



# ASC Quality Collaboration

---

September 24, 2018

## VIA ELECTRONIC SUBMISSION

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1695-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

### **Re CMS-1695-P: Medicare Program: Proposed Changes to 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-1695-P (83 FR 37046, July 31, 2018) 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) community through a 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 and its efforts to make improvements. We welcome this opportunity to provide feedback regarding the agency's recent proposals for the ASCQR Program and other related matters.

#### **I. Proposed Changes in the Removal Factors for ASCQR Program Measures**

In 2014, CMS proposed and finalized the factors it considers when determining whether to remove measures from the ASCQR Program. Those factors are as follows:

1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped-out” measures).
2. Availability of alternative measures with a stronger relationship to patient outcomes.
3. A measure does not align with current clinical guidelines or practice.

4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

#### **A. Proposed Deletion of Measure Removal Factor 2**

At the time of their proposal, the ASC QC remarked on the duplicative nature of Factors 2 and 6. We suggested the possibility of an error because Factor 2 for the ASCQR Program was different than the Factor 2 included in both the Hospital IQR and Hospital OQR programs (which was “performance or improvement on a measure does not result in better patient outcomes”). Nonetheless, the ASC factors were retained as proposed, resulting in the current disparity across quality reporting program removal factors. CMS has since reevaluated those comments and has come to agree that ASCQR measure removal Factor 2 and Factor 6 are repetitive. The agency is now proposing to remove Factor 2, “availability of alternative measures with a stronger relationship to patient outcomes,” beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period. We support this proposal.

#### **B. Proposed New Measure Removal Factor 2**

CMS is also proposing to implement a new removal Factor 2 that specifies, “performance or improvement on a measure does not result in better patient outcomes”. This new factor is identical to measure removal Factor 2 in the Hospital OQR Program, and what we believe Factor 2 should have been all along. With this change, ASCQR Program measure removal factors would be aligned with the Hospital OQR Program removal factors, providing consistency across quality reporting programs. If adopted, this new second removal factor would be implemented on the effective date of the CY 2019 OPPS/ASC final rule with comment period. We support this proposal.

#### **C. Proposed New Measure Removal Factor 8**

CMS is proposing to adopt another new factor when evaluating measures for removal from the ASCQR Program measure set, namely Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program. This proposal is part of an agency effort to ensure that the ASCQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. In referencing cost, CMS has identified several different types of costs, including, but not limited to: (1) facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with any other applicable federal and/or State regulations.

Measure removal Factor 8 has recently been adopted for other CMS quality reporting and value-based purchasing programs, including the Hospital IQR Program. It has also been proposed for the Hospital OQR Program in this notice of proposed rulemaking.

The ASC QC supports the adoption of measure removal Factor 8. We appreciate the agency's willingness to seriously consider cost and burden. We believe that a balance between promoting quality and managing the encumbrances of quality reporting is needed to promote a sustainable quality reporting program. Ultimately, if ASCs were to find the costs and burdens of meeting ASCQR Program requirements to be greater than the 2% payment update penalty for failing to do so, it is possible some ASCs would choose to forgo participation in the ASCQR Program entirely. This would be unfortunate, and therefore we support CMS's effort to take action to address the mounting costs of participation. We further hope CMS will also carefully consider the matters of cost and burden when determining whether to propose and adopt measures into the ASCQR Program in the future.

## **II. Proposed Removal of ASC-1, ASC-2, ASC-3, and ASC-4 Beginning With the CY 2021 Payment Determination**

CMS is proposing to remove ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission based on its assessment that performance on these four measures is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. CMS uses a statistical measure of the truncated coefficient of variation to determine when a measure is "topped-out", and on this basis has stated "removal from the ASCQR Program measure set is appropriate as there is little room for improvement. In addition, removal would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measures. As such, we believe the burden associated with reporting these measures outweighs the benefits of keeping them in the program." CMS is proposing to remove the measures beginning with the CY 2021 payment determination.

