technology required by the Promoting Interoperability performance category. The new release of USCDI v2 includes gender information, social determinants, and sexual orientation. Because these efforts to collect these data are a significant undertaking, CMS believes there is a need to identify better race and ethnicity in the short term. As a short-term solution, CMS seeks feedback on the application of an algorithm to indirectly estimate race and ethnicity of Medicare Beneficiaries using a combination of other data sources that are predictive of race and ethnicity to permit stratification of measures in the aggregate (facility-level) until more accurate forms of self-identified demographic information are available. CMS notes that despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration, there is a small risk of unintentionally introducing measurement bias. **Overall, 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.**

In addition, the current payment system also adds complexity to the scope of this work—caring for dual-eligible patients can be clinically 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.

Quality Measure Recommendations

CMS seeks recommendations for other types of quality measures or measurement domains to prioritize when stratifying by dual eligibility, race and ethnicity, and disability.

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Measures of Inclusivity

The ACS strongly supports the development of PROs and patient experience measures to gather feedback directly from the patient without interpretation of the patient's response by a clinician or anyone else. CMS should prioritize measures that focus on patients' feeling of inclusivity. **Inclusivity measures are a much-needed area of development in health care and could encompass a patient's experience when 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.

Measures of Access

Another area for consideration is measures that focus on access to surgical care. These types of measures can provide information on whether patients gained timely access to a surgeon when/if they needed surgery. This could be a set of measures that track whether the system was able to ensure 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.

Measures of Patient Risk

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

3) Improving Demographic Data Collection

CMS seeks comments on the possibility of facility 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.

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

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

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

If the collection of these data were more commonplace, we envision integrating it into clinical workflows through clinical decision support (CDS) modules available through the physicians' EHR and other platforms. Throughout the phases of care, the CDS tools could apply algorithms that evaluate the patient's

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electronic health information (EHI), including other risk variables, to trigger follow-up reminders and alerts for certain medications or interventions specific to the patient's needs.

To achieve more widespread collection, aggregation, and tracking of SDOH data, improvements in collection methodologies and standardization are necessary across the entire healthcare system. In many instances these data are not widely collected, and if they are, there is variation in how it is identified, classified, and what fields are used in EHRs and other systems. While some systems have taken steps to develop and implement internal processes to administer surveys and gather self-reported data from patients, these practices are not widely adopted and there is still much to be done to address the gaps. **From the ACS perspective, the development of standardized data definitions for race, ethnicity, and SDOH is a foundational barrier that if addressed, would allow stakeholders to gather more complete data sets that can be leveraged for research, quality measurement, and much more.**

Combatting Bias Resulting from Use of Digital Health Tools

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

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

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also be applied periodically following the implementation of the tool, to ensure that as the algorithms take in real-time data, they are still achieving a high-level of accuracy.

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

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

PROPOSED UPDATES TO THE AMBULATORY SURGICAL CENTER PAYMENT SYSTEM

Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

Proposed Changes for CY 2022 to Covered Surgical Procedures Designated as Office-Based

CMS proposes to designate new CPT code 42XXX (*Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic*) as temporarily office-based for CY 2022. CMS states that it is assigning a temporary office-based status for this service based on a review of its clinical characteristics, utilization, and volume of related procedure codes. **We seek clarity from CMS regarding the premise of such designation—even if it is temporary—when CPT code 42XXX has not been priced for the office setting.**

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PROPOSED REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM

Proposed Changes to Previously Adopted Measures in the ASCQR Program Measure Set

Proposal to Require Previously Suspended Outcome Measures ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and Subsequent Years

In the CY 2019 OP/ASC proposed rule, CMS proposed to remove the *ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission* measures from the ASCQR because the measure performance was so high and unvarying that meaningful distinctions and improvements in performance could no longer be made. At that time CMS decided not to remove the measures based on stakeholder feedback, but CMS did finalize a suspension of these measures citing concerns that the data collection method could impact the completeness and accuracy of the data submitted by ASCs. The data collection method required specific Quality Data Codes (QDCs) to be added to eligible claims, and ASCs cannot correct the QDCs if the claim had been submitted and processed for payment. Beginning with the CY 2023 reporting period/CY 2025 payment determination, CMS proposes to again require and resume data collection for these measures. ASCs would be required to submit data using the hospital quality reporting (HQR) system. **The ACS agrees that these are important events to report and track. However, due to the rarity of these events, we do not believe that these measures should be part of a payment incentive program. We suggest that CMS consider determining a threshold for how many of these events can be allowed, and should a clinician or ASC surpass the threshold, the information should be publicly reported if it is reliable and valid.**

