

## PUBLIC COMMENT SUMMARY REPORT

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### **Project Title:**

Development of Facility-Level Quality Measure of Unplanned Hospital Visits after General Surgery Ambulatory Surgical Center Procedures

### **Dates:**

The Call for Public Comment period ran from July 11, 2017 to August 7, 2017.

The Public Comment Summary Report was made public in September 2017.

### **Project Overview:**

The Centers for Medicare & Medicaid Services (CMS) is developing a quality measure of hospital visits following general surgery procedures performed at ambulatory surgical centers (ASCs):

#### **1. Hospital Visits after General Surgery Ambulatory Surgical Center Procedures**

Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) is leading the work under contract to CMS (contract name: Development, Reevaluation, and Implementation of Outpatient Outcome/Efficiency Measures; contract number: HHSM-500-2013-13018I).

The measure assesses ASC-level quality, using near-term hospital visits that patients experience following ASC procedures, to evaluate the quality of general surgery procedures performed at ASCs. CMS plans to use this measure to report on the quality of ASCs and to prompt improvements in care for Medicare beneficiaries. CMS will calculate the measure score using routinely submitted claims. Therefore, facilities will not need to submit any new data to CMS for this measure.

As part of its measure development process, CMS requested interested parties to submit comments on the measure.

### **Project Objectives:**

The primary goal of this project was to develop an administrative claims-based outcome measure of general surgery ASC quality.

### **Information About the Comments Received:**

CMS solicited comments on one measure:

#### **1. Hospital Visits after General Surgery Ambulatory Surgical Centers Procedures (hereinafter, general surgery ASC measure)**

CMS solicited public comments by:

- Posting an announcement on CMS's Public Comment website (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>).
- Sending emails to relevant stakeholders and stakeholder organizations, including:
  - Individuals with subject matter expertise (for example, expertise in ambulatory surgery and/or performance measurement).
  - Business and consumer advocacy organizations.
  - Organizations focused on improving healthcare quality.
  - Insurance and purchaser organizations.
  - Medical associations and societies.
  - Research organizations.
  - Topic knowledge-related organizations.
- Sending email notifications to CMS listserv groups

CMS received comments from four commenters during the public comment period. Specifically, we received comments from (see [Table A1 in Appendix](#)):

- One acute care hospital that is part of a joint venture with a multi-specialty, outpatient surgical facility (Wyoming Medical Center).
- One health system with an ASC provider (Bon Secours Virginia Health System).
- Two associations:
  1. ASC Quality Collaboration.
  2. American Society of Anesthesiologists.

### **Stakeholder Comments – Measure-Specific**

CMS received comments from the four commenters on various aspects of the measure. Comments focused on the measure's cohort, outcome, risk-adjustment model, testing, and implementation. Commenters sought additional information or clarification about the measure's cohort and outcome.

### **Summaries of Measure-Specific Comments**

#### *General Comments*

- Two commenters commended CORE for developing the general surgery ASC measure and supported the measure's potential impact on improving quality of care provided by ASCs.

Response: We appreciate the commenters' support of the measure.

## Cohort

One commenter expressed concerns with the measure's cohort.

- The commenter pointed out that over half the procedures in the cohort are skin procedures. The commenter acknowledged that while general surgeons perform some of these procedures, the majority are performed by other types of surgeons.

Response: We agree with the commenter that in addition to general surgeons, other types of surgeons and non-surgical specialists perform skin and other procedures included in the cohort. We included skin procedures in the cohort because we found that the group of procedures that are within the scope of general surgery practice, including skin procedures, share in common (1) a risk of post-surgery hospital visits and (2) relatively similar reasons for return to the hospital. Members of our TEP also felt the care practices that would best lower the risk of hospital visits were similar across these procedures. Procedural volume was not a criterion for inclusion of procedures in the cohort.

- The commenter suggested renaming the measure to “Unplanned Hospital Visits After Skin Surgery and General Surgery Procedures Performed at Ambulatory Surgical Centers” to accurately reflect the dominant number of skin procedures in the cohort and to improve face validity.

Response: We appreciate the commenter's thorough review of the cohort and suggestion to rename the measure. We agree that it is important for the measure title to accurately reflect the focus of the measure. The scope of the measure was defined by the scope of practice of general surgeons. We have chosen not to include “skin procedures” in the title given that many types of procedures in the measure are performed by both general surgeons and other specialists, and including one specific procedure type, skin, in the title may make the scope of the measure less clear. To further clarify the scope, however, CMS has revised the measure's title to, “Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers” to clarify the scope of the procedures included in the measure's cohort.

- The commenter recommended not including two specific procedures in the cohort because they are not performed by general surgeons: 1) CPT® code 29893 – endoscopic plantar and 2) CPT® code 69222 – clean out mastoid cavity. The commenter further recommended that the general surgeons on the TEP review each of the procedures included in the cohort for appropriateness.

Response: We appreciate the commenter's suggestion to remove endoscopic plantar (CPT® code 29893) and mastoidectomy cavity cleaning (CPT® code 69222) procedures from the cohort. We agree that these procedures are not typically done by general surgeons.

