



# ASC Quality Collaboration

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September 10, 2017

## VIA ELECTRONIC SUBMISSION

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1678-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

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

Dear Administrator Verma:

On behalf of the ASC Quality Collaboration (ASC QC), please accept the following comments regarding CMS-1678-P (82 FR 33558, July 20, 2017) Section XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. 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 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 (please see Appendix A to this letter for a complete listing). Collectively, these organizations represent over 1,500 ASCs.

The ASC QC sincerely appreciates the ongoing effort the agency devotes to the ASCQR Program. We are pleased to have this opportunity to provide feedback regarding the agency's recent proposals for the ASCQR Program and other related matters.

#### **I. Proposed Removal of ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing Beginning with the CY 2019 Payment Determination**

CMS adopted ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing for the ASCQR Program beginning with the CY 2014 payment. Program measure data for CY 2014 through 2016 shows such high and unvarying performance for this measure that there is little room for improvement and distinctions between ASCs cannot be made. The measure appears to be "topped out" and CMS is proposing to remove it from the program beginning with the CY 2019 payment determination. A similar measure was removed from the Hospital OQR Program in the CY 2015 OP/ASC final rule due to being "topped out".

The ASC QC supports the removal of ASC-5 from the ASCQR Program. We plan to continue to maintain the measure. If performance in this area needs to be addressed again in the future, the measure would be available for re-introduction into the Program.

## **II. Proposed Removal of ASC–6: Safe Surgery Checklist Use Beginning With the CY 2019 Payment Determination**

CMS adopted ASC–6: Safe Surgery Checklist Use beginning with the CY 2015 payment determination. For the last two years, the nationwide rate of “Yes” responses for the Safe Surgery Checklist Use measure has been nearly 100 percent, leaving little room for improvement and little ability to distinguish the performance of any given ASC from another. As a result, CMS is proposing to remove ASC–6 from the ASCQR Program beginning with the CY 2019 payment determination. CMS is also proposing to remove a similar measure from the Hospital OQR Program.

The ASC QC supports the proposal to remove ASC-6 from the ASCQR Program.

## **III. Proposed Removal of ASC–7: ASC Facility Volume Data on Selected Procedures Beginning With the CY 2019 Payment Determination**

CMS adopted ASC–7: ASC Facility Volume Data on Selected Procedures beginning with the CY 2015 payment determination. Since then CMS has adopted more measures assessing performance on specific procedure types based on the belief these procedure-type-specific measures will provide patients with more valuable information than the ASC–7 measure. Consequently, CMS is proposing to remove ASC–7 from the ASCQR Program beginning with the CY 2019 payment determination. CMS is also proposing to remove a similar measure from the Hospital OQR Program.

The ASC QC supports the removal of ASC-7 from the ASCQR Program.

## **IV. Proposal to Delay ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2020 Payment Determination**

In last year’s final rule, CMS adopted five measures (ASC–15a–e) based on the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, with data collection scheduled to begin with January 2018 dates of service. CMS is now proposing to delay the implementation of the five survey-based measures, which assess patients’ experience with care following a procedure or surgery in an ASC or hospital outpatient surgical department. CMS is also proposing to delay the implementation of these measures in the Hospital OQR Program.

We appreciate the investment CMS made in developing the OAS CAHPS survey. We fully support the use of a standardized instrument focusing on the patient’s experience of care, especially because the survey addresses the experience of surgical care received in both hospital-based outpatient surgical departments (HOSDs) and ASCs, increasing consumers’ ability to make

comparisons across outpatient surgical facilities. However, for many ASCs, the costs related to implementing the OAS CAHPS survey would prove to be in excess of the 2% payment update penalty for failing to meet ASCQR Program requirements.

As one of the stakeholders who recently wrote to you and Secretary Price expressing concerns regarding the OAS CAHPS Survey and CMS policies regarding its administration, we support the proposal to delay the implementation of the survey-based measures. Recognizing that the survey data would provide information that is important to both patients and providers, we hope CMS will address the issues as quickly as possible. We look forward to further action toward implementation once needed changes have been made.

As we have stated in the past, there are a number of significant matters that were not resolved at the time of the original development of the survey, as well as policies that impose unnecessary burden on providers. Specifically, the following issues need to be addressed during this opportunity to reassess and refine:

- The survey is too long.
- The survey modes do not take advantage of cost-saving information technology.
- An option for on-site survey distribution to all patients should be made available and the mode effects should be tested during the delay.
- The survey results should be publicly reported in a way that allows consumers to tie information directly to an individual facility; testing data collection and reporting by NPI should be accomplished during the delay.
- CMS policy regarding the minimum number of completed surveys affects small, low volume ASCs disproportionately; policy revisions are needed.

There are effective ways to address these concerns that would allow the survey to be more affordable for providers while still providing consumers with key patient experience data. A brief summary of these alternative approaches is presented below. For additional information, please see our prior detailed communications to Secretary Price and yourself, CMS, and OMB regarding the O/ASPECS and OAS CAHPS.

### **A. Shorten the OAS CAHPS Without Sacrificing Key Information**

This implementation delay offers a perfect opportunity to reduce the number of items included in the OAS CAHPS in order to maximize the usefulness of the patient experience data while minimizing the cost of the survey. We are pleased to learn CMS continues “to evaluate the utility of individual questions as we collect new data from the survey’s voluntary national implementation, and will consider different options for shortening the OAS CAHPS Survey without the loss of important data in the future.”

