ASC Quality Collaboration

August 31, 2015

VIA ELECTRONIC SUBMISSION

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1633-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System

Dear Acting Administrator Slavitt:

On behalf of the ASC Quality Collaboration (ASC QC), a cooperative effort of non-profit organizations and companies interested in ensuring ambulatory surgical center (ASC) quality data is appropriately developed and reported, please accept the following comments regarding CMS-1633-P (80 FR 39200, July 8, 2015), Section XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. The ASC QC's stakeholders include ASC corporations, ASC industry associations, physician and nursing professional societies, and accrediting bodies with an interest in ASCs. Please see Appendix A for a list of these organizations, which represent over 1,500 ASCs.

The ASC QC's strong commitment to quality is reflected in our ongoing efforts to facilitate meaningful quality reporting by ASCs. This includes the development of fully tested facility-level quality measures appropriate to the ASC setting, participation in Federal projects pertaining to ASC quality measurement, and our publication of a quarterly public report of ASC quality data that is freely available online. These quarterly reports are made possible through the voluntary efforts of participants in the ASC QC and may be accessed at the ASC QC's website at: http://www.ascquality.org/qualityreport.html.

We appreciate the ongoing effort the agency applies to the ASC Quality Reporting (ASCQR) Program and are pleased to have this opportunity to offer insights and recommendations regarding the agency's recent proposals for the ASCQR Program and related matters.

I. ASCQR Program Quality Measures for Future Consideration

In this proposed rule, CMS has invited public comment on two measures developed by the ASC Quality Collaboration that the agency states it may consider for future inclusion in the ASCQR Program.

The first of these is the Normothermia Outcome measure, which assesses the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. The second is the Unplanned Anterior Vitrectomy measure. This measure assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy.

Both measures are fully developed and have been specifically tested in the ASC setting. The measures were reviewed by the Measure Applications Partnership (MAP) last year and received conditional support pending endorsement by the National Quality Forum (NQF); reliability testing was completed in 2014 with very strong results, which were shared with CMS at that time. These measures are already in use in the ASC Quality Collaboration's quarterly public reporting program.

We would support the inclusion of these measures in the ASCQR Program in the future. We note that, in spite of the MAP's recommendation, NQF endorsement is not necessary. The requirement that measures reflect consensus among affected parties has been met through our collaboration within the ASC industry, and, in the case of the Unplanned Anterior Vitrectomy measure, 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.

II. ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure: Dry Run and Other Concerns

As CMS is aware, we have ongoing concerns regarding the scientific acceptability of this measure despite its endorsement by the NQF. We continue to oppose its inclusion in the ASCQR Program due to significant and ongoing problems with its validity, reliability, and other characteristics, which are discussed in detail below. Though some of the issues discussed here have been shared with the agency previously, we consider them unresolved.

A. Lack of Measure Validity Testing in the ASC and Hospital Outpatient Department (HOPD) Settings

Validity testing for this measure was never conducted. The validity data presented for this measure was collected during the development of an entirely different inpatient measure using inpatient hospital claims. We remain amazed that the developer, CMS and NQF have accepted validity testing on inpatient claims for another measure as a satisfactory substitute for testing the validity of this measure, which is an *entirely different measure* based on *outpatient claims*.

As CMS is well aware, Medicare's inpatient and outpatient claims payment systems are governed by different sets of rules that significantly impact the coded information submitted on

claims. Inpatient reimbursement is primarily diagnosis driven, resulting in a strong emphasis on fully characterizing the patient's diagnoses and comorbid conditions. In contrast, outpatient reimbursement is service driven, and diagnosis coding in ASCs is focused on establishing the medical necessity of those services. In fact, the ASC billing format does not support the reporting of diagnosis codes that are not explicitly associated with the services provided to the patient during the encounter. Because this measure relies *entirely* on coded information for risk adjustment, it is essential to establish that the codes submitted are, *in fact and not in supposition*, reflective of the clinical aspects of care that the measure purports to measure. Given the different claims structures for inpatient versus outpatient claims, the inpatient results cannot be assumed to apply to the outpatient setting.

Further, this measure purports to evaluate both HOPD and ASC performance, asserting that head-to-head comparison of results would be appropriate, but these two settings do not even use the same claim format. 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. Without testing, one cannot claim that HOPD results can be fairly and appropriately compared to ASC results.

We continue to believe the impact of these differences – outpatient versus inpatient, and HOPD versus ASC - must be systematically tested to assure the measure results are attributable to differences in quality rather than differences in claims architecture and coding practices. The measure score should be directly validated against outpatient medical records and measure results across settings must be assessed to ensure that any comparisons are valid.

B. The Measure Is Not Valid Due to Systematic Undercounting of HOPD Events

This measure has also been finalized for inclusion in the Hospital OQR Program. Though CMS has stated the measure is "well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability," this is not true. Although the measure is likely to do a good job of counting hospital visits following ASC care, it would *systematically undercount hospital visit rates following HOPD care* occurring in the seven-day period following outpatient colonoscopy. As the measure is currently specified, comparisons across the two settings cannot be made on equal footing.