The ASC QC does not support the removal of these measures from the ASCQR Program.

We believe these measures should be retained in the ASCQR Program for several reasons. Firstly, ASC-1, ASC-2, and ASC-3 are all serious reportable events and are critical to ensuring patients are protected from harm while receiving care. It is expected that these events would be rare. It is further desired that these preventable events would never occur at all. Because they are rare - and not yet zero - does not mean they should not be reported. Private insurers have begun to incorporate these measures as part of their quality incentive programs. We believe consumers should have an opportunity to understand how well a facility protects its clients from harm. If CMS does not report these measures, there is no other national-level platform for their reporting.

All four of these measures are also crucial because they are applicable to all ASCs. Other than the OAS CAHPS-based patient experience measures (which are currently on hold), there are no other measures in the ASCQR Program that can be reported by all centers. Without these measures, patients would only have access to quality data related to specific procedures, which may or may not be pertinent to their situation.

We believe all these measures are of abiding interest and enduring importance to patients because they help answer some of the most common questions consumers have, such as: whether they will be safe when in the care of the facility; whether they can expect to return home for recovery after their surgery or procedure; and how many patients end up being transferred or admitted to a hospital instead of going home.

Finally, and most critically, we have observed flaws in the implementation of these measures. Since they were first adopted, and continuing to the present day, CMS only requires ASCs to report these measures on 50 percent of their claims in order to meet program requirements. For several years, we urged CMS to increase the threshold for successful reporting, and for the last couple of years, we have urged CMS to abandon claims-based submission in favor of requiring ASCs to report data for these measures for *all patients* via QualityNet. The current reporting requirements *allow selection bias* and therefore make it *appear* there is no room for improvement when industry experience suggests this is not the case. As we have stated in past comments, data for these measures should not be limited to selected Medicare patients. If reporting were moved to QualityNet, CMS and the public would have access to 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. As the measure developer and steward for all these measures we can affirm they are suitable for submission through the QualityNet site. We also believe making this change in the data submission method would lead to reduced burden and cost for both ASCs and CMS, and generally simplify the requirements of the ASCQR Program.

As we have pointed out in the past, removing measures based on statistics alone is too simplistic. Certain types of measures - such as patient safety measures whose goal is to drive toward and sustain zero harm, outcome measures such as surgical site infection rates, and patient experience measures - could, over time, develop performance scores with the statistical characteristics CMS applies. Despite this, we believe they remain valuable to consumers and providers. As CMS has indicated previously and reiterated in this rule, while the measure removal factors are used to guide the possibility of measure removal, each measure is considered on a case-by-case basis. CMS has the option to decide to retain a measure that meets the criteria of a selected measure removal factor if it determines that there are other benefits to beneficiaries. We believe CMS should exercise this option in the case of these measures.

We further believe that these measures could easily be applied to other outpatient surgical settings, including Hospital Outpatient Departments (HOPDs). Expanding the adoption of these measures to other settings would significantly increase the alignment of measures across programs and would allow consumers more opportunities to compare quality and safety across settings of care. There is little burden associated with collecting and reporting data for these measures. The events captured by ASC-1, ASC-2, ASC-3, and ASC-4 are an essential part of assuring quality in the outpatient surgical setting. Data for these measures is routinely collected in the course of ASC operations, and we are aware of HOPDs that also collect this data.

CMS notes in its remarks that NQF endorsement for several of these measures has been removed during the period of the last several years. It is true that NQF endorsement was *allowed to lapse*. Endorsement was not removed because the measures were submitted and failed the endorsement maintenance process. As the measure developer and steward, we made the decision not to submit the measures for reconsideration of endorsement. The affected measures had all received initial NQF endorsement and had also been re-endorsed in previous cycles. With no

changes to the evidence base, scientific acceptability or other NQF criteria, we felt our limited resources would be better used developing new measures rather than rehashing established measures in the cumbersome and increasingly fraught process of NQF endorsement and endorsement maintenance. We also note that the measures continue to meet the statutory requirement of consensus among affected parties as evidenced by the ongoing support of the ASC community and their continued submission of data for these measures to the ASC QC's public reporting project at [ascquality.org](http://ascquality.org). We note that CMS did not suggest it was removing the affected measures due to the lapse in endorsement.