We initially included them because we defined the cohort not at the individual procedure (CPT® code) level but using a higher-level procedure grouper, the Clinical Classifications Software (CCS) developed by the Agency for Healthcare Research and Quality (AHRQ). We reviewed each CCS and the individual procedures within it, and included all of the procedures in the CCS in the measure cohort if most or all of the procedures were within the scope of general surgery. The advantage of defining the cohort at the CCS level, rather than at the procedure level, was that

over time it will be easier to maintain a consistently defined cohort, as minor shifts in codes and coding occur. A disadvantage of using the grouper is that it inevitably includes some procedures that are outside the scope of general surgery. For the preliminary measure specifications, we therefore included CCS procedure categories performed largely by general surgeons. This approach was reviewed by our general surgery consultants and TEP.

In light of the comments received on the measure, we reconsidered this approach. CMS/CORE, as requested, re-reviewed the individual procedures within the CCS categories at the procedure (CPT® code) level in consultation with general surgeons. Based on our re-review, we identified and removed 15 individual procedures, defined using CPT® codes, that were outside the scope of general surgery from the measure's cohort ([Table 2](#)), including the two procedures flagged by the commenter (CPT®-codes 29893 and 69222). Removing the 15 individual procedures from the cohort reduced the number of patients included in the cohort by approximately 0.3% or 464 patients.

Table 1. List of 15 procedures (CPT®-code level) not included in the measure cohort because they are outside the scope of general surgery practice

| Procedure type   | CCS procedure category and label                             | CPT® code | CPT® code short description  |
|------------------|--|-----------|------------------------------|
| Skin/soft tissue | 170 – Excision of skin lesion                                | 29893     | Scope plantar fasciotomy     |
|                  | 172 – Skin graft   | 15840     | Graft for face nerve palsy   |
|                  |  | 15841     | Graft for face nerve palsy   |
|                  |  | 15842     | Nerve palsy microsurg graft  |
|                  | 174 – Other non-OR therapeutic procedures on skin and breast | 61885     | Insrt/redo neurostim 1 array |
|                  |  | 61886     | Implant neurostim arrays     |
|                  |  | 61888     | Revise/remove neuroreceiver  |
|                  |  | 15788     | Chemical peel face epiderm   |
|                  |  | 15789     | Chemical peel face dermal    |
|                  |  | 15793     | Chemical peel nonfacial      |
|                  |  | 28280     | Fusion of toes               |
|                  | 175 – Other OR therapeutic procedures on skin and breast     | 15781     | Abrasion treatment of skin   |
|                  |  | 15780     | Abrasion treatment of skin   |
|                  |  | 15819     | Plastic surgery neck         |
|                  |  | 61215     | Insert brain-fluid device    |
| Wound            | 169 – Debridement of wound, infection or burn                | 69222     | Clean out mastoid cavity     |

### Outcome

Three commenters addressed the measure's outcome.

- One commenter suggested additional types of outcomes for ASC quality measures: rates of surgical site infection, mortality, post-operative hospital admissions, deep vein thrombosis or pulmonary embolism, postoperative pneumonia, dehiscence, and ileus.

**Response:** We appreciate the commenter's feedback. To clarify, the measure's outcome includes post-operative hospital admissions. The measure's outcome is any unplanned hospital visit defined as an emergency department (ED) visit, observation stay, or unplanned inpatient admission, occurring within 7 days of the general surgery procedure performed at an ASC. Many

of the events the commenter lists are likely to result in an unplanned hospital visit and are already captured in the measure.

- A second commenter expressed concerns with the outcome's appropriateness. The commenter flagged 11 top reasons for hospital visits that likely reflect the indication for the index surgery (for example, lymphoma diagnosis after hemic operation), not quality of care as intended by the measure. The commenter further noted that some listed diagnoses are not truly complications of care or acute illnesses within 7 days of the ASC procedure (for example, postmenopausal atrophic vaginitis) and suggested providing a full list of included admissions for expert review. See [Table 2](#) for the full list 11 of diagnoses, which the commenter flagged.

Table 2. Table submitted by the commenter that list the 11 diagnoses for any hospital visit within 7 days of general surgery procedures

| AHRQ clinical category  | Top 10 primary ICD-9 hospital diagnoses | ICD-9 diagnosis description | Top 10 primary ICD-10 hospital diagnoses | ICD-10 diagnosis description                                  |
|---|---|-----------------------------|--|---|
| 67 – Other therapeutic procedures, hemic and lymphatic system | -                                       | -                           | C8387                                    | Other non-follicular lymphoma, spleen                         |
|   |   |                             | C8510                                    | Unspecified B-cell lymphoma, unspecified site                 |
|   |   |                             | C8593                                    | Non-Hodgkin lymphoma, unspecified, intraabdominal lymph nodes |
|   |   |                             | N952                                     | Postmenopausal atrophic vaginitis                             |
| 78 – Colorectal resection                                     | 605                                     | Redun prepuce & phimosis    | -  | -   |
| 87 – Laparoscopy  | -                                       | -                           | C801                                     | Malignant (primary) neoplasm, unspecified                     |
| 166 – Lumpectomy, quadrantectomy of breast                    | 1749                                    | Malign neopl breast NOS     | C50911                                   | Malignant neoplasm of unspecified site of right female breast |
|   |   |                             | C50912                                   | Malignant neoplasm of unspecified site of left female breast  |
| 167 – Mastectomy  | V4571                                   | Acq absnce breast/nipple    | -  | -   |
| 175 – Other OR therapeutic procedures on skin and breast      | -                                       | -                           | C50911                                   | Malignant neoplasm of unspecified site of right female breast |

Response: We appreciate the commenter's review of the top reasons for any hospital visit within 7 days of general surgery procedures.

