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September 24, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) proposed rule: *Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model* published in the Federal Register on July 31, 2018.

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 provided in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), the College has an interest in CMS' payment systems and related quality improvement efforts for both care settings, and we believe that we can offer insight to the Agency's

proposed modifications to these policies. Our comments below are presented in the order in which they appear in the proposed rule.

PROPOSED UPDATES AFFECTING OPPS PAYMENTS

Proposed Recalibration of APC Relative Payment Rates

Proposed Changes to Packaged Items and Services

Under the Outpatient Prospective Payment System (OPPS), CMS packages payments for multiple interrelated items and services into a single payment, which the Agency believes creates incentives for 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 often occurs if separate payment is provided.

Proposed CY 2019 Packaging Policy for Non-Opioid Pain Management Treatment

In 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis was established to study ways to prevent and treat drug abuse. The Commission issued a report directing CMS to examine payment methodologies for non-opioid pain management therapies that function as a surgical supply and recommended that the Agency "review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain." The Commission's report stated "the current CMS payment policy for 'supplies' related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications."[1] Under the existing OPPS and ASC payment programs, CMS provides one all-inclusive bundled payment to HOPDs and ASCs for "surgical supplies," which includes products intended to manage patients' procedure-related pain, regardless of the costs of the products.

[1] President's Commission on Combating Drug Addiction and the Opioid Crisis. (2017). *Final report*. Retrieved from: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

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For calendar year (CY) 2019, CMS examined the impact of its packaging policy on the use of drugs that function as a surgical supply in the HOPD and ASC settings. In its evaluation, the Agency used currently available data to analyze the utilization patterns associated with Exparel, a liposome injection of bupivacaine intended for the management of postsurgical pain, over a five-year time period (CYs 2013 through 2017) to determine whether its packaging policy has affected the use of this drug. Exparel had pass-through payment status from CYs 2012 through 2014 and was separately paid for in HOPDs and ASCs during this three-year period; the drug was subsequently packaged as a surgical supply in CY 2015 under the OPPS and ASC payment systems. CMS notes that Exparel is currently the only non-opioid analgesic alternative subject to packaged payments for procedures furnished in HOPDs and ASCs.

CMS first reviewed the total number of units of Exparel paid under the OPPS in the HOPD setting between CYs 2013 and 2017. During this time, CMS identified an overall increase in the Medicare utilization of Exparel, asserting that it found no evidence to support the notion that the OPPS packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management in the HOPD setting. The Agency states that, if the 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.

During the same five-year period of CYs 2013 through 2017, CMS observed different effects on Exparel utilization when examining its packaging policy under the ASC payment system; in the ASC setting, the Agency found a 25 percent decrease in the total number of Exparel units used, along with a 16 percent decrease in the total number of Medicare claims reporting Exparel. After Exparel's pass-through payment status expired at the end of CY 2014, the total number of units of the drug used in the ASC setting decreased by 70 percent, and the total number of claims reporting Exparel decreased by 62 percent. However, ASC data from CYs 2013 and 2014—when the drug received pass-through payments—indicates that the total number of Exparel units used increased by 238 percent, and the number of claims reporting Exparel increased by 192 percent, suggesting that the payment rate of the average sales price (ASP) plus 6 percent for the drug may have had an impact on its usage in the ASC setting.

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As a result of its evaluation of packaging policies under the OPPS and ASC payment systems, CMS states that a change in how it pays for non-opioid pain management drugs that function as surgical supplies may be warranted. In particular, the Agency suggests it might be appropriate to pay separately for evidence-based, non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these products and to encourage use of these types of therapies rather than prescription opioids. Therefore, CMS proposes to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019. However, the Agency indicates that it continues to believe it is appropriate to package reimbursement for Exparel in HOPDs and does not propose any modifications to its payments for non-opioid alternatives under the OPPS.

The use and abuse of prescription opioids has increased dramatically in recent years, and the ACS applauds CMS' efforts to identify and eliminate regulatory obstacles that inhibit utilization of non-opioid alternatives for pain management, including those obstacles related to coverage or reimbursement. **Specifically, to eliminate payment-related barriers to the use of non-opioid alternatives by physicians, we urge CMS to provide separate reimbursement for opioid-sparing therapies administered by surgeons during the perioperative period**; 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. **The College thereby supports CMS' proposal to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in ASCs; however, we urge the Agency to expand this proposal to allow for <u>all</u> care settings in which surgical procedures are furnished, including HOPDs and inpatient facilities, to bill for the administration of non-opioid therapies separate from a procedure.** By changing reimbursement policies to allow pass-through payments for non-opioid alternatives, CMS may encourage and increase the utilization of such pain management therapies that are clinically appropriate and effective for the postsurgical patient.

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Addressing the opioid epidemic requires a collaborative effort among healthcare providers, insurers, consumers, and all levels of government to appropriately alter prescribing practices, enhance prescriber and patient education, and improve drug dispensing guidelines. The College, with its 100-year history in establishing standards for the improvement of surgical care, is committed to the implementation of a multimodal plan focused on policy, physician education, and patient/caregiver education to address opioid abuse. We put the welfare of our surgical patients above all else, and we believe that surgeons, as prescribers, can play a role in optimizing pain management strategies that will decrease frequent and prolonged opioid use. Pain is an inevitable, but undesirable, consequence of surgery, and while opioid-based pain control for the postsurgical patient is a therapy supported by numerous national medical specialty societies, opioid medications carry risks, which include abuse, addiction, and overdose. In the midst of this public health crisis, surgeons have a major responsibility to understand and mitigate the risks associated with prescribing opioids and to participate in a broader solution that removes barriers to the access and utilization of non-opioid alternatives.