### **III. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)**

Quality data for ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission measures is submitted using QDCs. We have noticed that CMS refers to these measures as "claims-based". These measures are claims-reported (or claims-submitted), but not claims-based. We think this nomenclature causes confusion because other ASCQR Program measures (namely ASC-12, ASC-17, and ASC-18) are actually claims-based. If the measures are retained, we believe it would be helpful to make this distinction going forward.

### **IV. Proposed Removal of ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel Beginning with the CY 2020 Payment Determination**

The agency is proposing to remove ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel beginning with the CY 2020 payment determination. CMS has concluded that the costs associated with this measure outweigh the benefit of its continued use in the program. The measure specifications require the ASC to identify personnel who have been vaccinated against influenza and for those not vaccinated, the reason why. In addition, the measure is reported through the National Healthcare Safety Network (NHSN), a data submission platform with its own unique administrative requirements that are currently the most challenging in the ASCQR Program. This measure is also proposed for removal from the Hospital OQR Program.

The ASC QC supports the removal of ASC-8. While we support the public reporting of vaccination rates among healthcare personnel, we share the concerns regarding the magnitude of the data collection and submission burden associated with the use of this measure. We further hope that CMS will work with CDC to determine if there are ways to simplify the NHSN administrative requirements and data submission process in the event that NHSN-reported measures are introduced into the ASCQR Program in the future.

### **V. Proposed Removal of ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients Beginning With the CY 2021 Payment Determination**

CMS adopted ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2016 payment determination. The agency is now proposing to remove ASC–9 beginning with the CY 2021 payment determination. This proposal is being made for a number of reasons, including: (1) the

cost and burden associated with this chart-abstracted measure outweigh the benefits of its continued use in the program, (2) the inclusion of ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy in the program contributes data on quality of care related to colonoscopy procedures, and (3) the same measure is included in the CMS Merit-Based Incentive Payment System (MIPS) program for clinicians. A similar measure in the Hospital OQR Program is also proposed for removal for the same reasons.

The ASC QC has never supported the inclusion of ASC-9 in the Program. As we pointed out several years ago, this measure was developed, tested and NQF-endorsed as a clinician-level measure. It was never tested nor endorsed as a facility-level measure for the ASC setting. Further, the measure seeks to evaluate the appropriateness of the recommended follow-up interval for a normal screening colonoscopy, a recommendation made solely by a physician. Given that accountability and actionability logically rests with the physician, we objected to having ASCs report data that was already being reported by clinicians under the (at the time) Physician Quality Reporting System (PQRS). We appreciate that CMS has come to see the issues with this measure and support the proposal to remove the measure from the ASCQR Program.

#### **VI. Proposed Removal of ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use Beginning With the CY 2021 Payment Determination**

CMS adopted ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use beginning with the CY 2016 payment determination. The agency is now proposing to remove ASC–10 beginning with the CY 2021 payment determination. This proposal is being made for the same reasons as those given for the removal of ASC-9, namely: (1) the cost and burden associated with this chart-abstracted measure outweigh the benefits of its continued use in the program, (2) the inclusion of ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy in the program contributes data on quality of care related to colonoscopy procedures, and (3) the same measure is included in the CMS Merit-Based Incentive Payment System (MIPS) program for clinicians. A similar measure in the Hospital OQR Program is also proposed for removal for these reasons.