#### **1. Regarding “Communications About Your Procedure”**

As you know, written discharge instructions are required by the ASC Conditions for Coverage at §416.52(c)(1), which states “[e]ach patient, or the adult who accompanies the patient upon discharge, must be provided with written discharge instructions.” A similar requirement is in

place for HOPDs. Yet item 13 of the OAS CAHPS asks if the patient received written discharge instructions. Given that the patient is not the only source of information about this very standard practice, this question adds cost without adding new information, and should be removed.

## **2. Regarding “Your Recovery”**

The section titled “Your Recovery” includes four items that ask whether the patient received information about what to do regarding pain control, nausea or vomiting, bleeding, or signs of infection. It is not possible to address every significant sign or symptom that might indicate a complication after discharge, so it would be more efficient to present a single survey question that addresses the topic at the core of each of the four items - patient’s need for information about what to do in the event a problem arises after their procedure. Consolidating four items (15, 17, 19 and 21) into a single question is a win-win proposition: it would reduce the length of the survey without sacrificing essential feedback regarding a key element of patient experience.

Closely related to the four questions above, items 16, 18, 20 and 22 focus on a very limited set of potential post-procedure signs and symptoms (pain, nausea/vomiting, bleeding, signs of infection). Unfortunately, the responses do not provide the context necessary for quality assessment or improvement. These “control questions” only identify the *small minority* of patients who experience the selected outcome and the logic that drives the algorithm for these control questions is flawed - the absence of the outcome *does not* mean information about what to do if it occurred would not be relevant.

In addition, item 16 is clearly focused on the experience of pain and should be removed. The question implicitly values a “No” response over a “Yes” response and implies patients should not experience pain. Regardless of whether or not the question is used for the ASCQR Program measures, data regarding this item would be provided to the facility, applying pressure on healthcare providers who are already being compelled to write prescriptions to appease patients.

## **3. Regarding “About You”**

Finally, the inclusion of 13 demographic items in the “About You” section of the survey is excessive. We were happy to learn CMS will consider removing the “gender” and “age” questions from the OAS CAHPS Survey, gleaning that information from ASC operational data instead. We continue to believe that only items actually used in patient-mix adjustment or required by law should be included. Supplemental items and those items the US Office of Minority Health identifies as optional all add burden and must be removed.

## **B. Maximize the Use of Information Technology to Minimize Burden**

Rates of information technology adoption in the United States are high and continuing to rise across all demographics. The proposed delay in implementation offers a timely opportunity to update the OAS CAHPS survey administration methods with information technology solutions to keep data collection burden as low as possible. Failing to incorporate these cost- and time-saving opportunities is not justifiable. In addition to the currently available survey modes, options that utilize information technology should be made available, including the ability to send survey

invitations via email as well as via text message (SMS), and the use of a web-based survey administration mode. These solutions are already used in other patient experience surveys both in this country and by other governments abroad.

### **C. Ease Burden by Allowing On-site Distribution**

CMS should allow distribution of the OAS CAHPS survey at the point of care, an option the agency did not offer before because it had not been tested to determine mode effects. Distribution at the point of care offers several advantages, including a lower cost per returned survey. In addition this option would allow more timely and accurate patient responses. Currently, CMS policy would result in patients receiving their survey roughly one to two months following their date of service.

We recommend this option be available within the context of two policies. First, *administration* of the survey at the point of care would be prohibited to preclude introduction of bias, the potential impact of recent sedation or anesthesia, and insufficient time having elapsed for self-reported outcomes. Second, if a facility opts to distribute the OAS CAHPS at the point of care, the survey must be given to each and every patient discharged from the ASC to prevent the introduction of bias.

### **D. Ensure Consumers Can Tie OAS CAHPS Survey Data to an Individual Facility**

We advocate transparent and consumer-centric public reporting of quality measure data, including reporting data in a manner that allows the public to directly correlate quality measure data with an individual facility. Current CMS policy dictates that surgical facilities sharing the same CCN combine data for the OAS CAHPS survey-based measures. However, combining results makes it impossible for consumers to discern the performance of any particular facility. At present, results are collected and reported at the CCN level because the OAS CAHPS Survey was tested at the CCN level. Since it will be necessary to conduct additional testing of the survey as part of addressing needed changes to the survey content and modes of administration, we urge CMS to incorporate testing of NPI level data collection and reporting during this delay in implementation.

### **E. The Number of Required Surveys Affects Small ASCs Disproportionately**

CMS has stated, “[a] minimum of 300 completed surveys annually is the target for each participating outpatient facility. If a facility patient volume is too small to yield 300 completed surveys per year, a census will be surveyed.” Based on our review of ASC volume data, a significant minority of ASCs - approximately 20 to 33 percent of centers - would be required to default to use of the more expensive mail and telephone mixed mode. And those ASCs whose patient volumes are too small to yield 300 completed surveys per year using the mixed mode would be expected to survey all their patients. The result of these policies is that a significant minority of ASCs – those with the lowest patient volumes - would face the greatest burdens associated with the use of the survey. CMS should consider options to address the disproportionate survey costs low volume ASCs would face under current regulations, including options such as requiring a lower number of completed surveys or a stratified requirement for completed surveys based on case volume.