ACS Guiding Principles to Prevent Opioid Abuse and Addiction

The ACS seeks to assure that surgical patients continue to have adequate pain control and receive the proper postoperative care needed to restore their overall health and avoid prescription opioid-related complications. We believe that surgeons have a responsibility to minimize their patients' pain after a procedure while also addressing the societal imperative to avoid overprescribing and, in 2017, developed the following five principles to guide our efforts in preventing opioid abuse and addiction:

1) **Promote the use of prescription drug monitoring programs (PDMPs) through the following activities:**
    - Set expectation that PDMPs are fully functional and interoperable with electronic health records
    - Establish state/federal grant programs to enhance PDMPs
    - Reduce barriers to PDMP access by nonphysician licensed independent practitioners and physicians' designated agents

2) **Support research and training, developed in collaboration with specialists in pain management, for safe prescribing practices of opioids and non-opioid analgesics through the following activities:**
    - Identify patients at high risk for opioid addiction, substance use disorder, or an opioid-related adverse drug event

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- Establish guidelines for acute pain management of the opioid-addicted patient
- Set expectations and educate patients and caregivers prior to surgery, during discharge, and throughout follow-up
- Provide evidence-based education and evaluation training programs on opioid and non-opioid alternatives for pain management for the entire surgical team—surgeons, residents, and other health professionals
- Strengthen postoperative surveillance by both patients and providers to expand the evidence on use, response to alternative therapies, and potential issues with long-term use in acute surgical and palliative care patients

3) **Recognize and address issues specific to military veterans by establishing the following programs:**
   - Fully functional opioid tracking system for Veterans Affairs (VA) patients
   - A system to track prescriptions issued at all federal facilities, including the VA, to outside treating providers and pharmacists
   - Expansion of the VA Opioid Safety Initiative

4) **Change the direct relationship between provider reimbursement and patient pain control through the following efforts:**
   - Detach questions regarding pain management on patient satisfaction surveys from physician reimbursement
   - Examine the impact of insurer and state-based government regulations on prescribing practices and patient experience

5) **Support patient safety legislation that includes the following provisions:**
   - Exemptions for the postoperative and/or injured surgical patients who are expected to require opioid analgesics for more than seven days
   - Exceptions from prescriber mandates for patients undergoing cancer treatment, cancer rehabilitation, and palliative care
   - E-prescribing of controlled substances to improve tracking, reduce opportunities for fraud, and limit episodes where patients in pain are without relief
   - Partial filling of opioid prescriptions

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- Disposal programs to prevent misuse or diversion of unfinished prescriptions[2]

Using these principles, the ACS encourages CMS to engage the physician community in advancing opioid-sparing, multimodal pain management techniques that leverage local anesthetics, enhanced recovery after surgery (ERAS) protocols, and other non-opioid treatment options. We stand ready to work with the Agency to improve pain management programs that allow for early intervention with non-opioid therapies (e.g., regional nerve blocks, gabapentin, high-dose non-steroidal anti-inflammatory drugs) and facilitate the frequent review of a postoperative pain control plan during a patient's hospital stay and following discharge.

PROPOSED OPPS PAYMENT FOR DEVICES

Proposed Device-Intensive Procedures

Proposed Changes to the Device-Intensive Procedure Policy for CY 2019

CMS proposes to modify its criteria for device-intensive procedures in response to stakeholder feedback requesting that procedures requiring expensive surgically inserted or implanted devices should qualify as device-intensive, regardless of whether the device remains in the patient's body after the conclusion of the procedure. Specifically, the Agency proposes to allow procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold and do not remain in the patient's body after the conclusion of the procedure to qualify as device-intensive. CMS notes that it no longer believes that a procedure involving a device that does not remain in the patient's body should affect its designation as a device-intensive procedure because the device could still comprise a large cost of the procedure. The Agency also proposes to reduce the device offset percentage threshold, which is the proportion of the procedure's costs that are attributable to the cost of the device, from 40 percent to 30 percent to allow a greater number of procedures to qualify as device-intensive.

The ACS supports CMS' modifications to its requirements for device intensiveness, such that procedures which (1) involve insertable or implantable devices that are subsequently removed from the patient's

[2] American College of Surgeons. (2017). *Statement on the opioid abuse epidemic*. Retrieved from: https://www.facs.org/about-acs/statements/100-opioid-abuse

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body, and (2) utilize devices that exceed 30 percent, rather than 40 percent, of the procedure's mean cost, meet the Agency's device-intensive criteria. Under current policy, bundled payments for expensive devices have often inhibited facilities' ability to afford and implement certain technologies for surgical care, and we believe that these proposals will increase patient access to single-use devices (e.g., drug-coated balloons containing anti-proliferative medication for angioplasties) and provide appropriate reimbursement for the use of such devices.

PROPOSED NONRECURRING POLICY CHANGES

Proposal and Comment Solicitation on Method to Control Unnecessary Increases in the Volume of Outpatient Services

In this proposed rule, CMS reiterates its long-running concerns about the volume increases in services paid under the OPPS. The Agency indicates that the OPPS has been the fastest growing sector of Medicare payments out of all payment systems under Medicare Parts A and B and states that payment incentives, rather than patient acuity or medical necessity, may be affecting site-of-service decision-making. CMS cites findings from the March 2018 Medicare Payment Advisory Commission (MedPAC) Report to Congress, noting that the "large source of growth in spending on services furnished in HOPDs appears to be the result of the unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs."[3]

CMS considers the shift of services from the physician office to the HOPD "unnecessary" if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher cost setting due to payment incentives. The Agency states that, because certain services—specifically, the clinic visit described by Healthcare Common Procedure Coding System (HCPCS) code G0463 (*Hospital outpatient clinic visit for assessment and management of a patient*)—could likely be safely provided in a lower cost setting, the growth in such clinic visits paid under the OPPS is unnecessary. Therefore, CMS proposes to use its authority under section 1833(t)(2)(F) of the Social Security Act ("*the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services*") to cap the OPPS payment made for office visits in off-campus provider-based departments (PBDs) for code

[3] Medicare Payment Advisory Commission. (2018). *Report to the Congress: Medicare payment policy*. Retrieved from: http://www.medpac.gov/docs/defaultsource/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0

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G0463 at the Medicare Physician Fee Schedule (PFS)-equivalent rate. The Agency asserts that this proposal will be an effective method to control unnecessary increases in the volume of services paid under the OPPS because all outpatient clinic visits delivered at off-campus PBDs will be reimbursed on a site-neutral basis at equivalent rates to physician offices.

The ACS believes that physicians should be able to exercise their clinical judgment regarding the appropriate site of service for patient care and that CMS should pay for covered services based on the resources required to deliver such services to a Medicare beneficiary. We request that the Agency continue to monitor utilization of these clinic visits and any site-of-service shifts that result from the implementation of this policy, if finalized, to ensure that patient access to care is not inadvertently compromised. The College also feels that the quality of care provided to a beneficiary and the reimbursement paid should always be held to the highest clinical standards, no matter the site of service, and asks that CMS ensure that the appropriate quality metrics are in place to assess how beneficiaries are treated in different care settings in order to collect data that can guide the Agency's efforts to create value-driven payment policies in the future.