The ASC QC was also opposed to the inclusion of ASC-10 in the ASCQR Program. As we remarked when the measure was proposed, it is a clinician-level measure already being reported by physicians under another of CMS's quality reporting programs. The duplicate reporting of the last several years has caused unnecessary provider burden without adding new information to the pool of quality data available to the public. At the time of its proposal, we also pointed out the practical difficulties and resultant burden associated with this measure. Specifically, unless the ASC in question was the site of service for the prior colonoscopy, measure data such as the date of the patient's last colonoscopy, the number, type(s) and location(s) of any polyps detected, and the presence of any extenuating circumstances would not be found in the ASC medical record and would have to be obtained from other providers.

We appreciate that CMS has reconsidered, and now recognizes the duplicative and burdensome nature of this measure. We support the proposal to remove ASC-10 from the ASCQR Program.

## **VII. Proposed Removal of ASC–11: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery Beginning With the CY 2021 Payment Determination**

The history of ASC–11: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery has been fraught with issues since CMS originally adopted the measure beginning with the CY 2016 payment determination. As a result of concerns regarding practical matters such as how ASCs would access both the preoperative and postoperative patient survey data needed to report on the measure, and how to assure the use of a consistent patient survey format, CMS ultimately determined it would make data collection and reporting of this measure voluntary.

CMS is now proposing to remove ASC–11 beginning with the CY 2021 payment determination because it is overly burdensome for facilities to report this measure due to the difficulty of tracking care that occurs outside of the ASC setting. In addition, the paucity of reported data results in very limited benefit to the consumer. A similar Hospital OQR measure is also proposed for removal.

When the measure was originally proposed, the ASC QC remarked on the implementation issues that would be posed by the measure, which was never intended for, or tested in, the ASC setting. We noted the measure’s data elements were intended to be abstracted from the medical records of the ophthalmologist or surveys distributed by their office and processed by a contracted third-party vendor. Because the data would either be not available at all, or not consistently available, in the ASC medical record, we stated these measures would impose a significant and unacceptable data collection burden. We also pointed out that the measure was already included in the PQRS for clinician reporting and did not feel the duplication of effort would add anything to the consumer’s ability to discern quality.

We are pleased to see that CMS has recognized these intractable issues and support the removal of the measure from the ASCQR Program. However, we believe these types of outcomes measures are important, and although there is no practical method for obtaining ASC patient-reported outcomes in the present day, we urge CMS to use its considerable influence to explore the development of a national (that is, including private insurers) solution to standardize measurement of, and facilitate the collection and attribution of, patient-reported outcome data.

## **VIII. Proposed Extension of the Reporting Period for ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy**

When CMS adopted ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy into the ASCQR Program for the CY 2018 payment determination and subsequent years, the agency also finalized a 1-year reporting period despite clear evidence this timeframe was inadequate. Analysis during measure development had already demonstrated that a minimum of three years of data would be needed to achieve adequate data reliability for *high-volume* facilities. Although we remarked on this issue at every opportunity for public comment, CMS remained unmoved.

We are pleased CMS has reconsidered and is now proposing to extend the reporting period to three years beginning with the CY 2020 payment determination. As we have stated in the past,

we believe the reliability of measure data intended for public reporting and accountability is of paramount importance. Publicly reported data has the potential to influence the decision-making of health care consumers and therefore must be highly reliable. We support this effort to make the measure data more reliable. However, we believe CMS should, in order to make the measure data as reliable as possible, increase the minimum case volume threshold from less than thirty cases to less than one hundred cases. The measure results for low volume ASCs are demonstrably less reliable and it is important for CMS to address this issue.

There are other problems with this measure that we have raised with the agency in the past and will continue to reiterate until they are resolved. One of the most significant of these is the implication that ASC-12: Facility 7-Day Risk- Standardized Hospital Visit Rate After Outpatient Colonoscopy and OP-32: Facility 7-Day Risk- Standardized Hospital Visit Rate After Outpatient Colonoscopy are comparable. Although the results for the two measures cannot be compared, a casual observer of the publicly reported data for these measures 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 - but mistakenly - conclude that comparisons are appropriate. The data reported for the two measures reflects 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 creates major challenges in identifying index HOPD visits, and therefore subsequent hospital visits related to HOPD care, resulting in 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, no adjustment is made when an ASC visit and an ED visit are billed on the same day even though the sequence of events is also unclear.
- HOPDs submit claims using the UB-04 while 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 could impact the measure's risk adjustment methodology.

