September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1678-P)

Dear Ms. Verma:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule (proposed rule) that was published in the Federal Register on July 20, 2017.

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. Our comments below are presented in the order in which they appear in the proposed rule.

OPPS GENERAL PROVISIONS

Proposed Nonrecurring Policy Changes

Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals

In the calendar year (CY) 2009 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (OPPS/ASC) final rule, CMS indicated that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in...
hospitals and provider-based departments of hospitals. In the CY 2010 OPPS/ASC final rule, CMS clarified that the direct supervision requirements apply to CAHs as well as to small rural hospitals with 100 or fewer beds. From March 15, 2010, through December 31, 2013, CMS implemented an enforcement moratorium on the direct supervision requirements for CAHs and small rural hospitals. Congress extended the nonenforcement of direct supervision requirements for CAHs and small rural hospitals until December 31, 2016.

In the CY 2018 OPPS/ASC proposed rule, CMS proposes to reinstate the nonenforcement of direct supervision requirements for outpatient therapeutic services for CYs 2018 and 2019 to give CAHs and small rural hospitals more time to comply with the supervision requirements and to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for a change in supervision level.

The ACS does not support the extension of the nonenforcement policy for direct supervision requirements for CAHs and small rural hospitals with 100 or fewer beds. While we share the concerns of CAHs and small rural hospitals regarding the shortage of general surgeons across the country, the ACS believes supervision requirements must be applied uniformly across all care settings for reasons of patient safety. We urge CMS to uniformly apply supervision requirements for CAHs, small rural hospitals and OPPS hospitals for the same services.

Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

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

As the ACS has previously commented, we do not consider the Consumer Price Index for Urban Consumers (CPI-U) to be an appropriate mechanism to update payments for ASCs because it does not accurately represent the changing costs borne by facilities to furnish 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 CPI-U do not reflect expenditures related to healthcare, let alone the purchasing experience of an ASC. The ASC payment system is also one of the last CMS payment systems to be tied to the CPI-U. Other payment systems use indices derived from the basket of goods actually purchased by those providers.

We urge the agency to align ASC payment updates with the OPPS payment updates by using the inpatient hospital market basket (HMB) for
both settings. While we appreciate that the HMB does not perfectly align with the ASC cost structures, it is more representative of the cost structure than the CPI-U or other existing update factors. Under the CPI-U, the proposed 2018 ASC payment rates for the highest volume services are on average at 53.5 percent of hospital outpatient department (HOPD) rates. Members of Congress are supportive of eliminating the use of the CPI-U for ASC payment updates, and have introduced the Ambulatory Surgical Center Quality and Access Act of 2017 (H.R. 1838/S. 1001), which would require CMS to use the HMB to update ASC payments. Therefore, we request that CMS begin updating the ASC payment system with the hospital market basket starting with CY 2018.

REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

The Hospital Outpatient Quality Reporting (OQR) Program is a pay-for-reporting program for outpatient hospital services. The program requires hospital outpatient facilities to meet CMS administrative, data collection, submission, validation, and reporting policies, or receive a reduction of 2.0 percentage points in their annual payment update for failure to meet these requirements.

Accounting for Social Risk Factors in the Hospital OQR Program

CMS seeks public comment on whether the Agency should account for social risk factors in the Hospital OQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods provided by CMS include: confidential reporting of stratified measure rates; public reporting of stratified measure results; and/or risk adjustment of a particular measure as appropriate based on data and evidence. CMS also seeks public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure.

The ACS applauds CMS on its responsiveness to recent findings examining the adjustment of social risk factors, including the concern regarding the potential impact of the lack of social risk factor adjustment. The ACS has long advocated for further study in this area and continues to believe further study is critically needed. The initial findings from the National Quality Forum (NQF) demonstrate that the NQF has only begun understanding this topic and therefore further research is necessary.¹ Recent findings from Office of the Assistant Secretary for Planning and Evaluation

(ASPE) also indicate the work completed to date is only the beginning of a body of “necessary work around fair and accurate quality measurement in the context of Medicare’s increasing use of value-based purchasing programs.”