This measure's reliance on the use of administrative claims has a significant and adverse impact on the validity of the measure results. As a result of Medicare's three-day payment window policy, there are major 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 7-day hospital visit rates. 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. In addition, outpatient services provided by a hospital, or any Part B entity wholly owned or wholly operated by the hospital, *on the first, second, and third calendar days preceding the date of a beneficiary's inpatient admission* are also deemed related to the admission, and 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. *Claims that do not exist cannot be counted*. As a result, this measure cannot identify inpatient admissions that may have resulted from colonoscopies performed in the HOPD setting when those unplanned admissions occur on the date of the colonoscopy, or during the three days subsequent to the procedure. The measure would only identify hospital visits occurring on days 4, 5, 6 and 7 following the index HOPD visit; index claims for days 0, 1, 2 and 3 *would not be created*, and therefore cannot be counted. This missing data skews the measure results by undercounting the number of inpatient admissions attributed to the HOPD.

In the time since we originally pointed out this design flaw, the developer has looked for ways to work around the three-day payment window policy. Currently, the measure algorithm identifies the index colonoscopy using claims in the Part B carrier file. ASC facility claims are identified directly, using ASC facility claims. However, HOPD claims are identified *indirectly, using physician claims*. Initially the measure developer planned to use physician claims for colonoscopy indicating an HOPD place of service (POS) that had an inpatient admission within 3 days *and* lacking a corresponding HOPD claim as a method for indirectly identifying the missing HOPD claims. Unfortunately, POS coding has a long history of inaccuracy, with error rates consistently in excess of 70%. As a result, during the NQF endorsement process, the methodology was revised, this time looking for the –PD modifier on physician claims as part of the strategy for indirectly identifying missing HOPD claims. *If* –PD modifier use were required of all physicians, this might be a satisfactory approach. However, use of the –PD modifier is only required when a physician's practice is *wholly owned* or *wholly operated* by a hospital. CMS recently indicated it "investigated the use of the PD modifier, but, based on low usage in the dry run data, we did not incorporate it into the 3-day billing rule algorithm."

The most recent statement of the measure methodology is this: "To ensure the comprehensive capture of HOPD colonoscopies potentially affected by the policy, we identified physician claims for colonoscopy in the HOPD setting from the Medicare Part B SAF with an inpatient admission within 3 days and lacking a corresponding HOPD facility claim. We then attribute the colonoscopies identified as affected by this policy to the appropriate HOPD facility using the facility provider ID from the inpatient claim." In response to this, we again point out what is well known to CMS: that POS coding has a long history of inaccuracy. Over a period of more than a decade, the Department of Health and Human Services Office of Inspector General (HHS OIG) has performed repeated audits of physician POS coding that *consistently demonstrate high error rates*. These errors result in physician claims that indicate the service was performed in the physician office, when in fact the service was actually performed in a hospital outpatient department or ASC. See, as some examples of many such OIG reports over the years: A- 02-04-01010 (error rate 88%), A-05-04-00025 (error rate 79%), A-06-04-00046 (error rate 76%), A-01-06-0052 (error rate 81%), A-01-09-00503 (error rate 90%) and, most recently, A-01-10-00516 (error rate 83%) of September 2011. *Errors in POS coding are not an isolated, infrequent or insignificant problem - and they have not been responsive to educational efforts on the part of CMS*. It's not possible to attribute any scientific credibility to a measure algorithm using POS coding on physician claims as part of the process to identify missing HOPD claims.

The practical impact on the measure is this: a significant number of the index HOPD claims that are missing due to the three-day payment window policy *will never be identified*. Any algorithm that employs POS coding on physician claims would systematically undercount HOPD events by failing to identify a significant number of the index HOPD visits. As a result, not only would the HOPD rates reported be inaccurate (too low), they would also not be comparable to ASC results. CMS appears to believe that as long as it is taking steps to identify those claims impacted by the three-day payment window policy "to the fullest extent possible", this should be sufficient to overcome any concerns about the lack of scientific validity. We do not accept this. CMS plans to report data from this measure to the public, and consumers will be led to believe that the information is a true and accurate reflection of performance. Anything short of truly valid results is just not acceptable when individual consumers will be making healthcare choices and decisions based on the data presented.