The diagnoses identified by the commenter (listed above in [Table 2](#)) can occur during an admission, ED visit, or observation stay. If they occur during an admission, then all but one type, ICD-9-code V4571 acquired absence of breast and nipple, are identified as planned admissions and are not counted in the measure outcome. CMS will consider updating the planned admission algorithm to include ICD-9 code V4571.

If these diagnoses occur as part of an ED visit or observation stay, they are included in the measure outcome because ED visits and observation stays are not routinely used for planned care. We understand that the ED and hospital observation setting may be used for planned care at times, but the measure is structured to count these events because these settings are not usually a desirable setting for planned care from the patient's point of view.

- Another commenter suggested that the measure developer provide a clear definition of planned admissions to ensure accurate reporting of admission diagnoses, which are critical to measure performance. They also recommended reporting cases that are excluded from the measure for planned admissions and to evaluate facilities with high numbers of exclusions.

Response: We appreciate the commenter's request for clarification and suggestions.

To clarify, for inpatient admissions occurring after general surgery procedures performed at ASCs, only unplanned admissions are included in the measure outcome. "Planned" admissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. To identify admissions as planned or unplanned, we applied an algorithm previously developed for CMS's hospital readmission measures, the CMS Planned Readmission Algorithm Version 4.0. In brief, the algorithm uses the procedure codes and principal discharge diagnosis code on each hospital claim to identify admissions that are typically planned. A few specific, limited types of care are always considered planned (for example, major organ transplant, rehabilitation, or maintenance chemotherapy). Otherwise, a planned admission is defined as a non-acute admission for a scheduled procedure (for example, total hip replacement or cholecystectomy). Post-discharge admissions for an acute illness or for complications of care are never considered planned. A full list of the specific procedure categories and discharge diagnosis categories that are used to classify admissions as planned is available in Appendix C of the technical report posted for public comment.

We appreciate the commenter's suggestion to report cases that are excluded from the measure. In our Medicare Fee-For-Service (FFS) CY 2015 dataset, 0.6% of admissions were unplanned. As done for its other publicly reported outcome measures, when it reports the measure, CMS will likely provide to each ASC the facility's patient-level data used for the measure score calculation, including each patient's outcome and whether an admission was planned or unplanned.

### *Risk-Adjustment Model*

Three commenters addressed the measure approach to risk adjustment.

- One commenter recommended ASCs implement a thorough health risk assessment as standard

protocol prior to performing general surgery procedures in order to assess a patient's underlying medical conditions, such as diabetes, and past surgeries for post-operative treatment planning.

Response: We agree that health risk assessments could facilitate adequate postoperative treatment planning that would prevent potentially avoidable hospital visits after general surgery ASC procedures. For this measure, however, CMS is utilizing claims data rather than requiring de novo data collection for risk adjustment in order to prevent undue burden upon facilities. The measure uses claims data from the 12-month period prior to the procedure for each patient in order to identify any diagnoses or prior surgeries for which the outcome of hospital visits after general surgery at an ASC may not reflect quality and warrant risk adjustment.

- One commenter suggested that risk adjustment may not be necessary since ASCs are not designed to manage high-risk patients.

Response: We appreciate the commenter's suggestion and have discussed this issue with our TEP. For fairness, CMS has decided to adjust this measure for the mix of patients and procedures across providers so that these differences will not affect the quality scores. Risk adjustment also ensures that quality measures will not create a disincentive to care for complex patients who are at greater risk of hospital visits.

- One commenter recommended risk stratifying the measure by socioeconomic status (SES), based on the National Quality Forum's recommendation to stratify measures by SES, rather than using risk adjustment.

Response: We understand that the commenter suggests risk stratifying by SES. We explored the need to risk stratify for SES during measure development. If there was a strong relationship between SES and the outcome empirically and a conceptual model suggesting a relationship that was unrelated to quality, that would argue in favor of stratification. As described in our technical report posted for public comment, we tested the measure score for the impact of race and SES based on Medicaid dual-eligibility status, African-American race, as well as a composite of SES validated by AHRQ. The measure scores were highly correlated when calculated with and without the SES variables, quartiles of populations based on the SES variables revealed limited differences in the measure score distribution, and there were no differences in the median rates of measure scores for the SES variables. Based on this finding, CMS decided this iteration of the measure will not utilize SES risk adjustment or stratification. However, similar to all measures seeking National Quality Forum (NQF) endorsement, this measure will undergo NQF review of the need for risk stratification.

### Testing

One commenter addressed the measure testing results.

- One commenter was concerned with the measure's reliability score.

Response: We appreciate the commenter's concerns about the reliability of the measure. The results of reliability testing are consistent with existing measures of patient outcomes in the ASC setting and similar outcome measures endorsed by NQF.

We tested the reliability of the measure score by calculating the intra-class correlation coefficient (ICC). The ICC evaluates the agreement between the risk-standardized hospital visit rates (RSHVRs) calculated in two randomly selected patient samples. Since we measured the underlying quality of general surgery procedures performed at the ASC using patient outcomes, we anticipated that two independent samples of patients from an ASC should generate scores that are similar. We calculated measure score reliability for a 2-year reporting period and found that the agreement between the two RSHVR values for each ASC was calculated for 2 years to be ICC [2,1] = 0.526, indicating moderate measure score reliability.

While NQF endorsement is not required for measure implementation, the measure will be presented to NQF committees to evaluate scientific acceptability. NQF committees consider their evaluation criteria to be rigorous, which state that moderate or high reliability is typically required for endorsement.