ASPE notes further research will be done on socioeconomic status (SES) factors not found in Medicare data, and recommends that future research focus on functional status or frailty on the relationship between SES and a provider’s performance, as well as care innovations associated with good health outcomes in this population.

There is also work to be done to specifically identify which social factors have an impact on vulnerable populations. For example, CMS solicits a response on whether OQR scores should be stratified based on the portion of their patients who have dual eligible status in Medicare. We would argue that this adjustment may be too blunt, and may lead to misinforming the public and incorrectly measuring providers. We also believe it does not identify or address the specific factors that result in higher spending and/or poorer health outcomes. Most of the research conducted to date only analyzes Medicare data, which has limited information on social factors. Much of the feedback from NQF’s measure developers and other stakeholders indicated that better patient-level and community-level data sources for SES are needed, as are greater standardization of SES variables and methods to improve testing measures for SES risk adjustment. The National Academy of Medicine report also highlighted the need for research on additional SES factors.

Furthermore, other research has demonstrated that racial and economic disparities fail to explain the poor health outcomes across the country and, when comparing our health system to other industrialized nations, the United States falls short in its investment in social services to support the broader social determinants of health. This is further supported in the ASPE report, which found that providers who cared for patients with lower SES performed worse in quality measurement; those differences persisted even after adjusting the measures. ACS strongly encourages CMS to look at how social determinants of health affect Medicare beneficiaries and how SES can be incorporated into measurement. ACS also recommends the Secretary encourage CMS to work with other HHS agencies to prioritize research

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efforts to examine the broader social determinants of health, as well as address ASPE’s and NQF’s recommendations.

In general, ACS supports SES risk adjustment for measures used in accountability applications (e.g., public reporting and pay-for-performance). It is established that without the use of appropriate risk adjustment for certain measures, clinical outcomes will be less reliable due to SES confounding variables. However, we would like to note that the approaches to account for SES risk will likely vary depending on the measure under consideration and we therefore caution CMS against a one-size-fits-all approach. That said, closely evaluating the SES confounding variables will lead to a deeper understanding of the relationship between these variables and clinical outcomes. Until there are further findings on the appropriate application of risk adjustment, including which factors to include in SES adjustment, and further study on social support services, the ACS recommends the following methodology, when appropriate:

- For purposes of accountability (e.g., public reporting, pay-for-performance), SES factors should be included in risk adjustment on a case-by-case basis and when such factors demonstrate a conceptual and empirical basis for adjustment.\(^6\)

- Stratified results are also important to consider because they can demonstrate to CMS where more resources are needed to overcome the challenges vulnerable populations face that vary with SES.

By providing both risk adjusted and stratified results, CMS can avoid unfairly penalizing outpatient facilities that have a high percentage of vulnerable patients, while also allowing providers and facilities to drill down on relevant SES factors to improve the outcomes of disadvantaged patients.

*Measures Proposed for Removal from the Hospital OQR Program*

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 to alleviate the maintenance costs and administrative burden to hospitals associated with their retention. CMS does not propose any new measures for this program. ACS has comments on select measures as discussed below.

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Measures Proposed for Removal or Delay:

- **Remove OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures Beginning with the CY 2020 Payment Determination**

  The Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures measure is submitted via a web-based tool and collects surgical procedure volume data on eight categories of procedures frequently performed in the outpatient hospital setting. CMS explains its belief that there is a lack of evidence to support this measure’s link to improved clinical quality—that the number of surgical procedures does not offer insight into the facilities’ overall performance or quality improvement in regard to surgical procedures. Based on CMS’ analysis of the lack of evidence to support the inclusion of this measure, and the added burden required to report it, the ACS supports the removal of OP-26.

- **Remove: OP-25: Safe Surgery Checklist Use Beginning with the CY 2021 Payment Determination**

  The Safe Surgery Checklist Use is a structural measure of hospital process that assesses whether a hospital employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period. CMS proposes the removal of this measure because it has determined that this measure is topped out with little room for improvement. CMS explains that removing this measure would alleviate administrative burden for hospitals. CMS believes that the safe surgical checklist is widely used and that hospitals will continue its use.

