

## PUBLIC COMMENT SUMMARY REPORT

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### **Project Title:**

Development of Facility-Level Quality Measures of Unplanned Hospital Visits after Selected Ambulatory Surgical Center Procedures

### **Dates:**

The Call for Public Comment period ran from August 12, 2016 to September 2, 2016.

The Public Comment Summary Report was made public in fall 2016.

### **Project Overview:**

The Centers for Medicare & Medicaid Services (CMS) is developing two quality measures of hospital visits following orthopedic and urology procedures performed at ambulatory surgical centers (ASCs):

1. Hospital Visits after Orthopedic Procedures Performed at Ambulatory Surgical Centers
2. Hospital Visits after Urology Procedures Performed at Ambulatory Surgical Centers

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 measures assess ASC-level quality. They use near-term hospital visits that patients experience following ASC procedures to evaluate the quality of orthopedic and urology procedures performed at ASCs. CMS plans to use these measures to report on the quality of ASCs and to prompt improvements in care for Medicare beneficiaries. CMS will calculate the measure scores using routinely submitted claims. Therefore, facilities will not need to submit any new data to CMS for these measures.

### **Project Objectives:**

The primary goal of this project was to develop administrative claims-based outcome measures of ASC quality.

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

CMS solicited comments on two measures:

1. Hospital Visits after Orthopedic Procedures Performed at Ambulatory Surgical Centers (hereinafter, orthopedic measure)
2. Hospital Visits after Urology Procedures Performed at Ambulatory Surgical Centers (hereinafter, urology 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 six commenters during the public comment period. Specifically, we received comments from:

- One individual (Maurizio Nichele)
- Three ASC providers (University Urological Associates – Providence, RI; Lake Ridge Ambulatory Surgery Center – Woodbridge, VA; and Center for Specialty Surgery, Orthopedic + Fracture Specialists – Portland, OR)
- One professional association (American Urological Association)
- One ASC quality collaborative (ASC Quality Collaboration)

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

CMS received comments from six commenters on various aspects of the measures. Comments focused on the measures' cohorts, outcome, risk-adjustment models, testing, and usability. Commenters sought to acquire additional information or clarification about the measures' use and usability, specifications, and further testing.

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

#### *Cohort*

- One commenter asked for clarification on how the cohort is defined for the urology measure.

Response: The target population for the urology measure is Fee-for-Service (FFS) Medicare patients aged 65 years and older undergoing outpatient urology procedures that are typically performed at ASCs by urologists. For a full list of procedures included in the cohort, please refer to Appendix A of the technical report that was posted for public comment on CMS's Public Comment website (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>).

## Outcome

Three comments addressed the outcome. Of these, two comments focused on the urology measure and one focused on the orthopedic measure.

- One commenter sought clarification about the outcome definition for the urology measure.

Response: The 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 urology procedure performed at an ASC. The outcome of hospital visits is the focus of this measure because this is a broad, patient-centered outcome that captures the full range of hospital visits resulting from adverse events or poor care coordination following outpatient surgery.

- One commenter expressed support for the outcome definition for the orthopedic measure, stating that measuring hospital visits within 7 days of an orthopedic ASC procedure is important.

Response: We appreciate the commenter's support of the measure outcome.

- One commenter did not support measuring all-cause hospital visits following orthopedic ASC procedures. The commenter expressed concern that some visits would be unrelated to the procedure and attached a list of more narrowly defined outcomes used by the Oregon Patient Safety Commission as an approach to defining the outcome.

Response: We appreciate the commenter's feedback. CMS measures all-cause hospital visits to encourage facilities to minimize all types of risks that may lead to the need for a hospital visit after an orthopedic ASC procedure. Measuring only hospital visits that are overtly related to a procedure, such as pain and bleeding, would limit the measure's impact on quality improvement efforts. Measuring all-cause patient outcomes encourages facilities to minimize the risk of a broad range of outcomes, including the risk of dehydration, nausea and vomiting, dizziness, and urinary retention. These are common problems that may or may not be related to a recent ASC surgery. Thus, the measure is structured so that facilities that most effectively minimize patient risk of these outcomes will perform better on the measure.