## **V. Proposed Adoption of ASC–16: Toxic Anterior Segment Syndrome Beginning With the CY 2021 Payment Determination**

The ASC QC is the measure developer and steward for the Toxic Anterior Segment Syndrome (TASS) measure, which assesses the number of patients diagnosed with TASS within two days of undergoing anterior segment surgery in the ASC. The ASC QC developed this measure to fulfill a need to assess complications associated with frequently performed ophthalmologic surgeries in ASCs.

The measure has been fully tested in the ASC setting and is currently in use as part of our online public report of ASC quality data. The measure was reviewed by the Measure Applications Partnership (MAP) last year and received conditional support pending endorsement by the National Quality Forum (NQF). NQF endorsement is not necessary because the requirement that measures reflect consensus among affected parties was met through our collaboration within the ASC industry, as well as our inclusion of the American Academy of Ophthalmology, American Society of Cataract and Refractive Surgery, and the Outpatient Ophthalmic Surgery Society in the review of the measure early in the development process.

If adopted as proposed, ASCs would begin collecting data for the measure in calendar year 2019. This data would then be submitted in aggregated form via QualityNet between January 1 and May 15 of the following year, impacting payment determination for calendar year 2021. This cycle would continue for each subsequent year.

We support both the adoption of this measure and submission of aggregated measure data via QualityNet.

## **VI. Proposed Adoption of ASC–17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures Beginning With the CY 2022 Payment Determination**

CMS is proposing to include the ASC–17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures measure in the ASCQR Program for the calendar year 2022 payment determination and subsequent years. This measure is claims-based, using Medicare administrative claims and enrollment data to calculate the results. As with ASC-12, there is no need for ASCs to do anything in the way of collecting or submitting data for this measure.

We think CMS’s consensus development efforts around this measure have been weak at best. Public comment opportunities were offered at times when the measure was incomplete, making it difficult to provide meaningful input. In addition, the agency has decided to ignore the recommendation of the Measure Applications Partnership (MAP), which was to “refine and resubmit *prior to rulemaking*” [emphasis added]. We do not support this measure.

We believe it is premature to finalize the measure and would like to see additional work done to ensure the measure performs as hoped. In particular, we think it would be beneficial to allow the project TEP and the public to review all measure data, including case mix, for each of the highest performing and lowest performing ASCs to validate the model.

## A. Measure Specifications

The ASC QC has reviewed the supporting documentation for this measure and has noticed several items that should be addressed.

### 1. Attribution of Outcomes

Based on our review of the limited results presented in Table 4 of the accompanying documentation for this measure titled “Top hospital visit diagnoses for any hospital visit within 7 days of orthopedic procedures (data source: Medicare FFS CY 2015 Dataset, 10/01/2014 – 09/30/2015)”, additional work needs to be done to ensure the outcomes identified by the measure are appropriate. Table 1 below summarizes some of the issues identified.

Some of these “top diagnoses”, namely those that reflect orthopedic aftercare, do not indicate an adverse outcome or complication of care but rather routine follow-up for things such as suture removal. We also identified the inclusion of a quality data code in the list of “top diagnoses” and are at a loss to determine how this would even appear on the list.

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

AHRQ Clinical Category	Top 10 primary ICD-9 hospital diagnoses	ICD-9 diagnosis description
145 – Treatment, fracture or dislocation of radius and ulna	V5489	Orthopedic aftercare NEC
148 – Other fracture and dislocation procedure	V5832	Attn removal of sutures
150 – Division of joint capsule, ligament or cartilage	V5489	Orthopedic aftercare NEC
	G8918	Patient without preoperative order for IV antibiotic surgical site infection (SSI) prophylaxis*

\*This is a Quality Data Code (QDC) used by ASCs to report data for the ASC-5 measure.

The public has only been given the opportunity to review the “top diagnoses” and it is possible there are other illogical outcomes in the dataset. Before proceeding further with this measure, CMS should provide for a detailed clinical review of all the measure results by several seasoned orthopedic surgeons to ensure the measure algorithm is appropriate.

### 2. Condition Categories

Table D2 of the supporting documentation presents condition categories, or CCs, that are not risk-adjusted for if they only occur at the time of the procedure. We do not understand the logic of including CC 82, Respirator dependence/tracheostomy status. This type of condition is not something that develops acutely within the timeframe of an ASC procedure, but rather is reflective of a more chronic patient condition.

## B. Reliability for Accountability and Public Reporting Purposes

According to the measure developer, “[t]he many small-volume ASCs make development and use of outcome measures to assess quality of care challenging. ASCs with few cases in a given year limit our ability to estimate risk-adjusted ASC-level measure scores, thereby limiting CMS’s ability to assess quality.” Low-volume situations tend to produce measure scores that lack reliability. In the case of this measure, the intra-class correlation coefficient (ICC), a statistical measure of reliability, was 0.226, a result that is only “fair”. Even when the dataset was limited to ASCs with a minimum of 250 qualifying cases over a two-year period, the ICC was 0.359, which is still only “fair”. In this proposed rule CMS states, “ASCs with at least 250 cases showed moderate reliability”, but this statement is not consistent with the information presented by the developer in the supporting documentation.