The ACS opposes the general removal of all measures based on topped out status. While we would support the continued inclusion of this measure, in order to address CMS’ concern about the utility of OP-25, ACS recommends the inclusion of high-value process measures as part of a composite. We draw on an analogy with the aviation industry to illustrate the need to maintain high-value topped out measures. In aviation, a pilot’s pre-flight checklist is performed immediately before departure. Although performance on this checklist process is typically high enough to satisfy CMS’ definition of “topped out”, pilots are still required complete the checklist before every flight in order to avoid errors and oversights and ensure full readiness for the flight. Medical
care is complex, spanning time, unique patients, and disparate care systems. It is every bit as crucial that we continue to incentivize the long-term tracking of key processes and outcomes—even those that are topped out. The Safe Surgery Checklist measure is a high value patient safety measure and very similar in concept to a pre-flight checklist. For these reasons, we urge CMS to keep this measure in the program and include it as part of a surgical composite.


CMS explains that since the adoption of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) measures, the survey has lacked important operational and implementation data. Therefore, CMS proposes to delay the measure because the Agency wants to: ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national OAS CAHPS survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting. CMS also explains that the national implementation of the voluntary survey, which began in January 2016 and will conclude in December 2017, will provide valuable information moving forward. CMS also notes concerns regarding the burden associated with reporting the survey but still believes that it addresses an area of care that is not adequately assessed in its current measure set.

The ACS commends CMS for initiating this important measurement of patient experience of surgical care to improve quality. However, we strongly believe that the OAS CAHPS should be NQF-endorsed, especially if CMS is going to implement the survey nationally for public reporting and reimbursement purposes. We also have concerns regarding the lack of transparency on the development and testing of the OAS CAHPS, and whether the measures were developed with multi-stakeholder input.

In addition to the absence of NQF-endorsement and transparency, the ACS is concerned about overlap between OAS CAHPS and the CAHPS Surgical Care Survey (S-CAHPS), which has been NQF-endorsed (NQF #1741) since 2012. Because the OAS CAHPS was not
harmonized with the S-CAHPS and many items on the OAS CAHPS overlap with the S-CAHPS, there would be an unnecessary survey burden on patients if CMS were to require the administration of both surveys simultaneously. Also, ACS believes that, even in the context of facility-level accountability, it is imperative to incorporate well-tested, clinician-focused measures that provide surgeons with actionable information to improve the patient-centeredness of care. S-CAHPS questions were designed specifically to evaluate the surgeon, and survey results are directly attributable to the surgeon to drive quality improvement.

In summary, the ACS believes the OAS CAHPS measures should be NQF-endorsed before implementation as part of a national program, including consideration of harmonization with the S-CAHPS. In addition, we believe that the survey development and testing data should be publicly available. The ACS supports using the S-CAHPS, which was developed based on feedback from surgical patients and is NQF-endorsed, for the measurement of patient experience before, during, and after surgery.

Hospital OQR Program Measures and Topics for Future Consideration

The ACS strongly encourages the use of measures meaningful to patients and providers that incentivize episode-based care with shared accountability. We encourage CMS to move away from the current fragmented, singleton measures that do little to support quality, improvement, and true accountability. The current measures only depict a moment in time, resulting in scattered pieces of information across care, and never represent the full picture of care a patient receives across the care continuum. CMS quality programs should begin with a framework similar to the ACS guiding principles of quality improvement: setting clinical standards, building the right infrastructure, using the right data, and verifying with outside experts.

Ultimately, the ACS believes that CMS should implement a measure framework that is inclusive of high-value process measures across an episode of care coupled with complementary patient reported outcome (PRO) and patient reported experience (PRE) measures. The majority of surgical procedures are elective with the goal of improving a patient’s quality of life and/or function. Therefore, for most procedures, the outcome reported by the patient is the best source of success to determine whether improvement

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in the patient’s health and quality of life has been achieved. To this end, the ACS believes that CMS should explore patient-centered measures that evaluate patient outcomes and the individual contributions attributed to the team-based episode of care with shared accountability. This framework should be built on reliable and valid measurement science.