Another new and recent development also disadvantages ASCs in favor of HOPDs. CMS detailed post-endorsement changes made to the measure in its "2015 Measure Specifications Report for Dry Run: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy" of April 2015. In this report, the agency discusses "refinements" made to the measure, one of which has been a new exclusion for same-claim ED visits. CMS states, "[t]he measure now excludes colonoscopies that occurred on the same hospital outpatient claim as an emergency department (ED) visit. While processing claims data for calculating the colonoscopy measure, CMS found a small number of colonoscopies that are coded on the same claim as an ED visit. CMS decided to exclude these colonoscopies from the measure calculation because the sequence of events in these cases is not clear. It is not possible to use claims data to determine whether the colonoscopy was the cause of, subsequent to, or during the ED visit." These same-claim visits reflect services provided on the same date. While this is certainly an important adjustment, if same-claim HOPD and ED visits are going to be excluded for HOPDs, a similar "same date" adjustment needs to be in place for ASCs. Applying the adjustment to HOPDs alone is another example of the measure's inconsistent treatment of ASCs and HOPDs, where same-day ASC and ED visits are counted, while same day HOPD and ED visits are not.

Until such time as all index HOPD services can be accurately identified despite the three-day payment window policy and the measure algorithm treats HOPDs and ASCs equally, the measure routinely disadvantages ASCs. *We continue to object in the most strenuous terms to the suggestion that such a methodologically flawed measure is a fair and appropriate means for the comparison of ASC and HOPD hospital visit rates following colonoscopy*. This measure does not pass the basic test of validity: *in the HOPD setting, it does not measure what it is intended to measure*. No other measure developer/steward would be allowed to circumvent this fundamental aspect of measurement science.

C. Reliability of the Measure is Too Low for Accountability and Reporting Purposes

The measure developer has acknowledged that the number of outcome events for this measure is already low. To manage 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 its characterization as a "facility-level measure"). Despite this, the results of the reliability testing for this measure were quite low. With two years of data, the intra-

class correlation coefficient (ICC) was, on average, 0.335, which according to conventional interpretation is only "fair."

As made clear by the reliability data presented to the NQF, this measure requires three years of data to achieve even modestly reliable measure scores for high volume facilities. The reliability of the measure was reported to be just "fair" for two years of data and therefore the one-year measure reliability score would be even lower due to the significantly smaller number of observations. In fact, the measure developer has stated elsewhere that it recommends three years of data. We note that the "dry run" was performed using three years of data, and wonder why CMS continues to plan to implement the measure using only one year of claims data. Clearly one year of claims will not be sufficient to develop reliable performance data. If the agency retains this measure, it should extend the data collection period to three years in order to fulfill its obligation to ensure the reliability of the ASC measure data it plans to report to the public.

We also note that the "fair" ICC for this measure was only obtained *after excluding low volume facilities* from the calculation. As the measure developer explained to NQF, "[b]ecause we expect facilities with relatively few cases to have less reliable estimates, we only included scores for facilities with at least 400 cases in the reliability calculation (i.e., with 200 cases in each of the split samples, about 100 cases/year). This approach is consistent with a reporting strategy that includes smaller facilities in the measure calculation but does not publicly release the measure score for smaller facilities (i.e., labels them in public reporting as having "too few cases" to support a reliable estimate)." However, in the "dry run" for this measure, CMS lowered the threshold for the number of colonoscopies too small to fewer than 30, which is about equivalent to 10 cases/year since the dry run incorporates three years of claims data. This is a significant change and one that would impact the reliability of measure scores. It is unclear which low volume threshold CMS plans to use if it implements the measure. CMS should not further degrade the measure results further by lowering the threshold to 10 cases/year from 100 cases/year.

In our opinion, the reliability of a measure intended for public reporting and accountability purposes should be significant. If facilities are to be judged based on the results calculated for this measure, the reliability of those measure scores should be "substantial" (an ICC of 0.61 to 0.80 per convention), at a minimum. We are also concerned about the lack of reliable measure scores for low volume facilities. If the agency persists in its plans to implement this measure, it 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.

D. The Measure Score Suffers from a Lack of Actionability in ASCs

CMS and the measure developer have pointed to the improvements in hospital readmission rates as evidence that this measure would produce comparable improvements in colonoscopy outcomes. It is true that selected hospitals have been successful in reducing readmission rates, but these reductions have resulted from analyses that extend well beyond the receipt of a CMS benchmarking report with a few columns of data about their readmissions. These improvements have resulted when systems have been put in place that allow the hospital to identify readmissions *to their own facility* in real time. These hospitals are successful precisely because they have access not only to the patient's records from the index admission, but also to the patient's records (and the patient) at the time of readmission.

CMS has not recognized that the ASC setting, as a result of legislation and regulation, is markedly different from the hospital setting in ways that significantly impact the ability of an ASC to develop a performance improvement initiative around the results of this measure. Per Federal regulation, ASCs are a unique supplier type that serves *solely* as the site for outpatient surgery and is involved with the care of the patient only immediately before, during and immediately after a surgical procedure. Unlike other outpatient surgical settings, such as clinician offices, ambulatory clinics or hospital outpatient departments, ASCs *may not provide post-operative follow-up care* after patient discharge. ASCs, as distinct entities that operate in an entirely separate capacity from physician offices, emergency departments, and hospitals, *do not have direct access to the records* of these other providers. As a result of this mandated isolation, ASCs must either interview the patient over the phone or obtain permission from the patient to obtain their medical records from the treating emergency department or admitting hospital in order to obtain details about what happened to the patient post-discharge. It is certainly possible that selected patients would cooperate with this effort, but in our experience, this willingness diminishes rapidly over time. If an ASC were to contact patients a year or more after their ASC care (which is when the ASC would receive a CMS report on their performance for this measure) we expect the number of patients agreeing to requests for interviews or medical record releases would be very small indeed.