ADVANCING TO DIGITAL QUALITY MEASUREMENT AND THE USE OF FAST HEALTHCARE INTEROPERABILITY RESOURCES (FHIR) IN OUTPATIENT 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

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various areas that will provide pathways for greater quality data collection and advanced interoperability.

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

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

1. Support the use of CDS to make clinical guidelines and pathways available as a digital service through platforms that are not constrained by proprietary efforts from EHRs.
2. Support the ability to gather condition or procedural cohort data for outcomes reporting and to assess conformance with guidelines-based care.
3. Support data aggregation and analytics for near real-time research and clinical trials for expanding sample sizes in randomized clinical trials (RCTs) and observational studies.
4. Support quality metrics payers seek for their payment incentive programs in a patient centered manner.

These open architecture platforms are essential to expand medical knowledge management and optimize care. By using open standards-based platforms, data can be assembled for the individual patient (not the single EHR level) to build a

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patient perspective inside health information exchanges (HIEs) and allow for more shared and coordinated care. This architecture can meet and exceed the payer needs for quality metrics as well as enrich clinical knowledge. Retooling the healthcare industry for digitally supported knowledge enhancements takes considerable capital investment. If Medicare continues to distract the health informatics development and operations (DevOps) by focusing merely on metrics tied to payment activities, these capital needs to support better outcomes will be delayed. **We encourage the Agency to think more broadly about the underpinnings of digital healthcare so that the four aspects of care outlined above--CDS, cohort analytics, research, and payer metrics--are recognized in the same capital plans.**

Furthermore, digital tools that enhance quality programs or enable payer metrics should be engineered with an architecture that can be implemented and scaled on an open standards-based platform that deploys open source, standards-based infrastructure, such as Fast Healthcare Interoperability Resources (FHIR), HL7 V2 messaging, etc. The Amazon Health Lake⁵ is an example of this architecture that offers such engineering and an array of advanced digital services, such as natural language processing and more.

Additionally, as CMS continues to require that certain digital services be implemented in EHRs, we ask that they consider all aspects of implementation, including cost to the system. Many EHR vendors have added these required digital services to their systems at a cost beyond reason for an open market. Their proprietary, closed systems still have not fulfilled the intent of the Congressional efforts to overcome the bidirectional impacts of EHR vendor data blocking. To fully reduce the burdens of implementation, the digital environment needs an open marketplace that can absorb these costs. It is not enough to reduce clinical burden of data aggregation if the fiscal burden of constrained, proprietary vendor actions consume more and more of the precious healthcare resources. In addition to affordable digital services, as data flows from the EHRs into clinical analytics, the EHRs should also provide a reasonable and affordable environment for data to become available to the EHR from other sources, such as the platforms and data lakes mentioned above. Without this ability, the EHRs will continue to data block elements of care.

Definition of Digital Quality Measures

CMS requests input on developing a definition of a digital quality measure (dQM). The Agency considers defining a dQM “as a software that processes

⁵ Amazon Health Lake. Retrieved from: <https://aws.amazon.com/healthlake/>

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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 (EHRs)
- Instruments (such as, medical devices and wearable devices),
- Patient portals or applications,
- HIEs, and
- Registries, etc.