While CMS is proposing to pay the PFS-equivalent rate for off-campus PBD clinic visits for CY 2019, the Agency notes that it is interested in other methods to control for unnecessary increases in the volume of outpatient services. Specifically, CMS seeks comment on the use of prior authorization (PA), which would require a physician to obtain approval of coverage for a service from CMS before furnishing that service, as an alternative way to manage overutilization. **The College strongly opposes the use of PA under the Medicare program, as the extensive PA requirements currently imposed by private payors—including Medicare Advantage organizations—already place an extraordinary administrative burden on physicians and their practices.** We believe that such insurers routinely and increasingly use PA to deter physicians from ordering or providing medically necessary treatment for patients, rather than as a legitimate mechanism for identifying overutilization, and do not support PA as a means for CMS to shift care between sites of service.

PROPOSED UPDATES TO THE AMBULATORY SURGICAL CENTER PAYMENT SYSTEM

Background

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Definition of ASC Covered Surgical Procedures

CMS proposes to revise its definition of "surgery" for CY 2019 to account for "surgery-like" procedures that are assigned codes outside the surgical range of Current Procedural Terminology (CPT®) codes (codes 10000-69999). Under this proposed revision, newly-eligible "surgery-like" procedures would include services described by Category I CPT® codes that are not in the surgical range but directly crosswalk or are clinically similar to procedures in the surgical range. Such codes would be limited to those that CMS have determined to not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

The ACS believes that any regulation intended to define "surgery" and its scope must include provisions that ensure that patients are safe and treated with the highest level of care. For the purposes of protecting surgical patients and promoting quality outcomes, the College established the following definition of surgery in 2007:

> *Surgery is performed for the purpose of structurally altering the human body by incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transportation of live human tissue, which include lasers, ultrasound, ionizing, radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery (this does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel. Patient safety and quality of care are paramount, and the College therefore*

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> *believes that patients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards.*[4]

While the College believes that the CPT® surgical range represents a logical and straightforward set of codes that can be used as a guide to identify which services are indeed surgical, we recognize that, in CMS' efforts to operationalize the expansion of procedures covered and reimbursed in ASCs, it may be necessary for the Agency to revise its definition of surgical procedures for the purposes of billing and claims processing. **The ACS is thereby comfortable with CMS' proposal to reclassify "surgery-like" procedures that are outside the CPT surgical range, but are similar to surgical procedures currently covered in the ASC setting, as "surgery" in order for such services to be included on the ASC covered procedures list and payable when furnished in the ASC setting.**

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

Covered Surgical Procedures

Proposal to Review Recently-Added Procedures to the ASC Covered Procedures List

As required by Section 1833(i)(1) of the Social Security Act, CMS must specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed in an ASC. The Act directs CMS to review and update this ASC covered procedures list (CPL) at least every two years. The Agency currently examines the CPL annually to determine whether procedures should be added to or removed from the list. CMS asserts that, because ASCs generally provide a subset of services that are offered by hospitals, and because Medicare beneficiaries tend to be frailer and exhibit a higher number of comorbidities than other patient populations, it may be appropriate to reevaluate procedures recently added to the CPL. Specifically, CMS proposes to review all procedures (i.e., 38 procedures) that were added to the CPL in CYs 2015, 2016, and 2017 to assess the safety, effectiveness, and beneficiary

[4] American College of Surgeons. (2007). *Statement on surgery using lasers, pulsed light, radiofrequency devices, or other techniques*. Retrieved from: https://www.facs.org/about-acs/statements/11-laser-surgery

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experience of these services when performed in the ASC setting. This proposed evaluation would determine if the 38 newly-added procedures continue to meet CMS' criteria for inclusion on the CPL, such as whether they (1) continue not to be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC and (2) continue not to be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure.

The College supports CMS' proposal to conduct a standard assessment of procedures recently added to the CPL to ensure that these services continue to meet the applicable criteria to be furnished in the ASC setting. We encourage the Agency to systematically review the entire CPL—not just those procedures added within the prior three calendar years—using all available data, including new clinical developments, prevailing medical standards and practice, and trends in utilization reflected in ASC claims and pricing information, to evaluate the safety and effectiveness of each service CMS has previously deemed appropriate to perform on an outpatient basis.

Calculation of the Proposed ASC Payment Rates and the Proposed ASC Conversion Factor

Proposed Calculation of the ASC Payment Rates

Updating the ASC Conversion Factor

Under current policy, CMS updates the conversion factor used to adjust annual ASC payment rates based on the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). As the ACS has previously commented, we do not consider the CPI-U to be an appropriate mechanism to update payments for ASCs, as it does not accurately represent the changing costs borne by such facilities to safely provide surgical procedures. The CPI-U estimates the average change over time in the price of consumer goods, and the vast majority of units measured to determine the index do not reflect healthcare-related expenditures, let alone ASC purchasing practices. In past years, the College has urged the Agency to align the ASC conversion factor with the hospital market basket (HMB) update, which we believe is a more suitable proxy for ASC costs, as well as to better align ASC payments with OPPS payments to reduce inappropriate site-of-service differentials.

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In response to stakeholder concerns that CPI-U inputs do not reflect providers' or facilities' experiences in buying the items necessary to furnish a medical service, CMS proposes to apply the HMB to ASCs for a five-year period of CYs 2019 through 2023. The Agency indicates that it will assess whether there is a migration of procedures from the hospital setting to the ASC setting, as well as whether there are any unintended consequences (e.g., an unnecessary increase in beneficiaries' out-of-pocket costs), associated with this change during the interim implementation period.

We thank CMS for accepting stakeholders' recommendations to eliminate use of the CPI-U as the basis for annual adjustments to the ASC conversion factor and support the Agency's proposal to instead update ASC payment rates using the HMB. However, the College encourages CMS to adopt the proposed application of the HMB permanently, rather than for a five-year period, unless the Agency obtains data that justify an alternative, more appropriate methodology for updating ASC rates during its ongoing assessment of the adequacy of payment policies and cost structures within the ambulatory care setting.

REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

Hospital OQR Program Quality Measures

Accounting for Social Risk Factors in the Hospital OQR Program

Last year, CMS sought comment in the CY 2018 OPPS/ASC proposed rule on whether the Agency should account for social risk factors in the Hospital Outpatient Quality Reporting (OQR) Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. In the current CY 2019 OPPS/ASC proposed rule, the Agency acknowledged the comments it received in the previous year, including many of the ACS' recommendations encouraging CMS to:

- Explore factors that could be used to stratify or risk adjust quality measures beyond dual eligibility;
- Consider the full range of differences in patients' backgrounds that might affect outcomes;
- Explore risk stratification approaches to identify gaps in care;
- Account for social risk factors in value-based payment programs; and

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- Continue to monitor and address the Assistant Secretary for Planning and Evaluation (ASPE) and National Quality Forum's (NQF) recommendations to improve the use of social risk factors in clinical quality measurement.