The rate of hospital visits is not expected to be zero because some patients will have visits for reasons completely unrelated to the procedure. The measure is risk-adjusted for patient demographics, clinical characteristics, and procedural complexity so that facilities that experience more unrelated visits due to a generally higher-risk patient mix are not disadvantaged.

## Risk-Adjustment Model

Two comments addressed the measures' approaches to risk adjustment.

- One commenter suggested the risk-adjustment model for the urology measure incorporate adjustment for procedure type (for example, transurethral procedures versus other procedures). The same commenter also suggested adjusting for anesthetic type.

Response: We appreciate the commenter's suggestions. We will consider additional adjustment for procedure type (beyond procedure-specific work Relative Value Units, which we use as a surrogate for procedural complexity). We are currently reviewing approaches to categorizing procedures and reviewing options with clinical experts. We do not risk adjust for anesthesia type because anesthesia

practices are discretionary and integral to the quality of care provided. Therefore, while the type of anesthesia used during a procedure may affect patient risk of hospital visits, we do not want to adjust for it in a quality measure. Based on this rationale, the technical expert panel (TEP), which CMS convened to advise on measure development, supported consideration of adjustment for procedure type and agreed with not adjusting for anesthetic type.

- One commenter expressed hesitation for a risk-adjusted measure of orthopedic ASC procedures, citing concern about the complexity of the public's understanding of a risk-adjusted measure.

Response: CMS recognizes that risk-adjusted measures are more complex measures than raw rates. However, for fairness CMS adjusts most outcome measures 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. CMS has extensive experience reporting and educating the public about risk-adjusted quality measures. Additionally, CMS plans to hold a national confidential reporting period (dry run) to educate providers about the measure that would be implemented in advance of public reporting.

### *Testing*

- One commenter expressed concern about the scientific acceptability of the measures, stating that the measures are still under development and measure testing (for example, validity and reliability testing) has yet to be completed.

Response: We have not yet completed testing and agree with the need for further testing. We held the comment period during measure development so that comments received on the measure concept and technical approach could be considered and incorporated into measure development and testing where appropriate. The technical reports posted for public comment outline the additional measure testing CMS will complete. Once the measures are complete, stakeholders will have additional opportunities to comment on its use through, for example, the National Quality Forum's (NQF's) Measure Applications Partnership process.

### *Implementation*

Several comments focused on the usability of the measures.

- Two commenters expressed concern about the burden associated with reporting of the orthopedic and urology measures. One commenter sought clarification about how the measures would be reported.

Response: We use Medicare claims data to identify procedures performed in the outpatient setting and subsequent hospital visits, as well as CMS enrollment and demographic data, and patient history. Therefore, ASCs would not need to submit any additional data for measure score calculation. For each measure, a measure score would be reported for each ASC.

- One commenter expressed concern about the usability of the orthopedic measure for quality improvement efforts. Specifically, the commenter noted that ASCs often do not have access to information about their patients' post-procedural hospital visits.

Response: We acknowledge that patient follow-up is often difficult and that the scope of ASC practice is limited. However, the measure is designed to measure outcomes from the patient's perspective and illuminate variation in risk-adjusted hospital visits following orthopedic surgery for quality improvement purposes. As done for other publicly reported outcome measures, CMS would provide patient-level data to ASCs to facilitate quality improvement efforts. The measure will enable ASCs to monitor the quality and safety of the care they provide, and identify opportunities that could lead to positive changes in patient care.

### **Preliminary Recommendations**

CMS and CORE have addressed or plan to address the comments received during the public comment period as follows:

- CORE reviewed with the TEP the comments received and CORE's proposed responses.
- CORE will consider risk adjustment for procedure type for the urology measure.
- CORE will conduct additional testing on risk-adjustment model performance, measure score reliability and validity, and the impact of sociodemographic factors on risk adjustment and measure score variability.
- CMS would provide patient-level data to ASCs to facilitate quality improvement efforts.