To support a “quality program” framework, we suggest that CMS change its emphasis from aggregating data with dQMs that focus on single metrics to developing a definition for the digital enhancement of quality improvement programs. Regarding the data sources that can be used to gather electronic health information (EHI), we suggest that CMS expand this list further to include data lakes which offer or host an array of emerging digital services. These could include services such as cohort identification, natural language processing, connectivity to HIEs to build patient profiles for specific conditions, and case management systems. In fact, sophisticated services can track care conformance with guidelines using process management or case management software, as well, such as BPM+ Health. We believe this approach encourages patient portals and applications that would consider separate data sources, instead of grouping them together in a large unmanageable single database. **Further, we ask that CMS include other patient-centered platforms, such as those hosted by specialty societies as a means for aggregating data to better inform patients and their providers.**

Digital tools will be an essential part of the continued enhancement of quality programs. The ACS envisions utilizing digital tools to track progress (such as clinical care or improvement cycles) and attest to meeting standards within the domains of quality verification programs. Not only could digital tools be used to attest to certain activities, but with the proper algorithms, the tools could automatically track relevant patient outcomes in real-time. This information could be displayed as a dashboard 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 facility participation in quality programs to be maintained and assessed automatically.

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Use of FHIR for Current eQMs

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

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

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

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

In this RFI, CMS discusses potential approaches for including quality measures that use standardized data and interoperability requirements that have expanded flexibility and functionality beyond CMS' current electronic clinical quality measures (eCQMs). The Agency is considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others that can calculate measure scores, and produce reports. This is an extremely important step in redesigning digital quality measures and supporting the data flows needed for running a comprehensive quality program.

Transitioning to self-contained tools that can track patients across the care continuum by gathering and analyzing data for quality metrics, PROs, as well as assess conformance with the care plan will be highly valuable in driving improvements in care.

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

CMS is considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. CMS also states that they are considering similar policies for third-party aggregators. **The ACS suggests that CMS also consider clinical association platforms, patient ID hubs within the HIE, and other similar patient-centered platforms as other sources of data aggregation for quality measurement.** We also have the technology to support tracking patients within appropriate firewalls to protect their identity while 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 the HIE. The data are then sent to a data lake where the data are aggregated and can be shared back to the platform where physicians can view the analyzed data in a dashboard.

The ACS asks CMS to understand the need for a knowledge management strategy that is all-encompassing and not piecemeal. It would be burdensome if each delivery site had to meet differing requirements to interface with each data aggregator to suit their customized needs of data. CMS could be instrumental in promoting all the digital information now being aggregated for use in optimally informing patients and their clinical teams. The ultimate goal of digital information is more than providing payers with quality metrics for payment.

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Digital information enables shared knowledge across care teams and with patients and their families. These shared knowledge assets help meet the needs in care process management, case management across the care continuum, outcomes assessment, safety, conformance with guidelines, and so forth. By enhancing the overall shared knowledge in a care environment, we move data from being a burden used in quality metrics for payment to becoming a key asset for optimal care.

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

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

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

The ACS has been a strong advocate for alignment across CMS quality programs. If CMS moves forward with this concept, CMS should not only align the current CMS quality measures across their programs, but also develop new measures that are aligned across a condition or the patient's total episode of care for purposes of quality improvement, including key process, structure, and outcome measures as part of a comprehensive quality program. These types of measures can then be used as actionable feedback for care teams in addition to meeting reporting requirements for federal programs. The ACS takes measure of CMS payment incentive programs by assessing how useful the information that emerges would be for patients and for their clinical teams. We ask if the CMS measures bring the various teams and elements of care together to inform care and drive teams to deliver care more optimally? The ACS wonders how CMS measures success of their program. Does CMS measure success based on the level of participation in measurement, the number of participants who received payment awards? We also ask how CMS evaluates the patient's use of Care Compare website and the value of the information they offer? **It would be helpful for CMS to provide more clarity on how they assess the successes and failures of their payment incentive programs.**

ADDITIONAL HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM POLICIES

Safe Use of Opioids- Concurrent Prescribing eCQM and eCQM Reporting Requirements in the Hospital IQR Program – Request for Information

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CMS seeks to gather input on the Safe Use of Opioids—Concurrent Prescribing eCQM as CMS prepares for NQF re-endorsement of the measure. The measure is scheduled to be submitted to the NQF in 2022. The measure assesses the proportion of inpatient hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge in an effort to encourage providers to identify patients on medication combinations that could lead to adverse drug events at discharge and to motivate providers to consider whether reevaluation of the current medication regimen is warranted. Patients who have cancer or are receiving palliative care would be excluded from the denominator. **The ACS supports the inclusion of this measure in the IQR, including support for exceptions that exclude patients with cancer, patients on palliative care, and patients with encounters or 120 days or longer.**

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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