The ACS applauds CMS' continued efforts in this area and the Agency's commitment to continue working with ASPE, the public, and other key stakeholders. We continue to endorse the bulleted recommendations above, and would like to reiterate that there should be further investment in researching socioeconomic status (SES) risk adjustment, including a coordinated effort across the U.S. Department of Health and Human Services (HHS) agencies to examine the broader social determinants of health.

The College acknowledges that accounting for social risk factors in clinical quality measurement is a complex task, including how to use the information gained to improve quality and how to incorporate social risk adjustments into federal quality reporting and payment programs. As the research in this field is ongoing, we are concerned about the ability to quantify all aspects of SES risk, and the degree to which SES factors can be accounted for each individual patient. Because of this possible shortcoming, hospitals that serve more vulnerable populations may not be able to achieve the performance of other hospitals at the national level, even when using the currently available SES adjustment methods. This is especially important when considering a program which compares all facilities that participate and provides payment incentives and public reports based on those comparisons. Because this program entails public accountability, we encourage CMS to explore policy solutions that prioritize improvement that is internal to the facility itself, rather than external comparisons which compare safety net hospitals to other facilities which may serve a population with a higher SES status. In this way, hospitals that serve a more disadvantaged population have the ability to be recognized for improving the quality of care at their institution, which better captures the essence of a quality improvement program.

It is also important to consider the support facilities will need when they receive feedback on SES factors, and how they can work to improve the health of their patients based on the social factors that impact their patients. Facilities may better understand the characteristics of their population but may not know how to use that information to drive improvement. To this end, there is a need for further study to understand how to use the information gained on SES factors. In our experience with

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ACS National Surgical Quality Improvement Program (NSQIP) hospitals, we found that many hospitals received information on the gaps in care at their hospital but did not have the tools for how to address those gaps and improve. In response to this, the ACS began providing additional support in developing programs to achieve goals that contribute to the improvement of quality. **We strongly encourage CMS to begin research on how facilities can use the knowledge gained from identifying SES factors to improve care.** In addition, the very nature of social economics may be defining societal impacts which are outside the scope of healthcare delivery and yet could impact the outcomes of care. For example, some patients are homeless and unable to receive therapies using refrigerated medications. Patients with behavioral health disorders may not have competencies for managing their own comorbid conditions, thus presenting for urgent surgical care while lacking chronic disease management. These patients are often outside the scope of the current business models of medical care. For a payor to reward or penalize delivery systems due to social metrics requires a rebuilding of the business models and aligning payment models.

Given our expertise in driving improvement, we welcome the opportunity to work with the Agency on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries.

Considerations in Removing Quality Measures from the Hospital OQR Program

CMS previously established a set of factors for determining whether to remove measures from the Hospital OQR Program. These factors are:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures);
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes;
- Factor 3. A measure does not align with current clinical guidelines or practice;
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

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- Factor 6. The availability of a measure that is more strongly associated with desired patient (outcomes for the particular topic; and
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences such as patient harm.

CMS proposes to adopt an additional removal factor for the Hospital OQR Program: Factor 8, "the costs associated with a measure outweigh the benefit of its continued use in the program." CMS proposes this same additional removal factor for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program and has the proposed Factor 8 for a range of other programs, including the Hospital Value-Based Purchasing Program, the Hospital Inpatient Quality Reporting Program, the Hospice Quality Reporting Program, the Inpatient Rehabilitation Facility Quality Reporting Program, and the Skilled Nursing Facility Quality Reporting Program.

Proposed New Measure Removal Factor 8

CMS identified several different types of costs to help assess Factor 8, "the costs associated with a measure outweigh the benefit of its continued use in the program": (1) facility information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other quality programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or state regulations (if applicable).

CMS states that its goal for the Hospital OQR Program measure set is to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. The ACS generally agrees with the principle outlining the removal of measures if they are extremely resource-intensive with little benefit, but we seek clarity on the process for stakeholder input when making the decision to propose a measure for removal. We worry that CMS may deem a measure too costly to implement, while providers continue to find it meaningful. Similarly, in the case of patient experience measures, CMS may find the implementation of the measures costly, but patients may value the measure for decision-making.

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We also recommend that CMS balance the removal of measures with the importance of maintaining a focus on important quality and public health issues, while ensuring progress among low performers. Consistency in the program's measure sets is also a critical factor to consider because the costs associated with changing measures and shifting the focus of quality improvement efforts are extremely burdensome for facilities, providers, and measure developers. It will be critical to gain the perspective of all key stakeholders early on in the measure process, prior to regulatory proposals, to ensure meaningful measures are retained and stakeholders are continually incentivized to invest in the development of innovative measures.

Clarification of Removal Factor 1: "Topped-Out" Measures

CMS previously finalized Measure Removal Factor 1, "measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures)." In general, the ACS does not support the removal of a measure based on "topped-out" status.

The CMS approach to topped-out measures might have merit in a payment program, but misses the mark for a quality program. In fact, a highly reliable quality system attempts to identify all the critical measures and seeks topped-out performance in all of them. High-value process measures are crucial to a coordinated surgical team. High-value topped-out process measures should be maintained in a composite that encompasses the various phases of care, not removed because of high levels of performance.

It is critical that CMS recognizes that medical and surgical care is complex and spans time, across unique patients, and disparate care systems. Tracking this information is critical for prevention—receiving information on a possible event can help providers prevent it from occurring altogether. Many surgical measures that are deemed topped-out tell an important story as part of the care continuum. For example, measuring antibiotics before surgical care was once adequate. However, we have come to realize that to track patients optimally, we need checklists of interrelated processes that are closely tied to outcomes (e.g., sepsis bundles). Another example is the use of ERAS protocols. ERAS is a more comprehensive, patient-centered approach to optimize care which requires nutritional plans, shared IV fluid strategies, a multi-modal analgesic

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program pain treatment plan, infection prevention protocols and outcome tracking. The multidisciplinary nature of successful ERAS strategies are well-documented and widely-supported throughout the medical literature. By pulling all the surgical teams together in a checklist for these processes, the goal is to achieve 100 percent performance on the processes and greater tracking of outcomes.

We strongly believe that the current OQR program values single measures which track sporadic, disconnected events. Instead, we encourage CMS to recognize composites of high value process measures that can demonstrate consistency and highly reliable care processes and that span the phases of care.

Proposed Removal of Quality Measures from the Hospital OQR Program Measure Set

In this proposed rule, CMS proposes to remove a number of measures for the CY 2020 and 2021 payment determinations. CMS explains that they propose to remove these measures based on measure removal factors: Factor 1, "measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures); Factor 2, "performance or improvement on a measure does not result in better patient outcomes; and Factor 8, "the costs associated with a measure outweigh the benefit of its continued use in the program," CMS does not propose any new measures for this program. The ACS has comments on select measures as discussed below.