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

The primary purpose of the majority of feedback received was to request clarification. Commenters recommended modifications to the risk-adjustment models and identified the need for additional testing, which we will evaluate and review with our TEP and clinical experts.

## Public Comment Verbatim Report

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization	Recommendations/ Action Taken
08/17/2016	<p>Hospital Visits after Orthopedic Procedures Performed at Ambulatory Surgical Centers</p> <p>Hospital Visits after Urology Procedures Performed at Ambulatory Surgical Centers</p>	<p>I feel that the reporting for procedures is getting way too complicated and are not really a good measure as to the quality of care rendered.</p> <p>It increases the paperwork, time spent administratively and cost of rendering care while reimbursement continues to go down.</p>	Maurizo Nichele	<a href="mailto:ritz@aol.com">ritz@aol.com</a>	Not applicable; individual commenter	See pages 2-5
08/18/2016	Hospital Visits after Urology Procedures Performed at Ambulatory Surgical Centers	<ol style="list-style-type: none"> <li>1. What is being defined as a hospital visit, is it ED, inpatient?</li> <li>2. Are specific urological procedures being targeted, or is it all procedures?</li> <li>3. Will we be reporting these as a measure? And how will they be reported?</li> </ol>	<p>Patricia Marshall</p> <p>University Urological Associates, Inc.; Providence, RI</p>	<a href="mailto:pmarshall@Lifespan.org">pmarshall@Lifespan.org</a>	ASC provider	See pages 2-5
08/18/2016	Hospital Visits after Orthopedic	My comment is that this measure would be impossible to answer as we would have no way of tracking any of our patients that have a hospital visit after surgery in our	Sandra Beahm	<a href="mailto:sandra.beahm@lakbridgesurg">sandra.beahm@lakbridgesurg</a>	ASC provider	See pages 2-5

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	Procedures Performed at Ambulatory Surgical Centers	<p>center. We would have no way to obtain that data unless the surgeon that performed the surgery at our center was aware the patient visited a hospital and for what reason and we would have to count on that surgeon reporting this information to us for reporting. So basically if I had to do the measure on this data, I would answer “none” because there is no possible way to know this information.</p> <p>I don’t think this is a measure that should be implemented because I think the data gathered would be seriously flawed.</p>	Lake Ridge Ambulatory Surgery Center, Woodbridge, VA	<a href="mailto:erycenter.com">erycenter.com</a>		
08/19/2016	Hospital Visits after Orthopedic Procedures Performed at Ambulatory Surgical Centers	<p>I’m sending some comments on the proposed measure Hospital Visits after Orthopedic Procedures Performed at ASCs. Currently in Oregon, we report several measures to the Oregon Patient Safety Commission. Having another reporting mechanism seems redundant. If this measure goes into effect, it would seem that there could be some effort to only have one reporting mechanism to suffice both needs.</p> <p>One comment that comes to our minds is being hesitant for the risk-adjusted measures, as the public may not totally understand this process. If these measures will be publicly reported, then public understanding will be important.</p> <p>Another comment is that we take issue with the inclusion of “all-cause hospital visits” after surgery in the ASC, as there will be patients that will have visits for reasons completely unrelated to the procedure in the ASC and these visits will be given the same weight in the measure.</p>	<p>Tina Caster, Executive Director</p> <p>Center for Specialty Surgery, Orthopedic + Fracture Specialists; Portland, OR</p>	<a href="mailto:tina.caster@oandfs.com">tina.caster@oandfs.com</a>	ASC provider	See pages 2-5