**Requirements for the Ambulatory Surgical Center Quality Reporting Program**

The ASCQR Program is a pay-for-reporting program that requires ASCs to meet administrative, data collection, and reporting policies, or receive a reduction of 2.0 percentage points in their annual payment update for failure to meet these requirements.

**Accounting for Social Risk Factors in the ASCQR Program**

Similar to the OQR Program, CMS seeks public comment 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. Examples of methods provided by CMS include: confidential reporting of stratified measure rates; public reporting of stratified measure results; and/or risk adjustment of a particular measure as appropriate based on data and evidence. CMS also seeks public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure.

The ACS applauds CMS on its responsiveness to recent findings examining the adjustment of social risk factors, including the concern regarding the potential impact of the lack of social risk factor adjustment. We have long advocated for further study in this area. For detailed comments, please refer to the OQR Program discussion on accounting for social risk factors found on page 3 of this letter.

**Proposed Measure Removal**

In this proposed rule, CMS proposes to remove/delay a number of measures for the 2019 payment determination and subsequent years. ACS has comments on select measures as discussed below.

- **Remove ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing**
  Beginning with the CY 2019 Payment Determination

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This measure assesses whether intravenous (IV) antibiotics given for prevention of surgical site infection (SSI) were administered on time. CMS explains that this measure has been determined to be topped out. The ASCQR Program previously finalized two criteria for determining when a measure is “topped out”: (1) when there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure’s truncated coefficient of variation (COV) is less than or equal to 0.10.9

CMS also explains that this measure lost its NQF endorsement in February 2015. During review by the NQF, the NQF Committee noted that the national average performance rate was 98 percent and questioned the specifications that only measure for the use of IV antibiotics. The Committee also found that some of the included antibiotics are not appropriate for the outpatient setting and argued that the evidence presented by CMS only related to inpatients and not to the ambulatory surgery setting.

Similar to our reasoning to retain certain high-value measures deemed to be topped out in the OQR program, the ACS opposes the general removal of all measures based on topped out status and, as an alternative, supports the inclusion of high-value process measures as part of a composite. We draw on an analogy with the aviation industry to illustrate the need to maintain high-value topped out measures. In aviation, a pilot’s pre-flight checklist is always performed immediately before departure. Although performance on this checklist process is typically high enough to satisfy CMS’ definition of “topped out”, pilots are still required to complete the checklist before every flight in order to avoid errors and oversights and ensure full readiness of the flight. Medical care is complex, spanning time, unique patients, and disparate care systems. It is every bit as crucial that we continue to incentivize the long-term tracking of key processes and outcomes—even those that are topped out. We encourage CMS to consider whether the Prophylactic IV Antibiotic Timing measure is a high-value patient safety measure for the ASC setting, and, if so, update the specifications to include antibiotics used in the outpatient setting, including oral antibiotics. If the measure is determined to be high-value, we encourage CMS to keep this measure in the program, but transition it to be included as part of a surgical composite.

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9 79 FR 66968 through 66969.
- **Remove ASC-6: Safe Surgery Checklist Use Beginning with the 2019 Payment Determination**

The *Safe Surgery Checklist Use* is a structural measure of hospital process and assesses whether a hospital employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period. CMS proposes the removal of this measure because it has determined this measure is “topped out” and that there is little room for improvement. CMS explains that removing this measure would alleviate administrative burden for hospitals. CMS believes that the safe surgical checklist is widely used and that ASCs will continue its use.

As discussed above, the ACS opposes the general removal of all measures based on topped out status and, as an alternative, supports the inclusion of high-value process measures as part of a composite. The *Safe Surgery Checklist measure is a high-value patient safety measure and very similar in concept to a pre-flight checklist*. For these reasons, we urge CMS to keep this measure in the program but transition it to be included as part of a surgical composite. For a more detailed rationale for the continued inclusion of this measure, please refer to page 6 of this letter.