- ***Proposed Measure Removals under Proposed Removal Factor 8: OP-5, OP-29, OP-30, and OP-31***

  Proposed Removal of OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

  CMS is proposing to remove *OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients* beginning with the CY 2021 payment determination and for subsequent years in the hospital OQR program. This measure assesses the percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat

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colonoscopy documented in their colonoscopy report. CMS states the rationale for removing the measure is due to Factor 8 (costs outweigh the benefits), as well as the preference for outcome measures in the Hospital OQR Program that provide valuable data for the same procedure and the existence of the same measure in the Merit-based Incentive Payment System (MIPS).

The ACS does not support the removal of *OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients* from the OQR program because we believe the benefit of this appropriateness of care measure outweighs concerns with costs. Literature demonstrates an inappropriate overuse of colonoscopy exams, and missed opportunities to screen patients who have never been screened or have not been screened in the recommended 10 years to identify new cases of cancer. Multiple studies have found that many physicians do not follow the recommended guideline of a 10-year colonoscopy screening interval for average risk patients.[5,6,7] One study in a multi-specialty setting found that 88 percent of colonoscopy screenings represented overuse over a 9-year period.[6]

Additionally, CMS asserts that *OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* will continue to be in the OQR program and that *OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients* is retained in MIPS. The ACS disagrees that tracking the hospital visit rate after outpatient colonoscopy will do enough to prevent the inappropriate use of colonoscopies because *OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* does not evaluate the time interval between colonoscopy screenings, which CMS acknowledges. Solely retaining this measure in MIPS will not provide enough coverage to truly determine the extent of inappropriate use, because MIPS is a self-reported measure program, meaning that clinicians choose whether

[5] Johnson, M. R., Grubber, J., Grambow, S. C., Maciejewski, M. L., Dunn-Thomas, T., Provenzale, D., & Fisher, D. A. (2015). Physician non-adherence to colonoscopy interval guidelines in the veterans affairs healthcare system. *Gastroenterology*, *149*(4), 938-951.
[6] Kruse, G. R., Khan, S. M., Zaslavsky, A. M., Ayanian, J. Z., & Sequist, T. D. (2015). Overuse of colonoscopy for colorectal cancer screening and surveillance. *Journal of General Internal Medicine*, *30*(3), 277-283.
[7] Goodwin JS, Singh A, Reddy N, Riall TS, Kuo Y. Overuse of Screening Colonoscopy in the Medicare Population. *Arch Intern Med.* 2011;171(15):1335–1343. doi:10.1001/archinternmed.2011.212

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they would like to report this measure. Because of this, physicians who are not following the clinical guidelines may not choose to report, and therefore this data cannot be used to reliably track inappropriate care.

Furthermore, we believe that the CMS risk-to-benefit analysis of this measure is incorrect, and that the benefit of tracking appropriate use of colonoscopies outweighs the costs. Instead, CMS should focus efforts on how to automate the tracking of this information in a digital environment to reduce the resource-intensive use of chart-abstracted data.

For these reasons, we do not support the removal of *OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients* from the OQR program.

Proposed Removal of OP-30: Endoscopy/ Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

Similar to CMS' proposal to remove *OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients*, the Agency is proposing to remove *OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use* beginning with the CY 2021 payment determination and for subsequent years in the OQR program. *OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use* assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy. CMS stated the rationale for removing the measure is due to Factor 8 (costs outweigh the benefits), as well as the preference for an outcome measures in the Hospital OQR Program that provides valuable data for the same procedure, and the existence of the same measure in the MIPS.

The ACS does not support the proposed removal of *OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use* from the OQR program because we believe the benefit of this

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appropriateness of care measure outweighs concerns with costs. Literature demonstrates an inappropriate overuse of colonoscopy exams, and missed opportunities to screen patients who haven't been screened in the recommended 3 or more years. There is some evidence that many physicians do not follow the recommended guideline of 3 or more years colonoscopy screening interval for patients with prior adenomatous polyp(s).[8,9]

Additionally, as discussed in our comment to *OP-29: Endoscopy/ Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients*, we do not believe that O*P-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* (NQF #2539) will do enough prevent the inappropriate use of colonoscopies because *OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* does not evaluate the time interval between colonoscopy screenings, which CMS acknowledges. Solely retaining this measure in MIPS will not provide enough coverage to truly determine the extent of inappropriate use, because MIPS is a self-reported measure program, which means clinicians choose whether they would like to report this measure. Because of this, physicians who are not following the clinical guidelines may not choose to report, and therefore this data cannot be used to reliably track inappropriate care.

Furthermore, we truly believe that the CMS risk-to-benefit analysis of this measure is incorrect, and that the cost of tracking appropriate use of colonoscopies outweighs the benefits. Instead, CMS should focus efforts on how to automate the tracking of this information in a digital environment to reduce the resource-intensive use of chart-abstracted data.

For these reasons, we ask CMS to not remove *OP-30: Endoscopy/ Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use* from the OQR program.

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[8] Stock, C., Hoffmeister, M., Birkner, B., & Brenner, H. (2013). Performance of additional colonoscopies and yield of neoplasms within 3 years after screening colonoscopy: a historical cohort study. *Endoscopy*, *45*(07), 537-546.
[9] Kahn, B., Freeland, Z., Gopal, P., Agrawal, D., Mayorga, C. A., Mithani, R., ... & Singal, A. G. (2015). Predictors of guideline concordance for surveillance colonoscopy recommendations in patients at a safety-net health system. *Cancer Causes & Control*, *26*(11), 1653-1660.

- ***Proposed Measure Removal Under Removal Factor 3: OP-9: Mammography Follow-up Rates***

  CMS proposes to remove *OP-9: Mammography Follow-up Rates* based on measure removal Factor 3, the measure does not align with current clinical guidelines or practice. This claims-based measure assesses the percentage of patients with mammography screening studies that are followed by a diagnostic mammography, ultrasound, or MRI of the breast in an outpatient or office setting within 45 days. CMS also explains that the measure has not been updated since 2008 and the advancements in imaging technology and clinical practice for mammography warrant updating the measure's specifications to align with current clinical practice guidelines and peer-reviewed literature. Therefore, CMS plans to investigate the respecification of this measure and consider it for adoption to the program through future rulemaking. CMS also explains it will consider ways to capture a broader, more comprehensive spectrum of mammography services including adding diagnostic digital breast tomosynthesis (DBT).

  The ACS supports the removal of *OP-9: Mammography Follow-up Rates* in order for the measure to be respecified and updated to align with the current clinical guidelines on mammography care.