We favor a different approach to the measurement of ED and hospital visits following ASC care and are testing measures that would involve the ASC in the timely collection of patient data in the near-term following patient discharge. Reaching out early in the post-discharge period would maximize the ASC's potential for successfully engaging patients and their families in gathering the information needed to identify opportunities for improvement. There is certainly a data collection burden associated with this approach, but we believe it is better to invest the effort in collecting actionable data that leads to improvement rather than to receive, without effort, information that is dated and not actionable.

E. Limited Ability to Make Distinctions Among Facilities

This measure suffers from very limited discriminatory power. The overwhelming majority of facilities (95%) would receive a measure score indicating their performance was better or no different than the national rate – with the implicit indication that no improvement effort would be necessary. While the developers state there is variability in performance, as a practical matter the risk-standardized results indicate little room for improvement. One could legitimately wonder if this measure would be a candidate for immediate removal from the ASCQR Program based on CMS criteria for determining when a measure is "topped out".

G. Measure "Dry Run"

The "dry run" was the first time this measure was actually pilot tested for the settings of its intended use. The period allowed for facility feedback – per the QualityNet website only July 1 through July 31, 2015 – was too short. The National Provider Calls explaining the dry run reports were not even held until July 14 and July 16. The time allotted for facilities to review three years of data and provide feedback should have been much longer to ensure a fair and adequate timeframe. CMS should immediately extend the "dry run" feedback period to allow providers adequate time to review the data, submit questions, receive a response, determine if the response is

satisfactory, and submit follow-up questions as needed.

We are particularly interested in learning how CMS plans to resolve the ongoing issues with this measure. The measure's planned admission algorithm was never fully adapted for outpatient use (the inpatient algorithm developed for a different measure was employed). The "dry run" has highlighted how poorly it functions for purposes of this measure. For example, the algorithm does not appear to take into account the identification of other types of malignancy at colonoscopy (e.g., primary lymphoma of the large intestine) that require admission for treatment. It also does not appear to take into account the use of colonoscopy in the work-up of carcinomas of unknown primary, or in cases where the patient presents with metastases (e.g., liver metastases) then requires subsequent admission for treatment for these conditions. It also does not acknowledge the need for treatment of paraneoplastic conditions (e.g., anemia in neoplastic disease 285.22). None of these can reasonably be attributed to the colonoscopy itself or be rationally considered a "complication" of the colonoscopy.

It has also become clear from provider feedback on "dry run" reports that the measure results include cases where the date of the index colonoscopy was *after* the hospital visit date. If the measure had actually been pilot tested prior to endorsement, these types of issues would have become apparent. Yet we have an NQF-endorsed measure that CMS has finalized for inclusion in two Federal quality reporting programs that does not work.

In the interests of transparency, CMS should publicly present tested solutions for the resolution of all the problems discussed in this section of our comments and also present detailed measure performance data for the dry run. We are particularly interested in the following information:

- A detailed presentation of the testing and statistical analyses done to determine the reliability of the dry run data, including the ICC for the dry run, should be presented to the public.
- The reliability estimate presented to NQF to secure endorsement for this measure was based on the exclusion of "low volume facilities", which were characterized as facilities having less than 100 cases per year. An explanation is needed as to why, in the dry run, the number of cases considered to be "too small" is less than 30 cases (which, over the three year period of the dry run, results in an average of less than 10 cases per year). An analysis of the impact on the reliability of the individual measure scores should be performed and presented to the public. What does CMS believe is the desired reliability? What number of cases will be considered "too small" if the measure is implemented?
- The measure methodology directly assesses outcomes for ASCs, but indirectly assess outcomes for HOPDs because of the three-day rule. A detailed presentation of the analyses that have been performed to determine the completeness of HOPD data capture, the amount of missing HOPD data, and an explanation of how the HOPD results have been adjusted to reflect this missing data is needed.
- The dry run report presents actual national data, but combines data for HOPDs and ASCs. A presentation of the national data with the totals broken out for HOPDs and ASCs is needed which includes the number of HOPDs versus ASCs that performed better than the national rate, the number of HOPDs versus ASCs that performed no different than the national rate, the number of HOPDs versus ASCs that performed worse than the national rate, and the number

of HOPDs versus ASCs with number of cases too small.