- **Remove ASC-7: ASC Facility Volume Data on Selected Procedures Beginning with the 2019 Payment Determination**

The *ASC Facility Volume Data on Selected Procedures* is a structural measure of facility capacity that collects surgical procedure volume data on six categories of procedures frequently performed in the ASC setting. CMS explains that the Agency adopted the ASC-7 measure based on evidence that volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality. CMS further stated its belief that publicly reporting volume data would provide patients with beneficial performance information to use in selecting a care provider. However, over time, CMS has adopted more measures assessing ASCs’ performance on specific procedure types (e.g., ASC-14: Unplanned Anterior Vitrectomy and ASC-16: Toxic Anterior Segment). CMS explains that it believes these procedure-type-specific measures will provide patients with more valuable ASC performance.
data than the ASC-7 measure. The ACS agrees with the rationale provided by CMS that procedure-type-specific measures will provide patients with more valuable ASC performance data and we therefore support the removal of the ASC Facility Volume Data on Selected Procedures measure.

Proposed New ASCQR Program Quality Measures for the CY 2021 and CY 2022 Payment Determinations and Subsequent Years

- Proposed adoption of ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures Beginning with the CY 2022 Payment Determination

The Hospital Visits after Orthopedic ASC Center Procedures measure assesses all-cause, unplanned hospital visits within seven days of an orthopedic procedure performed at an ASC. CMS clarifies that applicable “hospital visits” include emergency department visits, observation stays, and unplanned inpatient admissions.

According to Medicare claims data, approximately 7 percent of surgeries performed in ASCs in 2007 were orthopedic in nature, which reflects a 77 percent increase in orthopedic procedures performed at ASCs from 2000 to 2007. Therefore, CMS believes this measure will incentivize ASCs to improve care and care transitions. Patients that have hospital visits that occur at or after discharge from the ASC may not be readily visible to clinicians because such patients often present to alternative facilities, such as emergency departments, where patient information is not linked back to the ASC. Furthermore, CMS explains that many of the reasons for hospital visits following surgery at an ASC are preventable; patients often present to the hospital for complications of medical care, including infection, post-operative bleeding, urinary retention, nausea, vomiting, and pain.

CMS also explains that this measure was reviewed by the NQF’s Measure Applications Partnership (MAP) in 2015. The MAP recommended it be refined and resubmitted prior to adoption, stating that testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting. The MAP also recommended that this measure be submitted to NQF for review and endorsement. Since then, CMS has completed testing and refinements for this measure in response to the MAP’s recommendations, which will be presented to the MAP in the fall of 2017. According to CMS, facility-level testing showed variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests
variation in quality of care and opportunities for quality improvement. Reliability testing showed fair measure score reliability. This measure is currently not endorsed by NQF, but CMS plans to submit it for endorsement once an appropriate NQF project has a call for measures. The ACS generally sees the value in measuring hospital visits after orthopedic ASC procedures, but has concern with the “all-cause” numerator—namely that the measure does not exclude hospital visits that are unrelated to the procedure. ACS strongly urges CMS to develop an exclusion for unrelated hospital visits. Additionally, the ACS does not believe that ASC-17 should be included in national payment programs, such as the ASQCR program, until it is NQF-endorsed and recommended by the NQF MAP.

- Proposed Adoption of ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures Beginning with the CY 2022 Payment Determination

The Hospital Visits after Urology ASC Procedures measure evaluates all-cause, unplanned hospital visits occurring within seven days of the urology procedure performed at an ASC. The measure cohort includes beneficiaries ages 65 and older undergoing outpatient urology procedures at an ASC who have 12 prior months of Medicare fee-for-service Parts A and B enrollment. The target group of procedures is those that: (1) are routinely performed at ASCs; (2) involve increased risk of post-surgery hospital visits; and (3) are routinely performed by urologists.