<u>Hospital OQR Program Measures and Topics for Future Consideration</u>

In this proposed rule, CMS is requesting comment on future measure topics for the Hospital OQR Program. In particular, CMS states its focus on greater use of outcome measures and away from use of clinical process measures across Medicare quality reporting and value-based purchasing programs. Specifically, CMS is seeking comment on outcome measures that would be useful to add, as well as process measures that should be eliminated from the Hospital OQR Program.

The ACS would like to point out that the OQR program, primarily set in the hospital outpatient department, is a low-event rate environment. Generally, the procedures performed in this setting are of lower risk and complexity, and as such, these are rare incidences that will be captured by traditional outcome measures. Additionally, procedures in this setting are usually planned in advance and are elected. Instead of focusing on these outcome events, we believe it would be more valuable to use patient - reported outcome measures (PROs) to show variability and areas for improvement from the perspective of the patient. In addition to prioritizing

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the use of PROs, it would be valuable for the OQR program to use high-value process measures, even if they are topped-out, due to the reasons explained earlier. Together, PROs and high-value process measures in the hospital outpatient setting will evaluate providers on following best practices and achieving the patient's goals of care.

REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING PROGRAM

ASCQR Program Quality Measures

Accounting for Social Risk Factors in the ASCQR Program

Similar to the OQR Program, CMS sought comment in the CY 2018 OPPS/ASC proposed rule on whether the Agency should account for social risk factors in the ASCQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. In the current CY 2019 OPPS/ASC proposed rule, the Agency acknowledged the comments they received in the previous year, including many of the ACS' recommendations encouraging CMS to:

- Explore factors that could be used to stratify or risk adjust quality measures beyond dual eligibility;
- Consider the full range of differences in patients' backgrounds that might affect outcomes;
- Explore risk stratification approaches to identify gaps in care;
- Account for social risk factors in value-based payment programs; and
- Continue to monitor and address ASPE and NQF's recommendations to improve the use of social risk factors in clinical quality measurement.

The ACS applauds CMS' continued efforts in this area and the Agency's commitment to continue working with ASPE, the public, and other key stakeholders. We continue to endorse the bulleted recommendations above, and would like to reiterate that there should be further investment in researching socioeconomic status (SES) risk adjustment, including a coordinated effort across HHS agencies to examine the broader social determinants of health.

The College acknowledges that accounting for social risk factors in clinical quality measurement is a complex task, including how to use the

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information gained to improve quality and how to incorporate social risk adjustments into federal quality reporting and payment programs. As the research in this field is ongoing, we are concerned about the ability to quantify all aspects of SES risk, and the degree to which SES factors can be accounted for each individual patient. Because of this possible shortcoming, hospitals that serve more vulnerable populations may not be able to achieve the performance of other hospitals at the national level, even when using the currently available SES adjustment methods. This is especially important when considering a program which compares all facilities that participate and provides payment incentives and public reports based on those comparisons. Because this program entails public accountability, we encourage CMS to explore policy solutions that prioritize improvement that is internal to the facility itself, rather than external comparisons which compare safety net hospitals to other facilities which may serve a population with a higher SES status. In this way, hospitals that serve a more disadvantaged population have the ability to be recognized for improving the quality of care at their institution, which better captures the essence of a quality improvement program.

It is also important to consider the support facilities will need when they receive feedback on SES factors, and how they can work to improve the health of their patients based on the social factors that impact their patients. Facilities may better understand the characteristics of their population but may not know how to use that information to drive improvement. To this end, there is a need for further study to understand how to use the information gained on SES factors. In our experience with ACS NSQIP hospitals, we found that many hospitals received information on the gaps in care at their hospital but did not have the tools for how to address those gaps and improve. In response to this, the ACS began providing additional support in developing programs to achieve goals that contribute to the improvement of quality. **We strongly encourage CMS to begin research on how facilities can use the knowledge gained from identifying SES factors to improve care.** In addition, the very nature of social economics may be defining societal impacts which are outside the scope of healthcare delivery and yet could impact the outcomes of care. For example, some patients are homeless and unable to receive therapies using refrigerated medications. Patients with behavioral health disorders may not have competencies for managing their own comorbid conditions, thus presenting for urgent surgical care while lacking chronic disease management. These patients are often outside the scope of the current business models of medical care. For a payor to reward or penalize

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delivery systems due to social metrics requires a rebuilding of the business models and aligning payment models.

Given our expertise in driving improvement, we welcome the opportunity to work with the Agency on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries.

Removal Factors for ASCQR Program Measures

Similar to the OQR Program, CMS previously established measure removal factors to help determine whether to remove measures from the ASCQR program. These factors are:

- Factor 1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures);
- Factor 2. Availability of alternative measures with a stronger relationship to patient outcomes;
- Factor 3. A measure does not align with current clinical guidelines or practice;
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences such as patient harm.

To ensure the ASCQR Program measure removal factors are fully aligned with the Hospital OQR Program, CMS proposes to adopt an additional factor, Factor 8, "the costs associated with a measure outweigh the benefit of its continued use in the program."

Proposed New Measure Removal Factor 8

Similar to CMS' proposal in the OQR Program, the Agency proposes to align the Measure Removal Factors across CMS programs, including adoption of Factor 8, "the costs associated with a measure outweigh the benefit of its continued use in the program."

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CMS identified several different types of costs to help assess Factor 8, "the costs associated with a measure outweigh the benefit of its continued use in the program": (1) facility information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other quality programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or state regulations (if applicable).

CMS states that its goal for the ASCQR Program measure set is to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. The ACS generally agrees with the principle outlining the removal of measures if they are extremely resource intensive with little benefit, but we seek clarity on the process for stakeholder input when making the decision to propose a measure for removal. We worry that CMS may deem a measure too costly to implement, while providers continue to find it meaningful. Similarly, in the case of patient experience measures, CMS may find the implementation of the measures costly, but patients may value the measure for decision-making.

We also recommend that CMS balance the removal of measures with the importance of maintaining a focus on important quality and public health issues, while ensuring progress among low performers. Consistency in the program's measure sets is also a critical factor to consider because the costs associated with changing measures and shifting the focus of quality improvement efforts are extremely burdensome for facilities, providers, and measure developers. It will be critical to gain the perspective of all key stakeholders early on in the measure process, prior to regulatory proposals, to ensure meaningful measures are retained and stakeholders are continually incentivized to invest in the development of innovative measures.