As such, we believe the measure is a reliable indicator of general surgery ASC quality.

- The same commenter focused on the limited variation in the risk-adjusted measure scores. Facility performance score categories identified few outliers, demonstrating little discernable variability in performance. The commenter suggested that a measure that identifies few underperforming facilities will not promote facility quality improvement and wondered if the measure would be a candidate for immediate removal from the ASC Quality Reporting (ASCQR) Program based on the CMS criteria for "topped out" measures.

Response: We appreciate the commenter's concerns. In the public comment materials, CMS calculated the results of the measure score in two ways for each facility – an estimated 7-day hospital visit rate and a descriptive category of their quality (better than, worse than, or no different than the national rate): As the commenter pointed out, this descriptive approach categorized few facilities as outliers. The approach to categorizing facility outliers is very conservative by design. It uses 95% confidence interval (uncertainty) estimates to identify outliers.

The distribution of the estimates of the hospital rates themselves, however, do convey meaningful variation. As presented in the public comment technical report using Medicare FFS CY 2015 data, we found that the facility measures scores ranged from 0.94% to 4.55%, with a median risk-standardized hospital visit rate of 2.19% (the 25<sup>th</sup> and 75<sup>th</sup> percentiles were 2.03% and 2.46%, respectively). The variation in these rates provides a quality signal, and we believe reporting facility-level measure scores will improve transparency and promote quality improvement.

To support continuous improvement across the full distribution of performance scores, CMS typically provides measure scores and patient-level reports to facilities that indicate whether their patients had a hospital visit within 7 days, and the diagnoses and locations of visits, and will likely provide these to ASCs when it reports the general surgery ASC measure.

Regarding the commenter's concern of whether this measure would be a candidate "topped out" measure in the future, CMS has outlined criteria to identify "topped out" measures in the ASCQR program (79 FR 41045 through 41046) and will continue to evaluate variation in measure



scores for measure retirement consideration.

### *Implementation*

Two commenters focused on the usability of the measure for ASCs and patients.

- One commenter thought the measure lacks actionability. The commenter did not favor the use of 2 years for measure score calculation and noted that by the time ASCs would receive their data, the data would be outdated.

Response: We appreciate the commenter's careful considerations about the measure's implementation.

We understand the commenter's concern about using 2 years of data and agree that it is important to provide timely information to facilities.

To clarify, at this time, CMS has not proposed the general surgery ASC measure for implementation in the ASCQR program. However, CMS has proposed two measures developed by CORE for the ASC setting (ASC-17: Hospitals Visits after Orthopedic ASC Procedures and ASC-18: Hospital Visits after Urology ASC Procedures) for reporting to be calculated using 2 years of data within the CY 2018 OPPI Proposed Rule (82 FR 33696) to ensure reliable estimates.

We acknowledge that the presence of many small-volume ASCs makes it challenging to use one year of data to assess the quality of ASC care. However, using two years of data allows CMS to provide a meaningful and reliable quality assessment for a greater proportion of the facilities that have relatively few cases. For this measure, CMS will continue to monitor the amount of data required for measure score calculation prior to and during any implementation of the measure and make a decision about the years of data to use weighing the tradeoffs between having an adequate number of cases for the greatest number of facilities and ensuring data are timely.

- The same commenter stated the amount of insight the general surgery ASC measure would offer would be limited, citing the ASC-12 measure (ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy) as an example. The commenter stated that the facility-level reports that ASCs have received to date for ASC-12 have not been additive as ASCs were already aware of the information before receiving it from CMS or it did not spark new quality improvement efforts.

Response: We believe measuring and publicly reporting risk-adjusted measure scores will encourage ASCs to engage in quality improvement and lead to better patient care over time. We note that for the ASC-12 measure, CMS has not yet provided ASCs with information on risk-adjusted performance. This is because the ASC-12 measure has not yet been publicly reported; it will be reported no earlier than December 2017 (79 FR 66974). Given this, we therefore presume the commenter is referring to the Claims Detail Reports (CDRs) that CMS has made available to ASCs in the intervals prior to the measure's public reporting. The CDRs are designed to enable ASCs to confirm the accuracy of their claims data and correct claims that would be used to calculate the publicly reported measure score. However, CDRs do not contain risk-adjusted measure scores, making it difficult for an ASC to compare its performance to its peers.

Prior to public reporting, CMS anticipates providing ASCs with the data used for final risk-adjusted measure score calculation (i.e., an ASC's patient risk factor information compared to risk factors for patients in other ASCs). We believe that the risk-adjustment information in the facility-specific reports will provide critical additional information that informs quality improvement at ASCs. As done for the ASC-12 measure, CMS will likely provide analogous information to facilities for the general surgery ASC measure (e.g., CDRs and facility-specific reports). We believe these efforts will provide ASCs with information to understand their performance and to improve the care they provide to patients.

- The same commenter referred to and favored the ASC QC's approach to measuring post-discharge ED visits and admissions, which they acknowledged burdens providers by necessitating data collection.

Response: We appreciate the commenter's suggestion and its preference for the ASC QC's approach. CMS encourages ASCs to collect data that supports quality improvement, and would be interested in hearing more about the specific approach the ASC QC is developing that would illuminate the outcomes assessed by this measure.

- A second commenter noted that the measure will strengthen efforts to improve quality of care at ASCs. The commenter noted that there is currently little incentive to use ASCs' limited resources to prevent complications when another facility, such as a hospital, can manage a patient's complications.