CMS is proposing to publicly report results for only those facilities with sufficient case numbers to meet “moderate” reliability standards. The agency says it would determine the case size cutoff for meeting moderate reliability standards using the ICC by testing the reliability of the scores at different case sizes. This would be an incremental improvement, but in our opinion, the reliability of a measure intended for public reporting and accountability purposes should be significantly higher. If facilities are to be judged in a government-sponsored public forum 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 further raising the minimum number of qualifying procedures per facility.

Based on past ASCQR Program experience, we are concerned that CMS will elect to implement this measure in ways that further degrade the reliability of the measure score, 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 even moderately 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 CMS to consider its unique obligation to ensure the data it provides to the public is meaningful.

### **C. Limited Ability to Make Distinctions Among Facilities**

According to the developer and CMS, “[t]he purpose of this measure is to illuminate variation in performance as an indication of variation in quality of care for orthopedic surgery procedures across ASCs, inform patient choice, and drive quality improvement.” Unfortunately, this measure suffers from very limited discriminatory power. Of the 2,734 ASCs that qualified for the measure, the performance of 2,727 centers (about 99.7%) was no different than the national rate. Of the remaining 7 ASCs, 2 performed better than expected, and 5 performed worse than expected. This means the overwhelming majority (about 99.8%) 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 indeed.

### **D. Measure Scores Not Helpful to Consumers**

This measure would do little to aid the consumer evaluating ASC performance in orthopedic surgery. As noted above, the performance of 99.8% 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 CYs 2014-2015 there were only 5 such centers.

We are also concerned that the necessity of a long data collection period (2 years as proposed) to generate measure scores that are even fairly reliable means the consumer will be presented with dated information. 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.

#### **E. Usability is Limited**

According to CMS, this measure would “foster quality improvement efforts”. They believe this measure “will provide ASCs with critical information and incentives... to reduce unplanned hospital visits.” It is true ASCs are not always aware of every hospital visit for each of their patients. However, preliminary experience with a similar measure, the ASCQR Program’s ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, indicates the amount of insight provided by measure data and scores will be quite limited. Several of our members have performed thorough evaluations of the claims detail reports for ASC-12 and found the ASC was already aware of almost every hospital visit. Further, the centers found the information provided by the reports did not spark any additional insight or offer any new direction to quality improvement efforts.

While CMS believes providing scores and patient-level reports for measures like these will lead to performance improvement, feedback we have received from facilities across the country indicates that ASCs are waiting until the final ASC-12 scores are presented in the context of the descriptive categories. If the center were to be categorized as underperforming, the ASC would then take the time to look at the claims detail reports and determine whether a performance improvement project would be warranted. Centers are taking this approach because 1) they have found they are already aware most of the visits in the claims detail report, and 2) they consider many of the principal diagnoses for the visits presented in the claims detail reports to be unrelated to the procedure.

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 limits the usefulness of the information.

Finally, this measure does not require any involvement on the part of individual ASCs. A center could never look at or act upon any report or measure score, yet still receive a full payment update.

#### **F. Provision of Facility-Specific Information Prior to Public Reporting**

If the measure is finalized, CMS proposes to perform a dry run before the official data collection period or any public reporting. ASCs would have the opportunity to review their report and provide feedback to the agency. The agency has become accustomed to performing these “dry runs” for entire provider groups and then expecting the providers to voluntarily donate staff time and expertise to fix flaws in its measures. CMS and its contractor should do this work in advance of finalizing measures and could do so by conducting pilot testing at volunteer ASCs.

The ASC QC requests that any dry run data for this measure be aggregated and provided in its entirety to the public for review and comment. It is difficult for us to gain insight into how the measure model is performing when the data is scattered among thousands of individual ASC reports.

### **G. Estimated Burden of the Proposed ASC-17**

As noted above, data used to calculate scores for this measure are collected via Medicare administrative claims and enrollment data. Because these measures do not require ASCs to submit any additional data, CMS does not believe there would be any additional burden associated with these proposals. We agree there is no data collection and submission burden, but point out that there would be burden associated with reviewing the claims detail reports and measure scores. A clinician would likely review these reports.

## **VII. Proposed Adoption of ASC–18: Hospital Visits After Urology Ambulatory Surgical Center Procedures Beginning With the CY 2022 Payment Determination**

CMS is proposing to adopt the ASC–18: Hospital Visits After Urology Ambulatory Surgical Center Procedures measure in the ASCQR Program for the calendar year 2022 payment determination and subsequent years. This measure is claims-based, using Medicare administrative claims and enrollment data to calculate the results. As with ASC-12, there is no need for ASCs to do anything in the way of collecting or submitting data for this measure.

As with the related orthopedic measure, CMS’s consensus development efforts around this urology measure have been unsatisfactory. The agency offered public comment opportunities when the measure was incomplete and has also ignored the recommendation of the Measure Applications Partnership (MAP), which was to “refine and resubmit *prior to rulemaking*” [emphasis added]. We do not support this measure.

More work is needed to ensure the measure performs as planned. It would be helpful to share the data, including case mix, for each of the highest performing and lowest performing ASCs with the project TEP and the public for review.

### **A. Measure Specifications and Supporting Documentation**

We have reviewed the supporting documentation for this measure and noticed several items that should be addressed.

