ASC Quality Collaboration

September 25, 2019

VIA ELECTRONIC SUBMISSION

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re CMS-1717-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma:

Please accept the following comments from the ASC Quality Collaboration (ASC QC) regarding CMS-1717-P (84 FR 39398, August 9, 2019) Sections XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program and XV. 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 ambulatory surgery centers (ASCs) through a collaborative effort involving a diverse group of ASC stakeholders. These stakeholders include leaders from ASC management companies, industry associations, accreditation organizations, information technology companies, 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. We welcome this opportunity to provide feedback regarding the agency's recent proposals for the ASCQR Program and other related matters.

The ASC QC sincerely appreciates the ongoing effort the agency devotes to the ASCQR Program and its efforts to make improvements. We appreciate the agency's willingness to consider how best to achieve balance between promoting quality measurement and managing the administrative burden of quality reporting.

I. Changing the Data Submission Method for ASC-1, ASC-2, ASC-3 and ASC-4

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 were adopted into the ASCQR Program beginning with the CY 2014 payment determination. In the past, these measures were calculated via quality data codes (QDCs) that ASCs submitted on individual Medicare Fee For Service (FFS) claims. To meet program requirements, ASCs were required to submit QDCs on a minimum of 50 percent of eligible claims. At present, CMS has

suspended data submission for these measures while it considers the matter of updating the data submission methodology. In this proposed rule, CMS states it has considered updating the data submission method to "a CMS online data submission tool" (currently QualityNet) and is requesting public comment regarding updates to the data submission method for these measures.

We are pleased to see these measures retained in the ASCQR Program. Of all the measures currently included in the Program, these are the only measures that can be reported by all ASCs, and therefore they provide a broad perspective on ASC quality. Without these measures, patients would only have access to quality data related to specific procedures, which may or may not be pertinent to their care. 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. Further, all four measures are of abiding interest and enduring importance to patients because they help answer common questions consumers have, such as whether they will be safe when in the care of the facility and whether they can expect to return home for recovery after their surgery or procedure. Monitoring and publicly reporting these types of events is important to maintain focus on efforts to prevent their occurrence.

We agree that a change in reporting methodology for these measures is desirable. In the past, if an ASC identified an erroneous or missing QDC on a claim that had already been submitted and processed, the center would have been unable to correct or add a QDC. The inability to correct QDC submission errors could potentially have impacted the completeness and accuracy of measure data.

More importantly, CMS required ASCs to report QDCs on a minimum of 50 percent of their claims in order to meet program requirements. This policy permitted selection bias within the Medicare FFS population. Although we initially urged CMS to increase the threshold for successful reporting, for the last several years the ASC QC has encouraged CMS to abandon claims-based submission in favor of requiring ASCs to report data for these measures for *all patients* via QualityNet. Using QualityNet for data submission would expand the scope and transparency of public reporting, as well as accountability, for these measures. The measure data would also be much more useful to stakeholders, giving CMS and the public access to aggregate data for all the patients served by each participating ASC. There would be no opportunity for gaps in reporting.

As the measure developer and steward for all four measures we can affirm they are suitable for submission through the QualityNet site. If the switch were to be made, the data collection time period would be for services furnished during the calendar year that was two years prior to the payment determination year. ASCs would submit their data for ASC– 1, ASC–2, ASC–3, and ASC–4 via QualityNet during the January 1 through May 15 data submission period in the year prior to the payment determination year. ASCs would be able to submit and modify their data throughout the data submission period.

Making this change in the data submission method would lead to reduced burden and cost. Many ASCs are pleased to avoid the delay in submitting claims that results from having to gather quality data for Medicare FFS patients so that the appropriate QDC(s) can be applied. In addition, we believe the amount of time spent submitting aggregate data to QualityNet for these measures would be less than the amount of time that was required to submit QDCs on individual Medicare

FFS claims. Submitting this data via QualityNet would also generally simplify the requirements of the ASCQR Program by streamlining the number of processes the Program requires for quality measure data submission. In summary, using QualityNet for data submission offers many benefits over the QDC process, and we ask CMS to make specific proposals for this change in next year's notice of proposed rulemaking.

II. CMS Request for Comment on the Potential Future Adoption of Four Patient Safety Measures for the Hospital OQR Program

CMS is seeking comment on the potential future adoption of four patient safety measures for the Hospital OQR Program that were previously adopted for the ASCQR Program: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/ Admission.