Response: We appreciate the commenter's support of the measure. We agree that the measure will incentivize improved care at ASC facilities. Our measure fulfills statutory requirements for ASCs to implement and maintain a data-driven quality assessment and improvement (QAPI) program in order to participate in the ASCQR program (42 CFR 416.43).

- The second commenter remarked that applying this measure may improve the decision-making and accountability of clinicians and other stakeholders. The measure may also highlight the role of anesthesiologists to ensure quality of care, reduce complications requiring hospital admission, and improve patient outcomes. The commenter found that the measure could help ASCs determine which patients were fit for surgeries performed at ASCs.

Response: We appreciate anesthesiologists' role in providing quality care to patients as well as the commenter's support of the measure outcome.

## Recommendations

CMS and CORE further investigated several of the issues identified in this comment. Specifically, CORE and CMS:

- Renamed the measure as "Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers" to reflect the procedures included in the measure cohort.
- Re-reviewed all of the individual CPT codes within CCS categories and removed 15 individual procedures (CPT® codes) from the measure that are outside the scope of general surgery practice, including the two specifically suggested for removal by a commenter.

- Will evaluate whether refining the CMS planned admission algorithm will better capture planned admissions for the diagnoses flagged by comments.

### **Overall Analysis of the Comments and Recommendations**

Although many comments demonstrated support for the general surgery ASC measure, several comments made recommendations for measure improvement. Commenters provided input on the cohort, risk-adjustment model, the number of years for data collection, and planned admission algorithm, which we will evaluate and review with general surgeon consultants and TEP members.

## Appendix. Public Comment Verbatim Report

Table A1. Verbatim public comments

| Date posted | Measure set or measure  | Text of comments  | Name, Credentials; and Organization of Commenter  | Email address  | Type of organization             |
|-------------|---|---|---|--|----------------------------------|
| 7/21/2017   | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p>I commend Yale/New Haven CORE for their work on this quality measure. I think this will help bolster efforts to improve quality of care at ambulatory surgery centers. Many such centers have a financial structure that could influence a decision to have care at an ASC rather than at a hospital. As hospitals face unprecedented financial pressure, managing the complications of surgery performed at an unaffiliated facility is a potentially preventable expense. While providing care at the least expensive level of service makes sense, the resources of ASCs are often inadequate to manage predictable complications, and there is little incentive to expand those resources when complications can be managed by another facility.</p> <p>The issue of risk adjustment is complicated. ASCs are not designed to manage high risk patients. One would not want risk adjustment to mask the quality issue of a facility failing to using wisdom in case selection.</p> | Carol Solie, M.D.<br>Chief Medical Officer<br>Wyoming Medical Center                                | <a href="mailto:csolie@wyomingmedicalcenter.org">csolie@wyomingmedicalcenter.org</a> | Acute care hospital              |
| 7/31/ 2017  | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p>Below are the metrics that we recommend be measured for ASCs. SSI, Mortality, Hospital Admission Rate postop (comparative metric to readmission rate), DVT/PE, Post-op PNA, Dehiscence, Ileus. We also recommend a thorough health risk assessment should be performed preoperatively to assess any underlying medical conditions (diabetes being a major concern), past surgeries, etc. to assess post op treatment planning. This protocol should be standard for all ASU procedures. Thank you!</p>   | Leigh T. Sewell<br>Vice President<br>Service Line Strategy<br>Bon Secours<br>Virginia Health System | <a href="mailto:Leigh_Sewell@bshsi.org">Leigh_Sewell@bshsi.org</a>                   | Health system, including one ASC |

| Date posted | Measure set or measure  | Text of comments  | Name, Credentials; and Organization of Commenter   | Email address  | Type of organization   |
|-------------|---|---|--|--|--|
| 8/7/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p>CMS and CORE Project Teams:</p> <p>On behalf of the ASC Quality Collaboration (ASC QC), please accept the following comments regarding the draft measure “Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers”.</p> <p>The ASC QC is a non-profit organization dedicated to advancing quality measurement and public reporting in the ambulatory surgery center (ASC) industry through a collaborative effort involving a diverse group of ASC stakeholders. These stakeholders include leaders from the ASC industry, accreditation organizations, and professional associations (please find a list of these stakeholders in Appendix A to this letter). Collectively these organizations represent over 1,500 ASCs.</p> <p>The measure is intended to assess adverse outcomes through detection of near-term hospital visits (defined as unplanned inpatient admissions, observation stays, and emergency department visits) following general surgery procedures performed at ASCs. CMS plans to use this to determine ASC-level quality of care and “prompt improvements in care for Medicare beneficiaries”. It is an administrative claims-based outcome measure; the measure scores would be calculated using routinely submitted claims, meaning facilities would not need to submit any new data to CMS.</p> <p>CMS is seeking public comment to further inform measure development. Specifically, CMS has asked for feedback on all aspects of the measure, including the measure rationale, the specific technical approach to the measure, the draft specifications, testing results, and the national distribution of measure scores across ASC facilities. We appreciate this opportunity to provide input.</p> | Donna Slosburg, BSN, LHRM, CASC, Executive Director, Ambulatory Surgical Center Quality Collaboration (ASC QC) | <a href="mailto:donnaslosburg@ascquality.org">donnaslosburg@ascquality.org</a> | A cooperative effort of ASC industry leaders and organizations |