#### **1. Number of Unplanned Hospital Visits Is Inconsistent**

Table 4 of the accompanying documentation for this measure is titled “Top hospital visit diagnoses for any hospital visit within 7 days of urology procedures (data source: Medicare FFS CY 2015 Dataset, 10/01/2014 – 09/30/2015)”. This table indicates that the total number of unplanned hospital visits is the same as the total number of ASC urology procedures as presented in section 2.1 of the document. Table 4 seems to be incorrect, and that leads us to wonder if the remainder of Table 4 is accurate or not, as we do not have any way to corroborate the remaining data.

## 2. Attribution of Outcomes

Based on our review of the limited results presented in Table 4 of the accompanying documentation for this measure, additional work needs to be done to ensure the outcomes identified by the measure are appropriate. Table 2 below summarizes some of the issues identified.

Some of these “top diagnoses” are not related the quality of care. For example, ureteral or renal calculi are not an “acute illness” or “complication of care”, but rather the indication for the index procedure. Similarly, a diagnosis of cancer is not a signal of poor quality or an adverse event related to ASC care, but a diagnosis established by the index procedure. Finally, a code indicating exposure to therapeutic radiation is a logical consequence of having received prostate brachytherapy services and is not an indication of an adverse outcome.

**Table 2. Questionable “top hospital visit diagnoses” for any hospital visit within 7 days of urology procedures**

AHRQ Clinical Category	Top 10 primary ICD-9 hospital diagnoses	ICD-9 diagnosis description
101 – Transurethral excision, drainage, or removal urinary obstruction	5921	Calculus of ureter
102 – Ureteral catheterization	5921	Calculus of ureter
	5920	Calculus of kidney
107 – Extracorporeal lithotripsy, urinary	5921	Calculus of ureter
	5920	Calculus of kidney
111 – Other non-OR therapeutic procedures of urinary tract	1889	Malignant neoplasm bladder NOS
117- Other non-OR therapeutic procedures, male genital	185	Malignant neoplasm prostate
	V153	Hx of irradiation

CMS should arrange a detailed clinical review of all the measure results by several experienced urologic surgeons to ensure other illogical outcomes are addressed and the measure algorithm is performing appropriately.

## 3. Condition Categories

Table E2 of the supporting documentation for this urology measure presents condition categories (CCs) that are not risk-adjusted for if they only occur at the time of the procedure. As

with the related orthopedic measure, we do not understand the logic of including CC 82, Respirator dependence/tracheostomy status. As noted above, this type of condition does not develop acutely within the timeframe of an ASC urology procedure and is reflective of a more chronic patient condition.

## **B. Reliability for Accountability and Public Reporting Purposes**

The same challenges related to small volumes that impact the orthopedic measure discussed above also affect this measure. Low volumes make it difficult to produce reliable measure scores. In the case of this measure, the ICC was 0.45, which is only “moderate”. Again, the reliability of a measure score intended for public reporting and accountability purposes should be significantly higher. Because facilities would be judged in a public arena based on the results, the reliability of those scores should be, at a minimum, “substantial”.

## **C. Limited Ability to Make Distinctions Among Facilities**

Like its orthopedic counterpart, this measure has limited discriminatory power. Of the 1,204 ASCs that qualified for the measure, the performance of 1,185 centers (about 98.4%) was no different than the national rate. Of the remaining 19 ASCs, 4 performed better than expected, and 15 performed worse than expected. The overwhelming majority of facilities (about 98.75%) would receive a measure score indicating their performance to be either no different from or better than the national rate – implying no improvement would be necessary. The number of underperforming facilities is small.

## **D. Measure Scores Not Helpful to Consumers**

CMS states this measure “will inform patient choice”, but the results are unlikely to aid the consumer evaluating ASC performance in urologic surgery. As noted above, the performance of 98.75% 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 CYs 2014-2015 there were only 15 such centers.

As with the related orthopedic measure, the two-year data collection period needed to generate measure scores that are even moderately reliable means the consumer will be presented with dated information. Again, the scores could obscure significant improvement or deterioration in recent performance and consumers would not be the wiser. If finalized, it would be helpful for CMS to include guidance with the results to alert consumers to these issues.

## **E. Usability is Limited**

The same usability issues associated with the orthopedic measure discussed above also apply to this measure: experience with ASC-12 indicates measures of this type offer little new information to the ASC, or offer information about visits that the ASC considers to be unrelated to the patient’s procedure. While CMS has made welcome efforts to provide interim reports, the measure results are still not timely due to the use of claims. Finally, the use of claims data for measurement is a double-edged sword; there is no data collection or submission burden on the one

hand, but there is little to no incentive for ASCs to be engaged with the measure data on the other.

#### **F. Provision of Facility-Specific Information Prior to Public Reporting**

If ASC-18 is finalized, CMS proposes to perform a dry run before the official data collection period or public reporting. The ASC QC requests that this dry run data be aggregated and provided in its entirety to the public for review and comment.

#### **G. Estimated Burden of the Proposed ASC-18**

As noted above, data used to calculate scores for this measure is collected using Medicare administrative claims and enrollment data. ASCs would not be required to submit any additional data so CMS believes there would not be any burden associated with this proposed measure. Even in the absence of a data collection and submission burden, there would still be burden associated with someone at the center, likely a clinician, reviewing the claims detail reports and measure scores.