Clarification for Removal Factor 1: "Topped-Out" Measures

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It is critical that CMS recognizes that medical and surgical care is complex and spans time, across unique patients, and disparate care systems. Tracking this information is critical for prevention—receiving information on a possible event can help providers prevent it from occurring altogether. Many surgical measures that are deemed topped-out tell an important story as part of the care continuum. For example, measuring antibiotics before surgical care was once adequate. However, we have come to realize that to track patients optimally, we need checklists of interrelated processes that are closely tied to outcomes (e.g., sepsis bundles). Another example is the use of enhanced recovery after surgery ERAS protocols. ERAS is a more comprehensive patient-centered approach to optimize care which requires nutritional plans, shared IV fluid strategies, a multimodal analgesic program pain treatment plan, infection prevention protocols and outcome tracking. The multidisciplinary nature of successful ERAS strategies are well-documented and widely supported throughout the medical literature. By pulling all the surgical teams together in a checklist for these processes, the goal is to achieve 100 percent performance on the processes and greater tracking of outcomes.

We strongly believe that the current ASCQR program values single measures which track sporadic, disconnected events. Instead, we encourage CMS to recognize composites of high value process measures that can demonstrate consistency and highly reliable care processes and that span the phases of care.

<u>Proposed Removal of Quality Measures from the ASCQR Program Measure Set</u>

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- ***Proposed Measure Removals Under Removal Factor 1: ASC-1, ASC-2, ASC-3, and ASC-4***

  In the 2012 ASCQR final rule, CMS finalized the inclusion of *ASC-1, ASC-2, ASC-3, ASC-4* for use in the ASCQR program. The applicable measure titles and descriptions are as follows:

  - *ASC-1: Patient Burn* (NQF #0263)
    - Description: Percentage of ASC admissions experiencing a burn prior to discharge
  - *ASC-2: Patient Fall* (NQF #0266)
    - Description: Percentage of ASC admissions experiencing a fall in the ASC.
  - *ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant* (NQF #0267)
    - Description Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant event.
  - *ASC-4: All-Cause Hospital Transfer/Admission* (NQF #0265)
    - Description: Rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC

  Beginning with the CY 2021 payment determination and for subsequent years, CMS is proposing to remove *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* under measure removal Factor 1: Topped-out Measures, "measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made."

  As discussed in our comments on measure removal Factor 1 (topped-out), there are many process measures which CMS has deemed topped-out which could be of critical value to patient care. These measures monitor rare events where the incidents of occurrence should be zero and are meant to achieve 100 percent performance rates. Experiencing a burn, fall, wrong site wrong side, wrong patient, wrong procedure, wrong implant, or a transfer/admission is devastating for a patient yet preventable. These measures should not be eliminated based on topped-out status, as it is necessary to stay vigilant to prevent and detect these incidences. Factor 1 (topped-out) of the measure removal criteria is a policy for a payment program and not consistent

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with true quality programs. As such, it might seem reasonable to apply this removal criterion for quality measures which track sporadic, disconnected events. However, as we discuss in the Topped-Out Measures section, topped-out measures which are determined to be high-value and worthy of continued measurement should be included as part of a composite whereby they continue to be measured and ensure the maintenance of high quality care and patient safety.

- ***Proposed Measure Removals Under Removal Factor 8: ASC-9, ASC-10, and ASC-11***

  Similar to CMS' proposal to remove *Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients* and *Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use* from the OQR Program, CMS proposes to remove these 2 measures from the ASCQR Program based on Factor 8 (costs outweigh the benefits), as well as the preference for an outcome measure in the ASCQR Program that provides valuable data for the same procedure and the existence of the same measure in MIPS.

  Proposed Removal of ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

  CMS is proposing to remove *ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients* beginning with the CY 2021 payment determination and for subsequent years in the ASCQR program. This measure assesses the percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. CMS stated the rationale for removing the measure is due to Factor 8 (costs outweigh the benefits) as well as the preference for outcome measures in the Hospital OQR Program that provide valuable data for the same procedure and the existence of the same measure in MIPS.

  The ACS does not support the removal of *ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients* from the ASCQR program because we believe the benefit of this appropriateness of care measure outweighs

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concerns with costs. Literature demonstrates an inappropriate overuse of colonoscopy exams, and missed opportunities to screen patients who have never been screened or haven't been screened in the recommended 10 years to identify new cases of cancer. Multiple studies have found that many physicians do not follow the recommended guideline of a 10-year colonoscopy screening interval for average-risk patients.[10,11,12] One study in a multi-specialty setting found that 88 percent of colonoscopy screenings represented overuse over a 9-year period.[11]

Additionally, CMS reasons that *ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539)* will continue to be in the ASCQR Program and that *ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients* is retained in MIPS. The ACS disagrees that tracking the hospital visit rate after outpatient colonoscopy will do enough to prevent the inappropriate use of colonoscopies because *ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* does not evaluate the time interval between colonoscopy screenings, which CMS acknowledges. Solely retaining this measure in MIPS will not provide enough coverage to truly determine the extent of appropriate use, because MIPS is a self-reported measure program where clinicians choose whether they would like to report this measure. Because of this, physicians who are not following the clinical guidelines may not choose to report this measure.

Furthermore, we truly believe that the CMS risk-to-benefit analysis of this measure is incorrect, and that the cost of tracking appropriate use of colonoscopies outweighs the benefits. Instead, CMS should focus efforts on how to automate the tracking of this information in a digital environment to reduce the resource-intensive use of chart-abstracted data.

[10] Johnson, M. R., Grubber, J., Grambow, S. C., Maciejewski, M. L., Dunn-Thomas, T., Provenzale, D., & Fisher, D. A. (2015). Physician non-adherence to colonoscopy interval guidelines in the veterans affairs healthcare system. *Gastroenterology*, *149*(4), 938-951.
[11] Kruse, G. R., Khan, S. M., Zaslavsky, A. M., Ayanian, J. Z., & Sequist, T. D. (2015). Overuse of colonoscopy for colorectal cancer screening and surveillance. *Journal of General Internal Medicine*, *30*(3), 277-283.
[12] Goodwin JS, Singh A, Reddy N, Riall TS, Kuo Y. Overuse of Screening Colonoscopy in the Medicare Population. *Arch Intern Med.* 2011;171(15):1335–1343. doi:10.1001/archinternmed.2011.212

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For these reasons, we do not support the removal of *ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients* from the ASCQR Program.

Proposed Removal of ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

Similar to CMS' proposal to remove *ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients*, the Agency is proposing to remove *ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use* beginning with the CY 2021 payment determination and for subsequent years in the ASCQR program. *ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use* assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy. CMS stated the rationale for removing the measure is due to Factor 8 (costs outweigh the benefits), as well as the preference for outcome measures in the ASCQR Program that provide valuable data for the same procedure and the existence of the same measure in MIPS.