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|-------------|---|--|---|--|--|
| 8/7/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>A.Draft Specifications: The Measure Cohort</b></p> <p>The measure focuses on outpatient procedures that are “within the scope of general surgery <i>training</i>” [emphasis added], including the following types of procedures: abdominal, alimentary tract, breast, skin/soft tissue, wound, and varicose vein. After reviewing the list of Current Procedural Terminology (CPT®) codes included in the measure cohort, we note that the services with the highest volume are not routinely performed in ASCs by general surgeons, but rather by other surgical and non-surgical physician specialties. We are particularly concerned with the inclusion of so many skin repair, graft and plastic repair surgeries of the face – including eyelids, ears, nose, lips, forehead, cheeks, and chin. It is our understanding that this broad range of procedures has been included in order to generate sufficient volume for the cohort. However, the resultant case mix diverges significantly from the typical practice of a general surgeon in the ASC setting. <i>Over half of the cases in the measure cohort are skin procedures.</i> Do not misunderstand: we are not saying general surgeons do not perform these surgeries. We are saying this does not reflect how general surgeons spend their operating time in ASCs. In addition, the measure includes a couple of CPT® codes that do not seem pertinent at all. For example, we note the inclusion of services such as 29893 – Endoscopic plantar fasciotomy and 69222 – Clean out mastoid cavity. The general surgeons on the TEP who practice in an ASC should carefully review all the procedures that are planned for inclusion in the measure to assure practicing general surgeons typically perform them in ASCs.</p> <p>Finally, the title of this measure sets the expectation that the results will be reflective of the practice of general surgery in the ASC setting. ASCs will quickly realize that the measure results only partially reflect what they consider to be general surgery cases. If CMS and the developer remain intent on retaining all the skin surgeries, it would be helpful to rename the measure so it better reflects what it truly assesses. A title such as “Unplanned Hospital Visits After Skin Surgery and General Surgery Procedures Performed at Ambulatory Surgical Centers” - putting skin surgery first since it is the predominant procedure type - would be reasonable. Changing the title would also help improve the face validity of the measure.</p> | Donna Slosburg, BSN, LHRM, CASC, Executive Director, ASC QC | <a href="mailto:donnaslosburg@ascquality.org">donnaslosburg@ascquality.org</a> | A cooperative effort of ASC industry leaders and organizations |

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| 8/7/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>B. Draft Specifications: Attribution of Outcomes</b></p> <p>Based on our review of the limited results presented in Table 4 of the measure documentation, which is titled “Top hospital visit diagnoses for any hospital visit within 7 days of general surgery procedures (dataset: Medicare FFS CY 2015)”, there is a significant amount of additional work that needs to be done to ensure the outcomes identified by the measure are appropriate. <a href="#">Table 1</a> summarizes some of the issues identified. Several of the “top diagnoses” have nothing to do with the quality of care, but rather reflect the indication for the index surgery. For example, a diagnosis of lymphoma following surgery on the hemic or lymphatic system is not an indication of an acute illness or complication of care. It reflects a new diagnosis established by the index surgery that is being treated in the week following the patient’s procedure. Similarly, a new diagnosis of a breast neoplasm is not an illness caused by the index breast surgery or a complication of the surgery itself. Finally, conditions such as the acquired absence of a breast/nipple are expected following a mastectomy.</p> <p>In addition, some of the conditions identified as an acute illness or complication of care are clearly neither one. For example, we are not aware of any clinical experience or literature that would support the implication that postmenopausal atrophic vaginitis is an “acute illness” or “complication of care” that can be attributed to a surgical procedure that took place in the preceding seven-day period.</p> <p>We are particularly concerned about this problem because the public has only been given the opportunity to review the “top” diagnoses, and it is not unreasonable to believe there are other illogical outcomes buried deeper in the dataset. The measure developer should provide for a detailed clinical review of all the measure results by several seasoned surgeons to ensure the measure algorithm is appropriate.</p> | Donna Slosburg, BSN, LHRM, CASC, Executive Director, ASC QC | <a href="mailto:donnaslosburg@ascquality.org">donnaslosburg@ascquality.org</a> | A cooperative effort of ASC industry leaders and organizations |

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| 8/7/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>C.Reliability for Accountability and Public Reporting Purposes</b></p> <p>The measure developer has acknowledged that the relatively high number of low-volume ASCs make the development of this measure challenging. To manage this, the measure has been specified in ways that generate larger case volumes (principally through the inclusion of large numbers of skin surgeries than can be performed by many physician specialties). The other problem that arises in low-volume situations is that measure scores tend to lack reliability. In order to deal with this, the developer has conducted testing on the measure scores using a two-year period of data collection and excluding those facilities with less than 25 qualifying procedures over that two-year period. Even with these steps, the intra-class correlation coefficient (ICC) was 0.526, which is considered “moderate”.</p> <p>In our opinion, the reliability of a measure intended for public reporting and accountability purposes should be higher. If facilities are to be judged based on the results calculated for this measure, the reliability of those scores should be, at a minimum, “substantial” (0.61 to 0.80 per convention). This could be achieved by raising the minimum number of qualifying procedures per facility. Setting such a low threshold for inclusion - currently the measure only requires an average 12 to 13 such cases in a given year per facility - does not provide sufficient information about quality and limits the ability to reliably estimate measure scores. Based on past ASCQR Program experience, we are concerned that CMS will elect to implement this measure using an inadequate data timeframe, as it has done with the related ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure. Despite the need for <i>three</i> years of claims data to assure reliable results for the colonoscopy measure, CMS implemented the measure using only <i>one</i> year of claims data. Publicly reported scores for that measure are unreliable, but the agency appears indifferent to this. We urge the developer to make modifications that improve the reliability of this measure, helping to minimize the impact of implementation practices that further degrade the meaningfulness of the scores.</p> | Donna Slosburg, BSN, LHRM, CASC, Executive Director, ASC QC | <a href="mailto:donnaslosburg@ascquality.org">donnaslosburg@ascquality.org</a> | A cooperative effort of ASC industry leaders and organizations |