Consumers could be making healthcare decisions based on the data CMS presents, so it is crucial these two measures be clearly distinguished. CMS should take immediate action to differentiate the measures. The agency could revise the names of the measures to make them distinct and/or add interpretive guidance clarifying that the measure results cannot be compared across the two

In addition, ASC-12 does not help the consumer make distinctions among ASCs. The measure data currently on display at the Hospital Compare website indicates that of 1810 ASCs eligible for evaluation, the performance of 1806 of the centers (99.8%) was no different than the national rate. While CMS and its contractor have repeatedly stated there is variability in performance, the risk-standardized results indicate the opposite. And there is certainly no meaningful assistance given to the beneficiary attempting to compare performance using these results. We believe that the measure is a candidate for removal based on measure removal Factor 1. Also, if measure removal Factor 8 is adopted as proposed, this measure should be a candidate for removal from the ASCQR Program on that basis as well. The amount of money and resources that CMS has expended on this measure (and others like it that have similar unhelpful results, such as ASC-17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures and ASC-18: Hospital Visits After Urology Ambulatory Surgical Center Procedures) is staggering, and all to no avail for the consumer.

## **IX. Possible Future Validation of ASCQR Program Measures**

In this proposed rule, CMS has raised the possibility of future validation of ASCQR Program measures. There is currently no validation of ASCQR measure data, and CMS has suggested the Hospital OQR Program validation policy could be a good model for the ASCQR Program.

The Hospital OQR Program requires validation of chart-abstracted measures. To validate these measures, CMS selects up to 450 hospitals at random and also targets up to an additional 50 hospitals for review each year. When specifically targeting hospitals for review, CMS uses the following criteria: (1) The hospital has failed the validation requirement that applies to the previous year's payment determination; or (2) the hospital has an outlier value for a measure based on data that it submits. An "outlier value" is defined as a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals and indicates a poor score. CMS requires hospitals to send copies of medical record documentation for cases selected for data validation to its contractors; these cases may include both Medicare and non-Medicare cases. The hospital must submit the supporting medical record documentation within 45 days of the date of the request. A hospital meets the validation requirement for the calendar year if it achieves at least a 75 percent reliability score, as determined by CMS through its contractor. Those hospitals that do not meet the 75 percent reliability score forfeit their annual payment update. Of note, it is possible for a hospital to be selected in consecutive years, even if it demonstrates satisfactory reliability in a prior year.

CMS is interested in possibility of the validation of ASCQR Program chart-abstracted measures using the Hospital OQR Program model. The agency believes it would be beneficial to start with validation of just one measure, such as ASC-13: Normothermia Outcome, prior to expanding to more measures. CMS says it considered starting with ASC-14: Unplanned Anterior Vitrectomy instead but believes ASC-13 would be the most feasible measure for validation because it would have a larger population of cases from which to sample and that ASC-14, which assesses rare, unplanned events that are less common, would have a smaller population of cases from which to sample.

The agency is asking for feedback on these possibilities and is specifically requesting comment regarding: whether Hospital OQR Program's validation policies could be an appropriate model for the ASCQR Program; the possible ASC sample size, sampling methodology, and number of cases to sample; validation score methodology; and reduced annual payment updates for facilities that do not pass validation requirements. CMS is also requesting comment regarding starting validation with ASC-13, before expanding to more measures.