As we have shared with CMS in past comments, these measures could readily be applied to other outpatient surgical settings, including Hospital Outpatient Departments (HOPDs). Expanding the adoption of these measures to the Hospital OQR Program would significantly increase the alignment of measures between the Hospital OQR and ASCQR Programs and would allow consumers more opportunities to compare quality and safety across settings of care. In some cases, patients have the option to choose between these two care settings. In these circumstances, patients may be interested in comparing performance at the different types of facilities.

Adopting measures across programs has precedent. In the past, CMS has taken measures that were not originally specified for the ASC setting and finalized them for inclusion in the ASCQR Program. Examples include the Safe Surgery Checklist Use, ASC Facility Volume on Selected ASC Surgical Procedures, Influenza Vaccination Coverage Among Healthcare Personnel, Improvement in Patient's Visual Function within 90 Days of Cataract Surgery, Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients, and Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps measures. CMS could take measures that were not originally specified for the HOPD setting and adopt them for inclusion in the Hospital OQR Program.

These four measures address an important Meaningful Measure Initiative quality priority, namely Making Care Safer by Reducing Harm Caused in the Delivery of Care. All four measures are easy to understand and provide information that healthcare consumers care about. ASC-1, ASC-2 and ASC-3 pertain to serious reportable events and are critical to ensuring patients are protected from harm while receiving care. These measures could be a valuable addition to the Hospital OQR Program, which currently does not include these types of measures. It could be beneficial to allow patients better insight into facility safety. While some detractors cite the low occurrence of these events, the fact remains that they are classified as seriously reportable events and any occurrence should be publicly reported. Further, it has always been the goal of patient safety experts to drive the numbers of these "never events" to zero. ASCs have been publicly reporting these events for several years now. Hospitals should not have any qualms about being similarly transparent.

ASC–4: All-Cause Hospital Transfer/ Admission is a measure that allows stakeholders to better understand how often the patient returns home, as expected, following elective surgical

procedures. We believe patients would appreciate the opportunity to understand how often patients admitted to HOPDs for elective outpatient surgery return home, as opposed to being admitted for an observation or inpatient stay. The Hospital OQR Program does not currently include a measure of this type.

As CMS notes, these measures are currently specified for the ASC setting. The agency states it is considering having them specified for the hospital outpatient setting and would seek collaboration with the measure steward if the agency does so. The measures could be readily modified to allow their application to both types of surgical facilities. We are aware of HOPDs that already use these measures to collect data for their own internal quality programs.

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 essential to assuring quality and safety in the outpatient surgical setting. Data for these measures is routinely collected in the course of day-to-day clinical operations.

CMS has indicated that if it proposes these measures for inclusion in the Hospital OQR Program, it will seek NQF endorsement. NQF endorsement for these measures has been removed over the last several years because the ASC QC allowed NQF endorsement 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 because the 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 in developing new measures.

If these measures were proposed for the Hospital OQR Program, submitting data using QualityNet would be beneficial. Using QualityNet, as opposed to claims, would be very important not only for the reasons impacting the ASC setting discussed above - allowing correction of data and avoiding case selection bias – but also due to Medicare's three-day payment window policy. The three-day payment window policy requires that outpatient services provided by a hospital, or any Part B entity wholly owned or wholly operated by a hospital, on the date of a beneficiary's inpatient admission must be billed with the inpatient stay. Part B entities affected by this policy include HOPDs, hospital emergency departments and wholly owned physician practices. Simply stated, CMS does not permit HOPDs to generate a claim when there is an inpatient admission during the three-day window, except in cases where the service was therapeutic and the hospital attests that the subsequent admission was unrelated. This policy results in challenges in identifying index HOPD visits - and therefore subsequent hospital visits related to HOPD care - which results in a systematic undercounting bias in the HOPD setting. *Claims that do not exist cannot be counted.* Events such as burns, falls, wrong events and hospital admissions would not be captured if the claims submission method were used. Data submission via QualityNet would avoid these issues.

III. Proposed New Quality Measure for the ASCQR Program Measure Set: ASC–19: Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

In this proposed rule, CMS is proposing to adopt one new quality measure for the ASCQR Program for the CY 2024 payment determination and subsequent years. The proposed measure is ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357). The measure is intended to assess adverse outcomes through detection of near-term hospital visits (defined as unplanned inpatient admissions, observation stays, and emergency department visits) following general surgery procedures performed at ASCs. CMS plans to use this to determine ASC-level quality of care and "prompt improvements in care for Medicare beneficiaries". It is an administrative claims-based outcome measure. The measure scores would be calculated using routinely submitted claims, meaning facilities would not need to submit any new data to CMS.

We appreciate the improvements in the measure specifications that have been made in response to public comment. However, there are other aspects of the measure that should be addressed prior to its inclusion in the ASCQR Program.