### **VIII. ASCQR Program Quality Measures for Future Consideration**

CMS has invited public comment regarding future consideration of the Ambulatory Breast Procedure Surgical Site Infection Outcome measure for inclusion in the ASCQR Program. Developed by the Centers for Disease Control and Prevention (CDC), this measure assesses the risk-adjusted Standardized Infection Ratio (SIR) for SSIs following breast procedures conducted at ASCs among adult patients. The measure compares the reported number of SSIs observed at an ASC with a predicted value based on nationally aggregated data.

The ASC QC and the Colorado Department of Public Health collaborated with CDC in the adaptation and testing of this measure in the ASC setting. It would fill an important gap in the ASCQR Program. Further, the measure is fully developed, was tested specifically in the ASC setting, and is currently being used in several State-based quality reporting programs. We support the inclusion of this measure in the ASCQR Program in the future.

We would like to point out the irony of CMS characterizing this measure as something for consideration in the future. During its last pre-rulemaking cycle, the MAP gave this measure a “Conditional Support” recommendation pending NQF endorsement. As you know, NQF endorsed this measure in January 2017, so *CMS should have proposed the SSI measure this year and did not*. Yet the agency is rushing to propose its two claims-based ASC-17 and ASC-18 measures that the MAP felt needed more work, as clearly expressed in its “Refine and Resubmit Prior to Rulemaking” recommendations. We find these actions disappointing.

If the SSI measure were proposed and ultimately adopted for the ASCQR Program, it is likely measure data would be reported via CDC’s National Healthcare Safety Network (NHSN). As you know, ASCs report quality measure data for ASC-8, Influenza Vaccination Coverage among Healthcare Personnel to NHSN. At this time, data for ASC-8 is collected at the CCN level, but all other ASCQR Program measure data is reported to CMS at the NPI level. Implementing NPI level data collection and reporting is needed to fully support consumers in their decision-making. CDC has indicated its willingness to consider changing from a CCN-based approach to an

NPI-based approach. Making this change now would be helpful. CMS should work quickly with CDC to implement data collection under the NPI in NHSN, and plan to report all future measures by NPI.

## **IX. Opportunities for Additional Comparative Quality Measures Across Settings**

The ASC QC is the measure developer for several of the ASCQR Program measures, including ASC-1 Patient Burn, ASC-2 Patient Fall, ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and ASC-4 Hospital Transfer/Admission. We do not have the means to test these facility-level measures for other outpatient surgical settings, but believe CMS should consider doing so. If testing yields satisfactory results, we would encourage CMS to implement these measures for other facility providers of outpatient surgical services, such as HOPDs. Applying the same facility-level quality measures to all settings offering outpatient surgery would expand the comparative quality data available to consumers.

## **X. Proposals Regarding Batch Submission of Data to QualityNet**

Presently, QualityNet only allows data submission on an individual facility basis. In past comments to the agency, the ASC QC suggested CMS develop a batch submission option for QualityNet to allow management companies to report quality data for many centers. We are pleased to see the agency has recognized this opportunity to enhance data submission efficiency for entities responsible for submitting quality measure data for multiple ASCs. CMS is proposing to expand the capabilities of the QualityNet platform to allow for batch submission of data for multiple facilities using a single electronic file via a single “agent” QualityNet account.

An ASC agent, such as a representative for a corporate entity consisting of multiple ASCs with separate NPIs, would be assigned a vendor ID. To authorize the agent to submit data and receive reports on behalf of a given ASC, a representative from the ASC would submit a Security Administrator (SA) form with the assigned vendor ID. In order to submit batch data, an agent would need to meet all QualityNet account requirements, such as establishing a QualityNet account and maintaining a QualityNet security administrator. Once approved, the agent may submit data for any ASC associated with that ID and access data reports for those same ASCs. Agents would only have access to data reports for facilities that have authorized this access. This feature would be available for data submitted during CY 2018 for the CY 2020 payment determination and subsequent years.

We support this proposal and applaud CMS for responding to stakeholder input. We ask that CMS have all necessary processes in place at the time of the issuance of its final rule in order to allow ASCs that select this option sufficient time to transition to the agent-based batch submission process prior to the 2018 data submission deadline.

## **XI. Extraordinary Circumstances Extensions or Exemptions for the CY 2019 Payment Determination and Subsequent Years**

CMS has established a process for requesting an exception from quality reporting program reporting requirements due to an extraordinary circumstance not within a provider’s control. In reviewing the policies for these programs, the agency has recognized that there are inconsistencies

from program to program in the nomenclature CMS uses to refer to the process. In some cases this is called “extraordinary extensions/exemptions” and in others it is called “extraordinary circumstances exceptions”. Under the ASCQR Program, the process is referred to as “extraordinary extensions/exemptions”. CMS is proposing to rename the process as the “extraordinary circumstances exceptions” (ECE) policy for consistency. We support this proposal.

## **XII. Request for Information and Public Comments on CMS Flexibilities and Efficiencies**

CMS has asked the public to submit ideas for regulatory, subregulatory, policy, practice, and procedural changes to improve efficiencies, as well as recommendations regarding how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers.