The ASC QC acknowledges the importance of validation of quality measure data and simultaneously fears the burden associated with the process. We are concerned that the relative burden of the validation process will be much higher for ASCs compared to HOPDs due to the low levels of adoption of EHRs in the ASC industry. As the agency is undoubtedly aware, ASCs were not included in provisions of the American Recovery and Reinvestment Act of 2009 establishing an incentive and penalty program to encourage physicians and hospitals to implement health information technology. Although ASCs were eligible to apply for a very limited portion of \$2 billion in grant and loan money available to states for investment in health information technology, this eligibility did not result in a significant increase in the use of EHRs in the ASC industry. We note that HOPDs have the option of submitting medical records for validation by paper copy or on CD, DVD or flash drive or electronically via the QualityNet Secure File Transfer system. We believe the majority of ASCs would need to submit the records by paper copy.

We have reviewed the materials regarding the Hospital OQR validation process posted to QualityNet in detail. We see a number of challenges with using the Hospital OQR process as a model for validation in the ASC setting. Chief among these is the matter of how CMS and its contractor would go about identifying the ASC medical records selected for abstraction of clinical data. As you know, under the Hospital OQR Program, chart-abstracted measure data are submitted to CMS via a clinical warehouse on a quarterly basis. This submission can either be done by a third-party vendor, or by the hospital itself using a CMS Abstraction & Reporting Tool (CART). Either way, the data submitted to the clinical warehouse for chart-abstracted measures includes patient identifiers, such as name and date of birth. If the hospital is selected for validation, these patient identifiers are used to develop the quarterly listing of medical records specifically chosen for review by the contractor.

There are a number of differences in the form and manner in which ASCs report quality data for chart-abstracted measures when compared to HOPDs. Importantly, data is submitted via QualityNet on an annual basis. The values for the measure numerator and denominator are submitted, but no information that would allow the identification of individual patients is shared with CMS. Also, CMS's current policy is to allow sampling for ASC-13. (For facilities with an annual population of 901 or more cases, the yearly sample size is 96; for facilities with an annual population of 900 or fewer cases, the yearly sample size is 63; and for facilities with an annual population of fewer than 63 cases, the total population of cases is required.)

The lack of patient identifying information means there is no method whereby CMS or its contractor can determine which patients' data is being provided. This would in turn appear to require that the individual ASC determine which patient charts are eligible for validation. And that would seem to *defeat the purpose of the validation exercise*, as there would be no method for ensuring that the patients chosen represented a random (or other appropriate) sample. The only way to avoid selection bias would be to require, for ASC-13, the submission of the entire sample. This would mean that, depending on facility volume, anywhere from 1 to 96 cases would be

validated. However, for the Hospital OQR, a maximum of 12 cases per quarter, or 48 cases per year are validated for chart-abstracted measures. We believe it would be unduly burdensome and frankly unfair to ask ASCs, which are largely small providers when compared to hospitals, to submit more cases for validation.

With respect to the question of whether ASC-13 or ASC-14 would be a better starting point, a few items are worth bearing in mind. First, although ASC-14 is expected to have a small numerator, both the number of ASCs submitting data for this measure and the denominator population for the measure across all facilities would be larger than for ASC-13. This is because, for the industry as a whole, cataract surgery is much more common than cases that require general or neuraxial anesthesia of 60 or more minutes duration. So, if CMS were seeking a larger number of ASCs and a larger population of cases to sample as per its remarks in the proposed rule, ASC-14 would provide, on the whole, more cases. We also point out that because ASC-13 data is itself a sample, the number of cases available for validation is further reduced from the measure's total denominator population.

As CMS considers the total number of ASCs to propose as the number selected for participation in the validation process, we point out that the chart-abstracted measures currently in the ASCQR Program do not apply to all centers, only those performing cases involving general/neuraxial anesthesia of 60 minutes or more in duration (ASC-13) and/or cataract surgery (ASC-14). Therefore, the total number of ASCs reporting on these measures would only represent a fraction of the total number of ASCs participating in the ASCQR Program. We believe setting the number of ASCs to undergo validation at or around 500 centers (a number comparable to that under the Hospital OQR Program) would represent a significantly larger percentage of the ASCs reporting chart-abstracted measures under the ASCQR Program than under the Hospital OQR Program. We think that given the currently available measures, CMS should designate a smaller number of ASCs, perhaps based on the percentage of HOPDs selected for validation under the Hospital OQR Program.