A. Focus on Uncommonly Performed Procedures

CMS states general surgery procedures – by which the agency means abdominal, alimentary tract, breast, skin/soft tissue, wound, and varicose vein stripping procedures - are commonly performed at ASCs. It states an analysis of Medicare fee-for-service (FFS) claims for patients aged 65 years and older, from January 1, 2015 through December 31, 2015, indicates that ASCs performed 149,468 general surgery procedures. However, the total volume of Medicare FFS claims for calendar year 2015 was approximately 6.3 million (MedPAC Report to the Congress: Medicare Payment Policy, March 2018). Therefore, all the "general surgery" procedures included in this measure represent less than 2.5% of the total number of procedures performed for Medicare FFS beneficiaries. Further, of the 3,251 ASCs that performed "general surgery" procedures, only 35.5 percent of centers performed at least 25 such procedures (the minimum volume threshold for the measure) during the calendar year. The measure assesses uncommonly performed ASC procedures, and produces scores for a minority of those centers that perform them.

B. Measure Title Does Not Orient Users to the Procedure Cohort

The title of the measure sets the expectation that the measure results reflect the practice of general surgery in the ASC setting. However, the *majority of cases* included in the measure are skin and soft tissue procedures. As a result of the inclusion of so many skin repair, graft and plastic repair surgeries of the face - including eyelids, ears, nose, lips, forehead, cheeks, and chin – the resultant case mix diverges significantly from the typical practice of a general surgeon in the ASC setting. This issue was also raised by the Hospital Workgroup of the Measure Applications Partnership, and has not been addressed.

The developer states, "[f]or this measure, we targeted surgeries that general surgeons are trained to perform with the understanding that other subspecialists may also be performing many of these surgeries at ASCs". When patients look at the results of a measure called "Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers", they will naturally assume they are looking at results related to operations that a general surgeon ordinarily does in an ASC. The typical patient is not going to figure out that the developer has focused on general surgery *training* rather than the *practice* of general surgery in the

ambulatory setting. CMS and the developer should revise the title of the measure so that consumers are properly oriented to what is being evaluated by the measure. Doing so would make the scope of the measure clearer to beneficiaries and would also improve the face validity of the measure. Although it would lengthen the title, the developer could consider referencing the procedure cohort, namely "abdominal, alimentary tract, breast, skin/soft tissue, wound, and varicose vein stripping procedures".

C. Further Refinements to the Procedure Cohort Are Needed

In this proposed rule CMS states, the "ASC–19 measure does not include gastrointestinal endoscopy, endocrine, or vascular procedures, other than varicose vein procedures, because for these procedures, reasons for hospital visits are typically related to patients' underlying comorbidities". There is another procedure type that should be removed from this measure for the same reason. The Measure Technical Report shows that results related to procedures classified as "Other therapeutic procedures, hemic and lymphatic system" were unusual. For this procedure category, the top 10 primary diagnoses included "Other follicular lymphoma, spleen", "Unspecified B-cell lymphoma, unspecified site", and "Non-Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes". This raises the concern that hospital visits for this group of procedures were typically related to the patients' underlying illness.

We noticed a similar occurrence in the Lumpectomy, quadrantectomy of breast and Mastectomy procedure categories. The top 10 primary diagnoses included "Malignant neoplasm of unspecified site of right female breast", "Malignant neoplasm of unspecified site of left female breast", and "Acquired absence breast/nipple".

These "top diagnoses" have nothing to do with quality of care, but rather reflect the patients' underlying condition and reason for the index surgery. A diagnosis of lymphoma following surgery on the hemic or lymphatic system is not an indication of an acute illness or complication of care. A diagnosis of a breast neoplasm is not an illness caused by the index breast surgery or a complication of the surgery itself. Conditions such as the acquired absence of a breast/nipple are expected following a mastectomy. Holding providers "accountable" for these outcomes is hard to justify. ASCs will have a hard time taking the measure scores seriously if these types of outcomes are flagged as "quality signals". The measure specifications should be revised to ensure that diagnoses of cancer and expected post-surgical states are not included in the measure results.

D. ASC-Level Measure Score Reliability is Too Low for Accountability and Public Reporting Purposes

The measure developer has acknowledged that the relatively high number of low-volume ASCs made development of this measure challenging. To manage this, the measure was specified in ways that generate larger case volumes - principally through the inclusion of large numbers of skin surgeries than can be performed by many physician specialties. The other problem that arises in low-volume situations is that measure scores tend to lack reliability. In order to deal with this, the developer has conducted testing on the measure scores using a two-year period of data collection and excluded those facilities with less than 25 qualifying procedures over that two-year

period. Even with these steps, the intra-class correlation coefficient (ICC) was 0.530, which is considered "moderate".