We believe CMS should take steps to simplify reporting for the ASCQR Program, which has numerous data submission pathways and requirements. At this time, measures are being reported via Medicare claims using quality data codes, through the QualityNet website, through the CDC’s NHSN website, and through extraction of Medicare claims data by a CMS contractor. We anticipate the OAS CAHPS survey-related measures would add yet another reporting method to this list. CMS should seriously explore options to streamline data submission methods and issue proposals for change in next year’s rulemaking.

Specifically, CMS should change the method of reporting ASC-1 through ASC-4 (if ASC-5 were to be retained for some reason, these comments would apply to that measure as well). These measures are currently reported using quality data codes on ASC Medicare claims, but it would be more beneficial to all stakeholders to submit this data via QualityNet. Another major advantage of making this change is that, rather than having data limited to Medicare patients, CMS and the public would have access to aggregate data for all the patients served by an ASC, considerably expanding the scope and transparency of public reporting as well as the accountability related to these measures. The ASC QC is the measure developer and steward for all these measures and we can attest that, as originally developed, they are suitable for the type of aggregate data collection and submission in use at the QualityNet site.

## **XIII. Existing ASCQR Program Quality Measures: Ongoing Concerns Regarding ASC-12 Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy**

We would like to reiterate ongoing concerns regarding ASCQR Program measure ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy. These issues have been raised in previous communications but have not been resolved.

### **A. Public Reporting of ASC-12 and OP-32**

CMS plans to publicly report data for both ASC-12 and OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy beginning on or after December 1, 2017. Although the results for the two measures cannot be compared, a casual observer is unlikely to be aware of this fact. Because ASC-12 and OP-32 have the same title, and because CMS has not explicitly stated the results from the two measures are not comparable, the public could understandably come to the conclusion that comparisons are appropriate. However, the results of the two measures reflect fundamental claim and billing policy differences between the

two settings that preclude valid comparisons. This is due to several factors, including the following:

- Medicare’s three-day payment window policy results in major challenges to identifying index HOPD visits, and therefore subsequent hospital visits related to HOPD care, creating a systematic undercounting bias in the HOPD 7-day hospital visit rates.
- ASC-12 identifies ASC facility claims *directly*, using ASC facility claims. HOPD claims for OP-32 during the three-day payment window are identified *indirectly, using physician claims* for colonoscopy in the HOPD setting with an inpatient admission within 3 days and lacking a corresponding HOPD facility claim. Place of service (POS) coding on the physician claim is used to establish the HOPD site of service. However, the Department of Health and Human Services Office of Inspector General has performed repeated audits of physician POS coding that consistently demonstrate high error rates, so this indirect methodology is flawed.
- OP-32 has exclusions for colonoscopies that are billed on the same hospital outpatient claim as an observation stay or an ED visit, as well as colonoscopies that are billed on a separate claim on the same day and at the same facility as an ED visit. This is because the sequence of events in these cases is not clear. However, a similar adjustment is not made when an ASC visit and an ED visit are billed on the same day even though the sequence of events in this case is also unclear.
- HOPDs submit claims using the UB-04; ASCs submit claims using the CMS-1500. Among their differences, the two forms vary in the total number of fields available for the submission of diagnosis codes and in the types of fields associated with diagnosis coding. For example, the CMS-1500 requires a pairing of each procedure code with a diagnosis code supporting its medical necessity; there is no method for coding underlying comorbidities that may impact the measure’s risk adjustment methodology.

Individual consumers will be making healthcare choices and decisions based on the data CMS presents so it is crucial these two measures be clearly distinguished as different. CMS should take immediate action to differentiate the measures. Possible steps include revising the names of the measures and adding interpretive guidance that makes it clear that the measure results cannot be compared across the two settings.

## **B. Reliability of the Facility-Level Measure Score**

In addition to the above concern, we continue to take issue with the reliability of the scores for this measure. The number of outcome events for this measure is low and in order to compensate for this, the measure has been specified in ways that generate large case volumes through the inclusion of physician office claims for colonoscopy in the measure denominator. Despite this and the inclusion of two years of data, at the time of reliability testing the intra-class correlation coefficient (ICC) was only “fair.” The reliability data presented to NQF demonstrated that this measure requires three years of data to achieve even modestly reliable measure scores for *high volume* facilities. The reliability of the measure was “fair” for two years of data; the reliability of measure scores that use only one year of data would be even lower due to the significantly smaller number of observations. To account for this, the measure developer recommended use of three years of data. The “dry run” was performed using three years of data, yet CMS implemented the measure using only one year of claims data and plans to publicly report

these scores later this year.

It should also be noted that the “fair” ICC for this measure was only obtained *after* excluding facilities with volumes of less than about 100 cases per year from the calculation. However, in the “dry run” for this measure, CMS lowered the threshold for the number of colonoscopies to fewer than 30, which is about equivalent to 10 cases/year because the dry run incorporates three years of claims data. This is a significant change and further impacts the reliability of measure scores.

In our opinion, the reliability of measure data intended for public reporting and accountability purposes is of paramount concern. CMS should extend the data collection period to three years and set the low volume threshold at 100 cases/year in order to ensure some semblance of reliability in the measure scores reported to the public.