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		<p>Therefore, since outpatient ASC’s are not tied to bundling programs (BPCI, CJAR); it would appear that there would be some criteria list similar to Oregon Patient Safety Commission. (see attached)</p> <p>Thank you for listening to our concerns!</p>				
09/01/2016	Hospital Visits after Urology Procedures Performed at Ambulatory Surgical Centers	<p>Dear Acting Administrator Slavitt:</p> <p>The American Urological Association (AUA) is a leading advocate for the specialty of urology, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy. On behalf of our nearly 15,000 members in the United States, the AUA appreciates the opportunity to comment on the Facility-Level Quality Measures of Unplanned Hospital Visits after Selected Ambulatory Surgical Center Procedures.</p> <p>While a measure aimed at unplanned hospital visits occurring within 7 days of a urologic procedure at an ASC is important, it is critical that the risk adjustment be accurate. In particular, the AUA is concerned with the importance of including procedure and anesthetic type when measuring unplanned hospital visits. Procedure type should be considered a risk factor as certain urologic procedures present a high risk for urinary retention. Therefore, procedure type should be included so as to avoid unfairly penalizing those providers appropriately performing transurethral procedures in an ASC. Additionally, anesthetic</p>	<p>Timothy Averch, MD, FACS, Chair AUA Quality Improvement and Patient Safety Committee</p> <p>American Urological Association; Seaford, NY</p>	<p><a href="mailto:spope@auanet.org">spope@auanet.org</a></p>	Professional association	See pages 2-5

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		<p>type impacts the risk for urinary retention, and length of anesthesia increases the risk for urinary retention. These are important factors to consider and account for.</p> <p>Again, thank you for the opportunity to provide comments on the measure on Hospital Visits after Urology Procedures Performed at Ambulatory Surgical Centers. If you have any questions regarding our comments, please contact Suzanne Pope at (XXX)XXX-XXXX or spope@auanet.org.</p>				
09/02/2016	<p>Hospital Visits after Orthopedic Procedures Performed at Ambulatory Surgical Centers</p> <p>Hospital Visits after Urology Procedures Performed at Ambulatory Surgical Centers</p>	<p>CMS and CORE Project Teams:</p> <p>On behalf of the ASC Quality Collaboration (ASC QC), please accept the following comments regarding two draft measures of unplanned hospital visits after selected orthopedic and urologic procedures in ambulatory surgical centers (ASCs). The ASC QC is a non-profit organization that has spent the last decade advancing quality measurement and public reporting in the ASC industry through a progressive and collaborative effort involving a diverse group of ASC stakeholders. These stakeholders include leaders from the ASC industry, accreditation organizations, and professional physician and nursing associations.</p> <p>The ASC QC’s commitment to quality is reflected in our ongoing efforts to facilitate meaningful quality reporting by ASCs. This includes initiatives such as the development of fully tested facility-level quality measures appropriate to the ASC setting, participation in Federal projects pertaining to ASC quality measurement, and our publication of a</p>	<p>Donna Slosburg, BSN, LHRM, CASC, Executive Director</p> <p>ASC Quality Collaboration</p>	<p><a href="mailto:donnaslosburg@ascquality.org">donnaslosburg@ascquality.org</a></p>	<p>ASC quality organization</p>	<p>See pages 2-5</p>

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		<p>quarterly public report of ASC quality data that is freely available online.</p> <p>The Centers for Medicare &amp; Medicaid Services (CMS) has invited public comment regarding two quality measures it is developing around the topic of adverse outcomes following orthopedic and urology procedures performed at ASCs: Hospital Visits after Orthopedic Procedures Performed at Ambulatory Surgical Centers and Hospital Visits after Urology Procedures Performed at Ambulatory Surgical Centers. CMS indicates it is, “developing measures of near-term hospital visits that patients experience following ASC procedures to better assess the quality of care provided at these facilities.” CMS plans to use these measures to “report on the quality of ASCs and prompt improvements in care for Medicare beneficiaries.”</p> <p>As presented, both measures are still in development, with key elements currently incomplete. There is also a lack of testing for key measure attributes such as validity and reliability. In the absence of this testing, we are unable to form any conclusions about the scientific acceptability of the measures. We hope CMS will also field test these measures in advance of implementing them.</p> <p>We note that despite being far from complete, both measures were submitted for inclusion on the Measures Under Consideration (MUC) List. We don’t believe the Measure Applications Partnership (MAP) should make recommendations regarding measure drafts. We urge CMS</p>				

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		<p>to take steps to promote a process in which consideration of fully developed measures becomes the standard.</p> <p>As the development of these measures proceeds, we hope there will be additional opportunities for public comment.</p>				