In our opinion, the reliability of a measure intended for public reporting and accountability purposes should be higher. If facilities are to be judged based on the results calculated for this measure, the reliability of those scores should be, at a minimum, "substantial" (0.61 to 0.80 per convention). This could be achieved by raising the minimum number of qualifying procedures per facility. Setting such a low threshold for inclusion - currently the measure only requires an average 12 to 13 such cases in a given year per facility - does not provide sufficient information about quality and limits the ability to reliably estimate measure scores.

E. Limited Ability to Make Distinctions Among Facilities

According to the developer and CMS, "[t]he purpose of this measure is to illuminate variation in quality of care for general surgery procedures across ASCs, inform patient choice, and drive quality improvement". Unfortunately, this measure suffers from very limited discriminatory power. The developers initially used *unadjusted* outcome rates to assert a variation in quality: "Among the 1,157 ASCs with at least 25 cases in the Medicare FFS CY 2015 dataset, the unadjusted rate of unplanned hospital visits ranged from 0% to 13.2%. Among these ASCs with 25 or more cases, 25.2% had a rate of 0%; however, the top 10% had rates exceeding 5.7%. The results show important variation in performance across ASC facilities. While many achieve very low rates, there is a wide range of outcome rates, suggesting room for improvement". However, it is essential to adjust for ASC case-mix differences such as patient demographics and comorbidities, as well as procedure type and complexity before drawing conclusions about variability in performance.

Using adjusted outcome rates, there is little discernable variability in performance. Using the standard 95 percent interval estimate to report the measure score, of the 1,651 ASCs that qualified for the measure, the performance of 1,642 centers (about 98%) was no different than expected. Of the remaining 31 ASCs, 15 performed better than expected, and 16 performed worse than expected. This means that the overwhelming majority (about 99%) of facilities would receive a measure score indicating their performance to be either no different from or better than expected – with the implicit indication that no improvement effort would be necessary. The number of underperforming facilities is very small.

While the developers state there is variability in performance, as a practical matter the risk-standardized results indicate little room for improvement. This measure would be a candidate for immediate removal from the ASCQR Program based on CMS criteria for determining when a measure is "topped out".

F. Measure Scores Not Helpful to Consumers

The developers indicate that another purpose of this measure is to inform patient choice. In our opinion, the measure does little to aid the consumer in evaluating ASC performance. As noted above, the performance of 99% of all ASCs measured was either no different from or better than expected. The consumer would have difficulty discerning differences in quality because it would

be so unusual for a facility to perform worse than expected – in CY 2015 test data there were only 16 such centers.

G. Provision of Facility-Specific Information Prior to Public Reporting

If this proposed measure is finalized, CMS plans to conduct a "dry run" before the official data collection period or any public reporting. The "dry run" would use the most current 2-year set of complete claims and the CMS contractor would generate confidential feedback reports for ASCs, including patient-level data indicating whether the patient had a hospital visit and, if so, the type of visit (emergency department visit, observation stay, or unplanned inpatient admission), the admitting facility, and the principal discharge diagnosis. During the dry run ASCs could review their measure results and ask questions. CMS states it expects the dry run to take approximately one month to conduct, during which facilities would be provided the confidential report and the opportunity to review their performance and provide feedback. We request that CMS offer a longer time period of two months for this process.

As a part of the dry run process, the ASC QC also requests that CMS arrange for its contractor to perform additional analyses of the results of those ASCs that perform better than expected and those that perform worse than expected. We would especially like to see whether the risk adjustment factors, particularly those for procedural complexity and procedure type have effectively leveled the field. We would also like to see a compilation of the diagnoses that were associated with any hospitals visits for those ASCs that perform worse than expected.

H. Data Sources

The proposed ASC–19 measure is claims-based. Part A and Part B Medicare administrative claims and Medicare enrollment data are to calculate the measure scores for each ASC. This measure does not require any ASC engagement in data collection or submission. In addition, there is no requirement that ASCs review their facility reports or scores. CMS assumes ASCs will look at their facility-specific reports, take the time to review any "hospital visits", and make changes in patient care practices based on the data. With no incentive to engage with the data, and with the vast majority of centers performing better than or as expected, it seems unlikely that the measure will have a significant impact on patient care.

IV. 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.

We are pleased CMS has reconsidered and extended the reporting period to three years beginning with the CY 2020 payment determination. As we have stated in the past, 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. In order to make the measure data as reliable as possible, CMS should also 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. 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 measure data 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 settings.