- A presentation of data showing the rates of hospital visits by subtype (inpatient admissions, observation stays and ED visits) for HOPDs versus ASCs over each of the three years included in the dry run is needed. The analysis should break out ASCs and HOPDs to determine if the risk model is stable between the two, or whether different coefficients are evident.
- A presentation of an analysis of the national-level dry run data showing the rate of hospital visits by subtype for HOPDs versus ASCs on day 0, day 1, day 2, day 3, day 4, day 5, day 6 and day 7 is needed.
- Given that the measure employs a hierarchical model, we are interested in which *facility-level* variables were tested for inclusion in the model, and which have actually been included to reflect differences in two settings incorporated under this measure. A presentation of these analyses and their results is needed.
- Presentation of a detailed account of the statistical testing and analyses that support the validity of a head-to-head comparison of HOPD data and ASC data is needed in light of the different claim formats used.

The measure developer has been attempting, unsuccessfully, to implement untested incremental "fixes" to this measure since we first pointed out its inherent methodological flaws in December 2013. We question their ability to resolve all the issues that have been brought to their attention openly and transparently prior to the planned implementation of the measure for claims for calendar year 2016. Implementation should be delayed until all the issues that were not addressed during the measure's initial development and endorsement phases are resolved in a manner that assures the results are valid, reliable and scientifically acceptable. If the issues cannot be resolved in such a manner, the measure should not be implemented.

III. ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel

In light of the challenges faced by ASCs in enrolling in and submitting data to NHSN, we wish to express our appreciation for the agency's decision to extend the deadline for submitting data to September 30, 2015. This will help ensure ASCs have additional time to resolve the issues that have been barriers to data submission. We urge the agency to reassess the situation again in September and issue another extension if there are enrolled ASCs that have not successfully submitted data for this measure.

IV. Public Reporting of ASCQR Program Data By Both National Provider Identifier (NPI) and CMS Certification Number (CCN)

When CMS originally considered the matter of the public reporting of ASCQR Program data, it determined that it would display these data at the CCN level. However, a CCN may be associated with multiple ASCs. As a result, publication of data by CCN would, in some cases, aggregate data for multiple facilities, making it difficult to determine the performance of any individual facility.

On the other hand, an NPI uniquely identifies an individual ASC. Further, ASCs report almost all their ASCQR Program quality measure data to CMS using their NPI. However, there is one measure that is currently reported by CCN: ASC-8, Influenza Vaccination Coverage among Healthcare Personnel. Because data are being reported under two different identifiers, CMS is now

proposing to (beginning with any public reporting that occurs on or after January 1, 2016) display quality measure data by the NPI when data are submitted by the NPI and display data by the CCN when data are submitted by the CCN.

We believe the primary aim of public reporting of quality data is to ensure that consumers can distinguish performance at the individual facility level. In our opinion, it makes little sense to have two methods for reporting data. We believe a better approach would be to collect all ASC quality data under the facility NPI. Given that the only data being collected by CCN is that being collected for ASC-8 using the National Healthcare Safety Network (NHSN), it makes more sense to make changes to NHSN such that data for ASC-8 would be collected under the ASC NPI. We have discussed this with the Centers for Disease Control and Prevention (CDC), the agency responsible for NHSN, and they have indicated their willingness to consider this change following the close of this year's ASC-8 data collection period. Making this change in the upcoming year would be particularly beneficial in light of the potential for the future use of NHSN for collection of data for an ASC SSI measure that is in development, and the future capabilities of the Outpatient Procedure Component of NHSN to collect data for certain ASCQR Program measures.

While we understand the obligation CMS has to report ASC quality data, and also understand that, in the near term, reporting data collected under two different identifiers will require two different methods, we do not think that CMS should finalize this approach for the long term. Instead, CMS should work with CDC to implement data collection under the NPI in NHSN, and then move quickly to consolidate reporting around the NPI.

V. Requirements for Data Submitted Via QualityNet

Currently, data for quality measures reported via QualityNet must be submitted during the period from January 1 to August 15 in the year prior to the affected payment determination year. CMS established a different time period – January 1 through May 15 - for data submission for ASC-8: Influenza Vaccination Coverage among Healthcare Personnel, which is submitted via the CDC's NHSN. The agency is now proposing to advance the deadline for data submission for all data reported via QualityNet, shortening the submission period to between January 1 and May 15 in the year prior to the affected payment determination year. If adopted, this policy would reduce the data submission period currently allowed for the following ASCQR Program measures *by three months*:

- ASC-6: Safe Surgery Checklist Use;
- ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures;
- ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;
- ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use; and
- ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (voluntary).

CMS is proposing this change in the belief that aligning all Web-based data submission deadlines with the end date of May 15 would allow for earlier public reporting of measure data and reduce the administrative burden of tracking multiple submission deadlines. While we

appreciate the effort to streamline program requirements and agree that selecting one data submission timeframe is desirable, opting to give ASCs less time to submit their data is not the correct choice. We again urge CMS to consider the cumulative impact of the many conditions the agency places on ASCs seeking a full Medicare payment update. Although it is in its infancy, the ASCQR Program is already more complicated and demanding than is necessary. Shortening the data submission time period would add to, rather than subtract from, ASC administrative burden.