CMS cites multiple study findings in its rationale for proposing this measure, including studies indicating that:

- Urology procedures accounted for 4.8 percent of unanticipated admissions;
- Urology surgery patients were almost twice as likely as orthopedic, plastic surgery, or neurosurgery patients to be admitted following surgery;
- Outpatient urology surgery has an overall 3.7 percent readmission rate; and
- Using a 5% national sample of Medicare beneficiaries ages 65 and older who underwent one of 22 common outpatient urologic procedures at ASCs from 1998 to 2006, there was a 7.9 percent, 30-day risk-adjusted rate of inpatient admission following surgery, with more frequent same-day admissions following outpatient surgery at ASCs than at hospitals.
Similar to the Hospital Visits after Orthopedic ASC Procedures measure discussed above, the MAP recommended that this measure be refined and resubmitted prior to rulemaking because it is currently undergoing field testing. The MAP agreed that testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting. The MAP also recommended that this measure be submitted to NQF for review and endorsement.

Similar to the Orthopedic ASC Procedures measure, the ACS has concerns for the implementation of Hospital Visits after Urology ASC Procedures measure. The ACS generally agrees that there is value in measuring hospital visits after urology ACS procedures, but has concern with the “all-cause” numerator—namely that the measure does not exclude hospital visits that are unrelated to the procedure. We strongly urge CMS to develop an exclusion for unrelated hospital visits. Additionally, we do not believe that this measure should be included in national payment programs, such as the ASCQR program, until it is NQF-endorsed and recommended by the NQF MAP.

ASCQR Program Measures and Topics for Future Consideration

In the proposed rule, CMS invites public comment on the possible future inclusion of the Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure in the ASCQR Program measure set. CMS explains that breast procedure SSIs represent a substantial proportion of SSIs overall in inpatient settings and have one of the highest infection risks of any procedure type in the outpatient setting. According to CMS, as discussed in this proposed rule, SSI rates following breast procedures vary from 1 percent to over 30 percent depending on procedure type. CMS explains that the trend in surgery transitioning to outpatient and ambulatory surgery settings due to advances in surgical techniques and economic incentives for ambulatory surgery make these events an outcome of interest for the ASCQR Program. However, after our review of the current literature on SSI following breast procedures, it is clear that there are inconsistent results across studies for both the rate of SSI and the effectiveness of the use antibiotics to prevent SSI. The ACS National Surgical Quality Improvement Program (NSQIP) demonstrates SSI rates of 1.4 percent to 3.2 percent.\textsuperscript{11, 12, 13} However, other studies demonstrate a much

higher rate of SSI, ranging from 3.2 percent to 18.9 percent, although the historically cited rate for clean surgical cases is 1.5 percent.\(^\text{14, 15}\) Furthermore, in key studies, the question as to whether perioperative antibiotic use decreases SSI remains unanswered.\(^\text{16}\) For these reasons, we believe further investigation is needed to determine the reason for an SSI outcome in breast procedures prior to the implementation of this measure, so as not to incentivize unintended consequences based on actions this measure may encourage, such as the administration of perioperative antibiotics across breast procedures.

Other Topics for Consideration

As discussed above, the ACS strongly encourages the use of measures meaningful to patients and providers that incentivize episode-based care with shared accountability. The ACS encourages CMS to move away from the current fragmented, singleton measures which do little to support quality, improvement, and true accountability. The current measures only depict a “moment in time,” resulting in scattered pieces of information across care, and do not represent the picture of care a patient receives across the care continuum. CMS quality programs should begin with a framework similar to the ACS guiding principles of quality improvement: setting clinical standards, building the right infrastructure, using the right data, and verifying with outside experts. Ultimately, ACS believes CMS should implement a measure framework that is inclusive of high-value process measures that span across an episode of care coupled with complementary patient reported outcome (PRO) and patient reported experience (PRE) measures.\(^\text{17}\)

The majority of surgical procedures are elective with the goal of improving a patient’s quality of life and/or function. Therefore, for most procedures, the outcome reported by the patient is the best determinant of success to determine whether improvement in the patient’s health and quality of life has been achieved.\(^\text{18}\) To this end, ACS believes CMS should explore patient-centered measures that evaluate patient outcomes and the individual contributions


attributed to the team-based episode of care with shared accountability. This framework should be built on reliable and valid measurement science.

The ACS appreciates the opportunity to comment 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 vollapally@facs.org or at (202) 672-1510, or Jill Sage, Quality Affairs Manager, at jsage@facs.org or at (202) 672-1507, in the ACS Division of Advocacy and Health Policy.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director