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 1804 ASCs eligible for evaluation, the performance of 1801 of the centers (99.8%) was no different than the national rate. Measure data displayed last year indicated 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. ASC-12 is a candidate for removal based on measure removal Factor 1 and Factor 8. The amount of money and resources that CMS has expended on this measure (and others like it that have similarly 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 significant, and all to no avail for the healthcare consumer.

V. ASCQR Program Quality Measures for Future Consideration

In this proposed rule, CMS states it goal is to "move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures". We encourage CMS to review measures that have already been through the MAP process and are eligible for inclusion in the ASCQR Program. CMS could also consider these measures for inclusion in the Hospital OQR Program. The 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 number of anterior segment surgeries performed in ASCs is enormous, numbering in the millions each year, with that number expected to grow as the population ages. Studies in the literature have reported TASS complication rates of 1.8 to 2.1%, pointing to a significant opportunity for improvement.

Eye professionals agree that major efforts should be focused on the prevention of TASS. The ASCRS and ASORN have published recommended practices for cleaning and sterilizing intraocular surgical instruments aimed at the prevention of TASS. These recommended practices were developed with guidance from AORN, APIC, SHEA, CDC and the FDA. In addition, American Academy of Ophthalmology (AAO), American Society of Cataract and Refractive Surgery (ASCRS), and the Outpatient Ophthalmic Surgery Society (OOSS) have released recommendations regarding the use of enzyme detergent for cleaning intraocular surgical instruments. Inclusion of the TASS measure in the ASCQR Program will help promote adherence to these recommended practices.

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 AAO, ASCRS, and OOSS in the review of the measure early in the development process.

Although some have asserted that data for the TASS measure is difficult to collect and that ASCs would not be notified if TASS were diagnosed outside of the facility, the experience of our members indicates that this is not the case. Centers performing anterior segment surgery monitor this outcome due to its severity. Data regarding TASS outcomes is routinely collected and these events are investigated. The measure is not difficult to implement because centers already collect and report this data to their governing bodies. As noted above, the large number of anterior segment surgeries makes this a very important outcome for patients to be aware of. 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 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. In the past, ASC measure data submitted to NHSN was collected at the CCN level, whereas 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. In the past, CDC has indicated its willingness to consider changing from a CCN-based approach to an NPI-based approach. Making this change prior to implementing the Ambulatory Breast Procedure Surgical Site Infection Outcome measure would be helpful. CMS should work with CDC to implement NPI-based data collection in NHSN for ASCs.

VI. Public Reporting of ASCQR Program Data

CMS publicly displays ASC quality data on the Hospital Compare website. This location makes ASC data hard to find. 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 prominently displayed, but rather one of several in a list of quality programs 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 for many other programs including nursing homes, dialysis facilities, home health care, and hospice care. In the interim, CMS could consider renaming the Hospital Compare website. A name such as "Facility Compare" would be appropriate.

VII. The Measure Applications Partnership (MAP)

The ASC QC appreciates the work of the individuals serving on the MAP Coordinating Committee and its various workgroups and we are grateful for the process improvements that have been made over the years. However, the ongoing absence of any meaningful ASC representation on the Hospital Workgroup of the MAP is a serious concern. We bring this issue to your attention because CMS is responsible for convening the MAP.

The Hospital Workgroup of the MAP is charged with developing recommendations regarding the ASCQR Program. ASC representation on the Workgroup is crucial, yet for the last four years the workgroup has not had any individual or organization able to provide the ASC industry expertise essential to developing sound recommendations for the ASCQR Program. Ongoing ASC organizational or subject matter expert presence on the MAP Hospital Workgroup is crucial to the development of informed recommendations. CMS should work with the National Quality Forum to ensure this deficiency is corrected with the next cycle of appointments in 2020.

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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 or provide additional information at your request.

Sincerely,

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

Accreditation Association for Ambulatory Health Care
Ambulatory Surgery Foundation
AmSurg
Association of periOperative Registered Nurses
California Ambulatory Surgery Association
Covenant Surgical Partners
Florida Society of Ambulatory Surgery Centers
Hospital Corporation of America, Ambulatory Surgery Division
HST Pathways
Kaiser Permanente
Merritt Healthcare
New Jersey Association of Ambulatory Surgery Centers
NueHealth
Outpatient Ophthalmic Surgery Society
Physicians Endoscopy
Pinnacle III
Practice Partners in Healthcare, Inc.
Provation
Regent Surgical Health
Surgery Partners
Surgical Care Affiliates
Surgical Information Systems
The Joint Commission
United Surgical Partners International
Visionary Enterprises, Inc.