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| 8/7/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>D.Limited Ability to Make Distinctions Among Facilities</b></p> <p>According to the developer and CMS, “[t]he purpose of this measure is to illuminate variation in quality of care for general surgery procedures across ASCs, inform patient choice, and drive quality improvement.”</p> <p>Unfortunately, this measure suffers from very limited discriminatory power. The developers initially used <i>unadjusted</i> outcome rates to assert a variation in quality: “Among the 1,157 ASCs with at least 25 cases in the Medicare FFS CY 2015 dataset, the unadjusted rate of unplanned hospital visits ranged from 0% to 13.2%. Among these ASCs with 25 or more cases, 25.2% had a rate of 0%; however, the top 10% had rates exceeding 5.7%. The results show important variation in performance across ASC facilities. While many achieve very low rates, there is a wide range of outcome rates, suggesting room for improvement.” However, it is essential to adjust for ASC case-mix differences such as patient demographics and comorbidities, as well as procedure type and complexity before drawing conclusions about variability in performance.</p> <p>Following this adjustment, there is little discernable variability in performance. Using the standard 95 percent interval estimate to report the measure score, of the 1,651 ASCs that qualified for the measure, the performance of 1,621 centers (about 98%) was no different than the national rate. Of the remaining 30 ASCs, 14 performed better than the national rate, and 16 performed worse than the national rate. This means that the overwhelming majority (about 99%) of facilities would receive a measure score indicating their performance to be either no different from or better than the national rate – with the implicit indication that no improvement effort would be necessary. The number of underperforming facilities is very small.</p> <p>While the developers state there is variability in performance, as a practical matter the risk-standardized results indicate little room for improvement. One could legitimately wonder if this measure would be a candidate for immediate removal from the ASCQR Program based on CMS criteria for determining when a measure is “topped out”.</p> | Donna Slosburg, BSN, LHRM, CASC, Executive Director, ASC QC | <a href="mailto:donnaslosburg@ascquality.org">donnaslosburg@ascquality.org</a> | A cooperative effort of ASC industry leaders and organizations |

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| 8/7/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>E.Lack of Actionability</b></p> <p>According to the supporting documentation, “[t]his measure’s goal is to assess and illuminate variation in risk-adjusted hospital visits following surgery for quality improvement purposes.” The developers state, correctly, that ASCs are not aware of all post-discharge hospital visits that occur among their patients. They believe this measure “will provide ASCs with critical information and incentives... to reduce unplanned hospital visits.”</p> <p>It is true that ASCs are not always aware of every hospital visit for each of their patients. However, based on the experience of our members, the amount of insight that this type of measure will offer appears to be limited. We say this based upon preliminary experience with a similar measure, the ASCQR Program’s ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure. The same claims-based methodology, outcomes, and approach to risk adjustment are used in both measures. Several of our members have undertaken thorough evaluations of the facility-level reports for ASC-12 and have found that the ASC was already aware of almost every hospital visit. Further, the centers have found that the information provided by the reports did not spark any additional insight or offer any new direction to quality improvement efforts.</p> <p>Additionally, because the measure relies on a retrospective analysis of claims over an extended period of time, the measure scores and results are not received until months after the patient’s visit. This delay significantly limits the usefulness of the information.</p> <p>We favor a different approach to the measurement of ED and hospital visits following ASC care and have developed measures that would involve the ASC in the timely collection of patient data in the near-term following patient discharge. Reaching out early in the post-discharge period maximizes the ASC’s potential for successfully engaging patients and their families in gathering the information needed to identify opportunities for improvement. There is certainly a data collection burden associated with this approach, but we believe it is better to invest the effort in collecting actionable data that leads to opportunities for improvement rather than to receive, without effort, information that is dated and not actionable.</p> | Donna Slosburg, BSN, LHRM, CASC, Executive Director, ASC QC | <a href="mailto:donnaslosburg@ascquality.org">donnaslosburg@ascquality.org</a> | A cooperative effort of ASC industry leaders and organizations |

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| 8/7/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>F.Measure Scores Not Helpful to Consumers</b></p> <p>The developers indicate that another one of the purposes of this measure is to inform patient choice. In our opinion, the measure does little to aid the consumer in evaluating ASC performance. As noted above, the performance of 99% of all ASCs measured was either no different from or better than the national rate. The consumer would have difficulty discerning differences in quality because it would be so unusual for a facility to perform worse than the national rate – in CY 2015 there were only 16 such centers out of a total of over 5,400 ASCs.</p> <p>In addition, the inclusion of so many procedures that are typically performed by physicians other than general surgeons tends to obscure the outcomes that are related to the actual practice of general surgery in ASCs. Patients would be unlikely to understand this, and could be led to believe that these skewed outcome rates reflect performance for the services they are planning.</p> <p>Finally, the necessity of a long data collection period (2 years) to generate measure scores that are even moderately reliable means the consumer will be presented with information that is dated. Even setting aside the significant time lag from the generation of claims to the reporting of measure results, the extended data collection timeframe means that past performance would continue to impact year-over-year measure scores. The publicly reported measure score would not be a true reflection of recent performance. In fact, the score could obscure significant improvement or deterioration in recent performance. As a result, consumers could be misled by the lack of timely data.</p> | Donna Slosburg, BSN, LHRM, CASC, Executive Director, ASC QC | <a href="mailto:donnaslosburg@ascquality.org">donnaslosburg@ascquality.org</a> | A cooperative effort of ASC industry leaders and organizations |