The ACS does not support the removal of remove *ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use* from the ASCQR program because we believe the benefit of this appropriateness of care measure outweighs concerns with costs. Literature demonstrates an inappropriate overuse of colonoscopy exams, and missed opportunities to screen patients who haven't been screened in the recommended 3 or more years. There is some evidence that many physicians do not follow the recommended guideline of 3 or more years colonoscopy screening interval for patients with prior adenomatous polyp(s).[13,14]

[13] Stock, C., Hoffmeister, M., Birkner, B., & Brenner, H. (2013). Performance of additional colonoscopies and yield of neoplasms within 3 years after screening colonoscopy: a historical cohort study. *Endoscopy*, *45*(07), 537-546.
[14] Kahn, B., Freeland, Z., Gopal, P., Agrawal, D., Mayorga, C. A., Mithani, R., ... & Singal, A. G. (2015). Predictors of guideline concordance for surveillance colonoscopy recommendations in patients at a safety-net health system. *Cancer Causes & Control*, *26*(11), 1653-1660.

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Additionally, as discussed in our comment to *ASC-10: Endoscopy/ Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use*, we do not believe that *ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* and the retention of *ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use* in MIPS will go far enough to prevent the inappropriate use of colonoscopies because *ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* does not evaluate the time interval between colonoscopy screenings, which CMS acknowledges. Solely retaining this measure in MIPS will not provide enough coverage to truly determine the extent of inappropriate use because MIPS is a self-reported measure program, meaning that clinicians choose whether they would like to report this measure. Because of this, physicians who are not following the clinical guidelines may choose not to report, and therefore this data cannot be used to reliably track inappropriate care.

Furthermore, we truly believe that the CMS risk-to-benefit analysis of this measure is incorrect, and that the benefits of tracking appropriate use of colonoscopies outweigh the costs. Instead, CMS should focus efforts on how to automate the tracking of this information in a digital environment to reduce the resource-intensive use of chart-abstracted data.

For these reasons, we do not support the removal of *ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use* from the ASCQR Program.

ASCQR Program Measures and Topics for Future Consideration: Possible Future Validation of ASCQR Program Measures

In this proposed rule, CMS is requesting comment on future measure topics for the ASCQR Program. In particular, CMS states its desire to focus on greater use of outcome measures and to move away from the use of clinical process measures across Medicare quality reporting and value-based purchasing programs. Specifically, CMS is seeking comment on outcome measures that would be useful to add, as well as process measures that should be eliminated from the program.

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The ASCQR Program measures clinical quality in a low-event rate environment. Generally, the procedures performed in this setting are of lower risk and complexity, and as such, these are rare incidences that will be captured by traditional outcome measures. Additionally, procedures in this setting are usually planned in advance and are elected surgeries. Instead of focusing on these rare outcome events, it would be more valuable to use PROs to show the most variability and areas for improvement. In addition to prioritizing the use of PROs, it would be valuable for the OQR Program to use high-value process measures, even if they are topped-out. Together, PROs and high-value process measures in the ASC setting will evaluate providers on following best practices and achieving the patient's goals of care.

PROPOSED UPDATED TO THE HCAHPS SURVEY MEASURE (NQF #0166) FOR THE FY 2024 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

In the fiscal year (FY) 2018 IPPS/LTCH PPS final rule CMS finalized a refinement to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure as used in the Hospital Inpatient Quality Reporting (IQR) Program by removing the previously adopted pain management questions and incorporating new *Communication About Pain* questions, beginning with patients discharged in January 2018, for the FY 2020 payment determination and subsequent years. These three survey questions within the HCAHPS Survey address how providers communicate with patients about pain:

- HP1: "During this hospital stay, did you have any pain?"
- HP2: "During this hospital stay, how often did hospital staff talk with you about how much pain you had?"
- HP3: "During this hospital stay, how often did hospital staff talk with you about how to treat your pain?"

Additionally, CMS finalized that hospital performance data on those questions would be publicly reported on the Hospital Compare website beginning October 2020 using CY 2019 data. CMS also stated that it would provide performance results based on CY 2018 data on the *Communication About Pain* questions to hospitals in confidential preview reports.

CMS stated it has received feedback from stakeholders expressing concerns that the new questions on communication about pain may impose

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pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey. Additionally, CMS notes that the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS pain management questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score. Because of this feedback, CMS is proposing to update the HCAHPS Survey by removing the *Communication About Pain* questions, effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years.

The ACS puts the welfare of our surgical patients above all else, and we believe that surgeons, as prescribers, can play a role in optimizing pain management strategies that will decrease frequent and prolonged opioid use. Pain is an inevitable, but undesirable, consequence of surgery, and while opioid-based pain control for the postoperative patient is a therapy supported by numerous national medical specialty societies, these prescriptions carry risks, which include chronic usage, addiction, and overdose. The College seeks to assure that surgical patients continue to have adequate pain control and receive the proper postoperative care needed to restore their overall health and avoid prescription opioid-related complications. In order to assure that surgical patients achieve adequate pain control during their recovery, managing and communicating about pain is critical. However, it is currently unclear whether the HCAHPS pain communication measures generate opioid use. **Therefore, we believe that additional research is needed to optimally gain the patient's experience in managing their postoperative pain, including the assessment of the relationship between the HCAHPS *Communication About Pain* questions and opioid prescribing practices, opioid use, and pain management.**

For these reasons, the ACS recommends that the three HCAHPS *Communication About Pain* questions be removed from the HCAHPS Survey and Hospital IQR Program as soon as operationally feasible. Additionally, until further research on the impact and utility of the HCAHPS *Communications About Pain* questions is performed, CMS should not publicly report performance data on these questions.

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 Ollapally, Regulatory Affairs Manager, at

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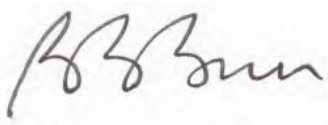
vollapally@facs.org, or Jill Sage, Quality Affairs Manager, at jsage@facs.org.

Sincerely,



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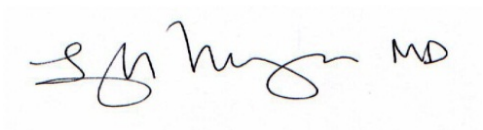

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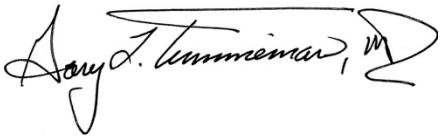

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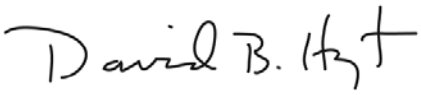

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