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VIA ELECTRONIC MAIL

Yale New Haven Health Services - Center for Outcomes Research and Evaluation (CORE)
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Re: Development of a Facility-Level Quality Measure of Unplanned Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers

CMS and CORE Project Teams:

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”. 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.

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.

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.

A. Draft Specifications: The Measure Cohort
The measure focuses on outpatient procedures that are “within the scope of general surgery training” [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. Over half of the cases in the measure cohort are skin procedures. 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.

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.

**B. Draft Specifications: Attribution of Outcomes**

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. Table 1 below 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.
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.

**Table 1. Questionable “top hospital visit diagnoses” for any hospital visit within 7 days of general surgery procedures**

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

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.

**C. Reliability for Accountability and Public Reporting Purposes**
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”.

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 three years of claims data to assure reliable results for the colonoscopy measure, CMS implemented the measure using only one 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.

D. Limited Ability to Make Distinctions Among Facilities

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.” Unfortunately, this measure suffers from very limited discriminatory power. The developers initially used unadjusted 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.

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.

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”.

E. Lack of Actionability

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.”

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.

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.

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.

F. Measure Scores Not Helpful to Consumers

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.

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.

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.

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In closing, we would like to reiterate our appreciation for the opportunity to provide feedback regarding this draft measure. Please do not hesitate to contact us if we can provide additional assistance or if further clarification of our remarks is needed.

Sincerely,

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Appendix A:
Current Participants in the Activities of the ASC Quality Collaboration

Accreditation Association for Ambulatory Health Care
Ambulatory Surgery Foundation
Ambulatory Surgical Centers of America
AmSurg
ASD Management
Association of periOperative Registered Nurses
California Ambulatory Surgery Association
Covenant Surgical Partners
Florida Society of Ambulatory Surgery Centers
Hospital Corporation of America, Ambulatory Surgery Division
Merritt Healthcare
Outpatient Ophthalmic Surgery Society
Physicians Endoscopy
Practice Partners in Healthcare, Inc.
Regent Surgical Health
Surgery Partners
Surgical Care Affiliates
The Joint Commission
United Surgical Partners International
Visionary Enterprises, Inc.