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| 8/8/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>Introduction</b></p> <p>On behalf of the more than 52,000 members of the American Society of Anesthesiologists® (ASA), I appreciate the opportunity to provide comment on the development of this facility-based measure assessing <i>Unplanned Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers</i> (ASC). ASA looks forward to future opportunities to comment and participate in measure development activities, including Technical Expert Panels (TEPs), especially those relevant to the specialty of anesthesiology. Our members and patients will benefit from having this facility-based outcome measure. Physician anesthesiologists are leaders in preventing financial and medical burdens that may accrue to patients, physicians and facilities by an unplanned post-procedure hospital visit. Anesthesiologists assess patients for risk prior to and throughout a procedure yet their work in preventing such hospitals visits is often underestimated. Developing and applying this measure at the facility-level may lead to improved decision-making among ASC clinicians and engender a greater understanding among patients of the role anesthesiologists play in ensuring quality of care and improving patient outcomes. This measure, when appropriately applied, may lead facility clinicians and other stakeholders to take effective action to improve their performance.</p> | Jeffrey Plagenhoef, MD, President of American Society of Anesthesiologists (ASA) | <p>On behalf of Jeffrey Plagenhoef, MD:<br/>Leslie Kociemba, MPH, ASA Quality Associate<br/><a href="mailto:L.Kociemba@asahq.org">L.Kociemba@asahq.org</a></p> <p>Matthew Popovich, PhD, ASA<br/>Director of Quality and Regulatory Affairs<br/><a href="mailto:gra@asahq.org">gra@asahq.org</a></p> | Professional society |
| 8/8/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>ASA supports the development of this important and necessary facility-based measure.</b></p> <p>Measuring hospital visits after general surgery procedures performed at Ambulatory Surgical Centers (ASCs) is a critical outcome measure that involves physician anesthesiologists and their expertise during the perioperative period. This measure will allow for facilities to improve care to reduce complications requiring hospital admission, as well as better decipher patients that are fit for surgery at an ASC. We continue to support measures that assess quality improvement at the facility level and embrace efforts to facilitate shared accountability between clinicians.</p>  | Jeffrey Plagenhoef, MD, ASA President  | <p>On behalf of Jeffrey Plagenhoef, MD:<br/>Leslie Kociemba, MPH, ASA Quality Associate<br/><a href="mailto:L.Kociemba@asahq.org">L.Kociemba@asahq.org</a></p> <p>Matthew Popovich, PhD, ASA<br/>Director of Quality and Regulatory Affairs<br/><a href="mailto:gra@asahq.org">gra@asahq.org</a></p> | Professional society |

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| 8/8/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>Yale/CORE should consider risk stratification instead of risk-adjusting the measure to best preserve the measure's intent.</b></p> <p>This measure will allow facilities and, in effect, clinicians to assess several components of care, including how clinicians assess and accept patients for outpatient procedures in Ambulatory Surgery Centers (ASCs). If the measure is implemented with a risk-adjustment model as proposed, we caution that the risk-adjusted measure may remove critically ill patients that may have been incorrectly accepted for surgery at an ASC from the measure score. Such a scenario would render the measure less meaningful. We recommend risk stratifying the measure by risk factors instead, based on the National Quality Forum's recommended approach for stratifying by socioeconomic factors.</p> | Jeffrey Plagenhoef, MD, ASA President            | <p>On behalf of Jeffrey Plagenhoef, MD:<br/>Leslie Kociemba, MPH, ASA Quality Associate<br/><a href="mailto:L.Kociemba@asahq.org">L.Kociemba@asahq.org</a></p> <p>Matthew Popovich, PhD, ASA<br/>Director of Quality and Regulatory Affairs<br/><a href="mailto:gra@asahq.org">gra@asahq.org</a></p> | Professional society |
| 8/8/17      | Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | <p><b>ASA recommends a clear definition of 'planned admission'.</b></p> <p>We are concerned that this measure, as written, could potentially lead to "gaming" in terms of accurately reporting "planned admissions." After careful review of the measure algorithm, it is evident that the admission diagnosis is critical to overall measure performance. We ask that the Yale/CORE TEP consider requiring cases excluded from the measure because of admission diagnosis be reported separately. The TEP should also consider, when implementing this measure, looking at those facilities with high numbers of exclusions.</p>  | Jeffrey Plagenhoef, MD, ASA President            | <p>Leslie Kociemba, MPH, ASA Quality Associate<br/><a href="mailto:L.Kociemba@asahq.org">L.Kociemba@asahq.org</a><br/>(847) 268-9266</p> <p>Matthew Popovich, PhD, ASA<br/>Director of Quality and Regulatory Affairs<br/>202-591-3703<br/><a href="mailto:gra@asahq.org">gra@asahq.org</a></p>      | Professional society |