#### **XIV. Public Reporting of ASCQR Program Data**

CMS publicly displays ASC quality data on the Hospital Compare website. This location is less than ideal for two reasons. First, the name of the website implies it is a location for hospital information, and ASCs are not hospitals. Secondly, the current link to ASCQR Program data on Hospital Compare is not prominent, but rather one of several in a list of quality program and other related links. This is not user-friendly for consumers trying to find ASC information. CMS should establish a website dedicated to ASCs, as it has already done for many other programs including nursing homes, dialysis facilities, home health care, and most recently, hospice care. In the interim, CMS could consider renaming the Hospital Compare website. A name such as “Facility Compare” would be a possibility.

#### **XV. Accounting for Social Risk Factors in ASCQR Program Quality Measures**

In this rulemaking, CMS indicates that socioeconomic factors such as income, education, race and ethnicity, employment, disability, community resources, and social support can play a major role in health. The agency states one of its objectives is to reduce health disparities in order to ensure that all beneficiaries, including those with social risk factors, receive high quality care. The agency is seeking public comment on whether it should account for social risk factors in the ASCQR Program, and if so, what method or combination of methods would be most appropriate.

We believe it would be important to definitively determine whether or not social risk factor disparities exist in the ASC setting prior to committing to adjusting any measures for these factors. Two of the measures CMS is proposing for inclusion in the ASCQR Program (ASC-17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures and ASC-18: Hospital Visits After Urology Ambulatory Surgical Center Procedures) have undergone disparities testing using factors indicative of socioeconomic status (SES). Two approaches to testing were used. First the measure developer assessed whether risk adjustment for Medicaid dual-eligibility status, African-American race, or the AHRQ-validated SES index affected ASC measure scores by comparing the facility-specific measure score with and without adjustment for each of these variables. Testing revealed the ASC-level risk-standardized scores were highly correlated (Spearman correlation coefficients of nearly 1.0) when calculated with and without the addition of these SES variables. Second, the developer assessed whether ASCs with a high proportion of dual-eligible patients,

African-American patients, or low SES patients as identified by the AHRQ SES index performed as well on the measure as ASCs with lower proportions of these patients. These analyses showed limited differences in the distributions of the risk-standardized hospital visit rates by quartile and the differences in the median rates were the same for all three SES variables. These testing results indicate ASC outcomes for these services were not impacted by SES variables. It seems unlikely that outcomes for other ASC services would be impacted by SES variables when these were not. In fact, we noticed CMS did not incorporate SES testing in the recent evaluation of a related skin and general surgery measure that it is developing.

Risk adjustment or stratification based on social risk factors would be a very resource intensive undertaking for measures that are not based on Medicare claims and enrollment data. Therefore we suggest that only those measures for which CMS systems would allow the agency to access to both patient level health information and demographics be considered for social risk factor adjustment in the future - if a need for such adjustment can be established as a result of scientific study. It would then follow that only those social risk factors found in CMS databases would be reasonable to include in risk adjustment or stratified reporting.

In addition to the potentially enormous provider burden, we also ask the agency to consider what impact requiring providers to collect patient social risk factor data would have on patient perceptions and experience of care. It is possible patients could perceive such inquiries as inappropriate and/or discriminatory.

## **XVI. The Measure Applications Partnership (MAP)**

CMS says it relies on the recommendations of the MAP when issuing proposals for measures for future inclusion in the ASCQR Program. We appreciate the work of the individuals serving on the MAP Coordinating Committee and its various workgroups, and applaud the improvements in the MAP process that have been made over time, but continue to be concerned about two issues: the absence of meaningful ASC representation on the Hospital Workgroup of the MAP and the CMS practice of submitting measure concepts for consideration. We bring these issues to your attention since CMS convenes the MAP.

The Hospital Workgroup of the MAP is charged with developing recommendations for CMS regarding the ASCQR Program. In light of this responsibility, it is essential to have plausible and appropriate ASC representation on the Workgroup. At present, this workgroup does not include any individual or organization able to provide the ASC industry expertise essential to developing sound recommendations for the ASCQR Program. This will be the second year in a row the MAP lacks this basic competence. While we agree it is important to bring new perspectives to the Hospital Workgroup, this should not be done at the expense of core expertise. An ongoing ASC organizational or subject matter expert presence on the MAP Hospital Workgroup is crucial to the development of informed recommendations. We ask CMS to address this deficiency as soon as possible.

In addition, we are troubled by CMS's ongoing practice of asking the MAP to make recommendations regarding its measure concepts and/or drafts. The agency and its contractors regularly submit incomplete measures to the Measures Under Consideration List. Not all concepts and drafts are successfully developed. Further, and as noted above, CMS has ignored last year's

MAP pre-rulemaking report regarding two of its measure drafts, for which a “Refine and Resubmit Prior to Rulemaking” recommendation was given. We do not believe any other measure developer/steward would be permitted to circumvent the process this way. We urge the agency to promote a measure development process and pre-rulemaking submission timeline in which the MAP is accorded the opportunity to duly consider fully developed measures from CMS.

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Thank you for considering these comments. We look forward to continuing our dialogue with the agency regarding the ASCQR Program and would be happy to assist with questions, provide additional information, or share copies of past comments at your request.

Sincerely,

A handwritten signature in black ink, appearing to read "Donna Slosburg". The signature is written in a cursive style with a large, stylized initial "D".

Donna Slosburg, BSN, LHRM, CASC  
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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 Surgical 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.