We also ask the agency to consider the many examples of new measure implementation glitches that have necessitated the extension of data submission deadlines in the past. We anticipate that the agency will continue to adopt new ASCQR Program measures, and also anticipate that each adoption will present new challenges for CMS, its contractors and ASC providers.

For these reasons, we think CMS would be wise to standardize the more generous data submission timeframe of January 1 through August 15 in the year prior to the affected payment determination year. While we recognize August 15 is not consistent with the deadline for other quality reporting programs that enter data for the influenza vaccination measure via NHSN, and is beyond the close of the influenza season, we support the August 15 date over the May 15 date. If the agency desires a consistent data submission deadline across settings for this measure, it should consider the August 15 date for the Hospital IQR and OQR Programs, as well.

VI. Public Reporting of ASCQR Program Data

On July 9, 2015 CMS announced via the ASC listserv that it was making ASC Preview Reports available through the QualityNet website. The announcement indicated that these were the "October 2015" preview reports and that ASCs would have until August 9, 2015 to view their reports. The announcement further indicated that data in the preview reports would be reported on Hospital Compare, with a later communication indicating that this would happen "soon".

A. No Rulemaking Process to Establish Data Publication Details

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), CMS finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. It also finalized reporting data by the CCN. In the same rule CMS specifically stated, "[w]e intend to propose more detail on the publication of data in a later rulemaking." (*Please see 76 FR 74514*.) In addition, the agency has indicated on the QualityNet website that "[e]ach ASC rule that has been published by CMS has discussed the plan for ASC data to be publicly reported on websites such as healthcare.gov. The time frames and methodology will be announced through the rule making process. The Support Contractor monitors this information and will provide educational opportunities when there are changes to the ASC reporting program." This statement was originally published on the website on June 19, 2014 and then updated on May 20, 2015. However, CMS has never issued any additional proposals regarding the public reporting of ASCQR Program data.

B. Preview Reports

We maintain that both advance notice of the release of the preview reports and education regarding the preview reports should have been provided. In the absence of any rulemaking or other communication on the topic, the industry was unaware of the agency's timeline for publication of ASCQR Program data and had no prior indication that the preview period would be so brief. The only educational information published regarding the preview reports was a one-page "Quick Reference Guide" that did not explain any of the data columns presented.

Although ASCs were given the ability to access preview reports and review them, CMS has not provided any means for ASCs to correct erroneous data. Nor has it developed any method for identifying and suppressing quality data that are clearly incorrect. Consequently, future preview reports should be presented well in advance of the withdrawal deadline for the ASCQR Program so that an ASC with erroneous data has sufficient opportunity to determine if it would like to withdraw from the ASCQR Program, as this would be its only recourse to avoid publication of incorrect quality data.

C. Public Reporting of Data for ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing

The preview reports for ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing include data for both 2013 and 2014 for all facilities, even those that never or very rarely administer prophylactic intravenous antibiotics. In its other quality reporting programs, CMS does not report data when the number of cases/patients is too small - that is, when the number of cases is greater than 0 but less than 11. Under these circumstances, the agency reports that the data is "Not Available", accompanied by a footnote indicating the number of cases/patients is too few to report. Despite these established practices, we note that for this particular measure, preview reports for facilities with denominators greater than 0 and less than 11 have an actual number reported in the "Rate" column that is not accompanied by a footnote - or any other indication - that the number of cases is too small.

We note the inclusion of appropriate footnotes *in the footnote legend* of the ASC preview reports, but they do not appear to be being used as intended in the data cells of the preview report. However, CMS has indicated in its communications to ASCs that the data in the preview reports is what will be reported on Hospital Compare. The reporting algorithm for ASC-5 appears to be incorrect when the number of cases is too few to report, and this must be corrected prior to any public display of data.

D. Public Reporting of Data for ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures

In our comments to the agency dated August 29, 2011 regarding ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures, we pointed out that the categories of services that CMS had established were large and diverse, and therefore unlikely to provide any meaningful consumer information. We questioned, for example, how a consumer needing a hernia repair would use the data in the "Gastrointestinal" category to distinguish a facility that performs a high volume of gastrointestinal endoscopies from a facility that performs a high volume of general surgery or how a consumer planning breast surgery would determine what volume of breast surgery a facility performed by looking at the "Skin" category data – and whether said consumer

would even realize that breast procedures were included in this category. We suggested a more granular approach, similar to that used for reporting volume data under the Hospital Inpatient Quality Reporting Program, would better serve consumers.