The fact that not all ASCs report data for ASC-13 and/or ASC-14 also raises a concern. Only those centers that have cases that qualify for these measures would undergo the validation process. This means these centers would bear more burden, be at greater risk for failing to meet program requirements due to the additional validation requirements, and generally face a higher threshold for retaining their annual payment update. We would prefer to see a process that, over the course of time as different ASCs are selected for validation, impacts all centers equitably. That would mean applying the validation process to measures that are reported by all centers rather than measures that are reported by some ASCs and not by others.

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

In this proposed rule, CMS states its goal is to “move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.” If the agency finalizes removal of all the measures it has proposed, the ASCQR Program would be parsimonious indeed. Beginning with data collection next year for the CY 2021 payment determination, there would effectively be only three measures in the program due to the delay in implementing the OAS CAHPS measures. Therefore, we encourage CMS to review again the measures that have already been through the MAP process and are eligible for inclusion in the

ASCQR Program. These measures are discussed briefly below.

### **A. Toxic Anterior Segment Syndrome Measure**

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. This measure aligns well with the CMS Meaningful Measures Initiative as a measure of preventable healthcare harm.

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) 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.

We encourage CMS to re-propose the adoption of this measure and submission of aggregated measure data via QualityNet in the next rulemaking cycle.

### **B. Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure**

The Ambulatory Breast Procedure Surgical Site Infection Outcome measure was 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 related to healthcare-associated infections under the Meaningful Measures Initiative. 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 and recommend that CMS propose the measure in the next rulemaking cycle.

If the SSI measure were proposed and ultimately adopted for the ASCQR Program, it is likely measure data would be reported via CDC's NHSN. As you know, ASCs currently 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 with CDC to implement NPI-based data collection in NHSN, and plan to report all future measures by NPI.

## **XI. 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 appropriate.

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

CMS says it relies on the recommendations of the MAP in making proposals for measures for inclusion in the ASCQR Program. We appreciate the work of the individuals serving on the MAP Coordinating Committee and its various workgroups and are grateful for the improvements in the MAP process that have been made over time. However, the ongoing absence of any meaningful ASC representation on the Hospital Workgroup of the MAP is a serious concern. CMS is responsible for convening the MAP, so we bring this issue to your attention.

The Hospital Workgroup of the MAP is charged with developing recommendations regarding the ASCQR Program. This responsibility makes it essential to have ASC representation on the Workgroup. For several years this workgroup has not included any individual or organization able to provide the ASC industry expertise essential to developing sound recommendations for the ASCQR Program. This is now the third year in a row the MAP lacks this basic competence. While it’s appropriate to bring new members and perspectives to the Hospital Workgroup, this cannot be at the expense of core expertise. Ongoing ASC organizational or subject matter expert presence on the MAP Hospital Workgroup is crucial to the development of informed recommendations. CMS should correct this deficiency with the next cycle of appointments.

\*\*\*

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,



Donna Slosburg, BSN, HRM, CASC  
Executive Director, ASC Quality Collaboration  
727-367-0072  
[donnaslosburg@ascquality.org](mailto:donnaslosburg@ascquality.org)

**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  
Association of periOperative Registered Nurses  
California Ambulatory Surgery Association  
Cerner  
Covenant Surgical Partners  
Florida Society of Ambulatory Surgery Centers  
Hospital Corporation of America, Ambulatory Surgery Division  
Merritt Healthcare  
New Jersey Association of Ambulatory Surgery Centers  
Outpatient Ophthalmic Surgery Society  
Physicians Endoscopy  
Practice Partners in Healthcare, Inc.  
Regent Surgical Health  
Surgery Partners  
Surgical Care Affiliates  
Surgical Information Systems  
The Joint Commission  
United Surgical Partners International  
Visionary Enterprises, Inc.