CMS responded, "[w]e agree with commenters that collecting and displaying information on the broad categories as currently specified may not be meaningful to consumers. Based on the public comments we received that the six broad categories will not be meaningful to consumers, we will further refine the specification for the categories by grouping the codes into procedure types commonly performed in ASCs within the 6 broad categories so that they are more meaningful to consumers. The codes in the 6 broad categories that ASCs would use to collect volume remain the same, but the information would be reported to CMS in the subcategories that will be defined in the Specifications Manual. We will include these refinements in the specifications for the measure that will be in an upcoming release of the ASC Specifications Manual. We agree with the commenter that obtaining stakeholder input as well as consumer testing prior to public reporting of the volume information will be beneficial, and will strive to do so, as we have done previously for information made available to the public from other quality reporting programs." (*Please see 76 FR 74508*.)

CMS did indeed create subcategories of procedures within the six broader categories in the Specifications Manual - though with insufficient granularity to address the common consumer information needs presented above - but then did not request subcategory volumes. What happened to CMS's plans to publish meaningful volume data for consumer use? We see little point in making facilities collect and submit data that has no value to the public.

In summary, we see a number of issues with the agency's plans for public reporting of ASCQR Program data: 1) although the CMS stated it would outline further proposals such as the timeframe for public reporting in rulemaking, it did not do so; 2) CMS did not provide sufficient advance notice of its issuance of ASC preview reports; 3) CMS did not provide adequate education for ASCs regarding the preview reports; 4) the preview reports do not appear to report data correctly for situations where the number of cases/patients is too few to report; and 5) CMS plans to publish volume measure data that is not meaningful to consumers.

VII. Minimum Threshold for Claims-Based Measures Using Quality Data Codes (QDCs)

The current minimum threshold for successful reporting for measures submitted using Quality Data Codes (QDCs) is that at least 50 percent of claims meeting measure specifications contain QDCs. In the past, CMS has stated it intends to propose increasing this percentage for future payment determinations. In light of isolated instances where ASCs, administrative contractors and billing clearing houses have experienced implementation challenges, we appreciate the consideration the agency has shown by continuing the 50 percent threshold in the initial years of the ASCQR Program. We believe these issues have been resolved, and therefore recommend CMS increase the minimum threshold in future rulemaking.

VIII. Proposals to Codify Existing and Proposed Policies in the Code of Federal Regulations (CFR)

CMS is proposing to establish a new Subpart H under 42 CFR Part 416 to codify many of

the administrative policies regarding the ASCQR Program and is inviting public comment on these proposals to codify the basis and scope for the ASCQR Program. Most of these proposals address existing policies related to program participation and withdrawal, data collection and submission, public reporting, retention and removal of quality measures, measures maintenance, extraordinary circumstances extensions or waivers, and the reconsideration process. However, in some instances CMS is also proposing to codify policies that are newly proposed in this rulemaking cycle.

While it makes sense to codify existing policies that are working reasonably well, we think it premature to codify policies that CMS has indicated it plans to change, policies that are not working well or that need refinement, and policies that might be finalized in this rulemaking cycle but that have yet to be implemented or demonstrated to be workable in actual use. In these cases, we think the agency would be wise to employ "[Reserved]" as a placeholder within the CFR for policies that are temporary, policies that require refinement, and policies that have yet to be proven practicable. As CMS is well aware, it has the option to use "[Reserved]" to indicate that it may insert regulatory information into a particular CFR location at some time in the future.

As an example of policies that are in transition, we point to the policy surrounding successful reporting of claims-based measures using Quality Data Codes (QDCs). CMS has indicated in the past that it plans to raise the minimum threshold for successful reporting of claims-based measures using QDCs, and we agreed with this. Currently the policy is that at least 50 percent of Medicare claims meeting measures specifications contain the appropriate QDC. Given the nature of the measures that are reported using QDCs, we anticipate the agency will, according to its stated intentions, take steps to increase the threshold. As the developer of these measures, we question the value of codifying a threshold that is clearly too low.

There are aspects of the current ASCQR Program that are not working well. In particular, we point to the issue of the public reporting of ASC quality data under both the CCN and NPI. This policy requires refinement to improve the value of publicly reported quality data to the consumer. We do not agree with codifying this policy at this time.

Finally, CMS is proposing to implement a number of new policies during this rulemaking cycle, and is simultaneously proposing to codify said policies. We have serious reservations about this rushed approach, as we have observed that although a policy may be finalized, subsequent experience with the implemented policy proves it to be suboptimal or unworkable. CMS should ensure its newly finalized policies are viable prior to codification. As noted above, we are particularly concerned regarding the feasibility of policy changes that would increase provider burden by shortening the timeframe for the reporting of measures submitted to QualityNet. We also remain skeptical of the scientific acceptability of CMS's planned policies surrounding the data timeframe for ASC-12, which is too short to produce reliable results. Neither of these proposals should be immediately codified if finalized.

The CFR is the codification of the general *and permanent* [emphasis added] rules published in the Federal Register. Therefore, we believe inclusion in the CFR should be reserved for established policies that have a proven track record of feasibility and demonstrated efficacy in achieving the goals of the ASCQR Program. Consistent with our statements above, we oppose the proposed codifications at 42 CFR 416.310(a)(3), 42 CFR 416.310(b), 42 CRF 416.310(c)(1)(ii),

and 42 CFR 416.315.

IX. Opportunities for Additional Comparative Quality Measures Across Settings

The ASC Quality Collaboration 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. Though these facility-level measures have not been adapted for, or tested for use in, other outpatient surgical settings, we believe CMS should consider doing so. If the 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 data available to the public and represent an important step toward additional harmonization of measures.

X. Alternative Data Collection Mechanisms

In the past, CMS sought public comment on alternative data collection strategies, particularly regarding the collection of patient-level data through registries or other third-party data aggregators and via certified EHR technology.

The ASC QC remains convinced CMS should allow ASCs to meet the requirements of the ASCQR Program using registry-based reporting and would like to take this opportunity to draw the agency's attention to this option once again. Registry-based reporting of quality metrics is already an option under the Physician Quality Reporting System (PQRS). This option should be extended to ASCs as well. In the case of the ASCQR Program, which already incorporates requirements that must be fulfilled through three separate reporting mechanisms, CMS should offer a registry-based reporting option that would allow ASCs to fulfill *all program requirements* through the single mechanism of a registry in order to simplify and streamline the process of data submission.

Registries that could serve this purpose are already in existence. Examples include the GIQuIC and Ophthalmic Patient Outcomes Database registries, which may currently be used to satisfy PQRS reporting requirements. These registries are potential avenues for registry-based reporting for selected single-specialty ASCs. As they are already operational, we encourage CMS to issue proposals for ASC registry-based reporting in next year's rulemaking.

In addition to a registry-based reporting option, ASCs should also have the option of submitting quality data to CMS through an EHR-based reporting mechanism. While the use of EHRs in the ASC industry is limited at this time, there are centers that have implemented this technology and could benefit from this option.

Finally, many ASCs, either through common ownership or on a contractual basis, rely on others to implement, maintain and support their IT infrastructure. For those measures that are reported but once a year into QualityNet, developing a mechanism that would allow required data to be submitted in a batch file for multiple ASCs would significantly reduce the data submission burden for these facilities. We encourage the agency to make this option a near-term priority.

XI. Measure Applications Partnership (MAP) Process Improvements Are Necessary

CMS relies on the recommendations of the MAP in 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 the improvements in the MAP that have been made over time, but continue to be concerned about two issues: the public comment process and the practice of submitting measure concepts for consideration.

MAP procedures for the consideration of public comment at critical junctures - including workgroup meetings, meetings of the Coordinating Committee and the issuance of the draft Pre-Rulemaking Report – remain unsatisfactory, treating public input as an afterthought not worthy of consideration. Although MAP agendas include opportunities for public comment, they are scheduled *after* voting on agenda items has been completed. As a result, there is no opportunity for the public to present important information, or correct misinformation, prior to decision-making. Similarly, there is no opportunity for the public to address the Coordinating Committee regarding topics under discussion until *after* it has completed deliberations. While the public is given the opportunity to comment on the draft Pre-Rulemaking Report issued by the MAP, these comments are not considered by the Coordinating Committee and therefore do not result in any revisions to the recommendations in the final report. Public comments are merely summarized in a very general fashion by NQF staff and then appended to the report. This lack of consideration must not be allowed to continue. MAP administrative procedures should be revised so that public comment is solicited prior to, rather than after, voting on agenda items. In addition, the MAP Coordinating Committee should be required to formally consider and respond to public comments regarding its draft report, and to then make any appropriate revisions to its recommendations prior to issuing a final report.

We also find CMS's practice of asking the MAP to make recommendations regarding measure "concepts" that have not been fully developed troublesome. There are many challenges in taking a measure from the conceptual stage to completed form; not all concepts and drafts are successfully developed. The agency appears to be advancing incomplete ideas to get a stamp of approval from the MAP, and then pointing to conditional recommendations regarding measure topics and incomplete measure sketches as evidence of consensus. It is not reasonable to for the MAP to issue recommendations based on measure concepts or measure drafts. Further, the inclusion of measure "concepts" results in an unreasonably large number of items for the MAP to review. As a result, thoughtful consideration of each is very difficult, if not impossible, in the compressed timeline allotted. We urge CMS to take steps to promote a pre-rulemaking process in which due consideration of fully developed measures becomes the norm.

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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
Ambulatory Surgical Centers of America
American Osteopathic Association, Healthcare Facilities Accreditation Program
AmSurg
ASD Management
Association of periOperative Registered Nurses
Covenant Surgical Partners
Florida Society of Ambulatory Surgical Centers
Hospital Corporation of America, Ambulatory Surgery Division
Outpatient Ophthalmic Surgery Society
Regent Surgical Health
Surgery Partners
Surgical Care Affiliates
The Joint Commission
United Surgical Partners International
Visionary Enterprises, Inc.