ASC Quality Collaboration

September 2, 2014

VIA ELECTRONIC SUBMISSION

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1613-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1613-P; Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated with Submitted Data

Dear Administrator Tavenner:

On behalf of the ASC Quality Collaboration (ASC QC), a cooperative effort of organizations and companies interested in ensuring ambulatory surgical center (ASC) quality data is appropriately developed and reported, please accept the following comments regarding CMS-1613-P (79 FR 40916, July 14, 2014), 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 advancement of quality is reflected in the steps we have taken independently to facilitate quality reporting by ASCs – all without federal incentive or penalty. This includes having developed six ASC facility-level quality measures and secured the endorsement of the National Quality Forum (NQF) for each, as well as continuing to publish 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 has devoted 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.

I. Proposed New ASCQR Program Quality Measure for the CY 2017 Payment Determination and Subsequent Years

CMS has proposed to adopt one new claims-based measure into the ASCQR Program for the CY 2017 payment determination and subsequent years, a measure titled *Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy*. The measure concept (but not the measure itself, as it had not been fully developed at the time) received conditional support from the Measure Applications Partnership (MAP) earlier this year. Importantly, this measure is also being proposed for inclusion in the Hospital Outpatient Quality Reporting (OQR) Program. We do not support inclusion in the ASCQR Program due to significant problems with the measure, including its validity, reliability, and usability, which are discussed in detail below.

As CMS is aware, this measure is currently being considered for NQF endorsement and it currently appears that the All-Cause Admissions and Readmissions Standing Committee will identify it as suitable for endorsement. Having reviewed the minutes of the Committee's discussions in their entirety, we are struck by the absence of consideration of key elements of the measure's construction and testing. Though we have commented on several important issues related to this measure, we have not received satisfactory responses from either the measure developer (a CMS contractor) or the Committee. If the measure is endorsed without resolution of these items, we plan to file an appeal with the NQF Board of Directors.

A. Lack of Measure Validity Testing in the Proposed Settings of Implementation

Validity testing for this measure relies primarily on work the developer did in the past related to a different measure for the inpatient setting; this work relied on the use of inpatient hospital claims. For reasons that are unclear, the developer has cited this work with inpatient claims as a basis for the validity of this measure, which is based on outpatient claims.

As CMS is well aware, claims are generated for purposes of reimbursement, and Medicare's inpatient and outpatient payment systems are governed by entirely different sets of rules. These rules have a significant impact on the coded information that is submitted on claim forms. Inpatient reimbursement is primarily diagnosis driven, and the coding practices surrounding inpatient claim submission reflects this, with a strong emphasis on fully characterizing the patient's diagnoses and comorbid conditions. In contrast, outpatient reimbursement is service driven, and coding practices are focused on accurately describing the services rendered. Diagnosis coding in ASCs is focused on establishing the medical necessity of those services; 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 that 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. The developer went to the effort of testing and establishing this for the inpatient measure it developed, but did not evaluate it for this outpatient measure. Why not? Given the different claims structures for inpatient versus outpatient

claims, the inpatient results cannot be assumed to apply to the outpatient setting. The sensitivity and specificity of using administrative claims data following outpatient colonoscopy must be determined in order to establish the validity of the measure.

Further, this measure intends to evaluate both Hospital Outpatient Department (HOPD) and ASC performance, but these two settings do not 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. Without testing, one cannot claim that HOPD results can be fairly and appropriately compared to ASC results.

These issues were brought to the attention of the measure developer and NQF through our comments on the draft report issued by the All-Cause Admissions and Readmissions Standing Committee. The measure developer responded, "CMS will take these points into consideration in field testing and implementing the measure." Yet we see no indication that CMS plans any kind of field-testing at all; rather, the agency is proposing to move directly to implementation. We object in the strongest possible terms to the implementation of an administrative claims-based outpatient measure that has not been validated against outpatient clinical records.

The impact of these differences – outpatient versus inpatient, and HOPD versus ASC - must be systematically assessed 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

As noted above, the *Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* measure is also being proposed for inclusion in the Hospital OQR Program. In its proposals, CMS states 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. The following explains why near-term events following care in the HOPD setting would not be counted accurately using this measure's algorithm.

The NQF's All-Cause Admissions and Readmissions Standing Committee did not evaluate the impact of the use of administrative claims on the validity of the measure results. Yet Medicare's three-day payment window policy has a profound impact on the measure, presenting significant challenges in identifying index HOPD visits, and therefore subsequent "hospital visits" related to HOPD care. 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 hospital outpatient departments, hospital emergency departments and wholly owned physician practices. The three-day payment policy applies to all non-diagnostic services provided during the payment window unless the hospital attests that the services are clinically unrelated. Diagnostic services are always subject to the payment window policy, irrespective of whether they are considered clinically related.

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 or counted. This missing data skews the measure results by undercounting the number of inpatient admissions attributed to the HOPD. As a result, measure scores cannot be compared across settings.

In the months since this measure was first brought before the MAP and we pointed out this flaw in the measure's design, the developer has looked for ways to work around the three-day payment window policy. Currently, they are proposing to identify colonoscopy claims in the Part B carrier file. ASC facility claims would be identified directly, using ASC facility claims. However, HOPD claims would be identified indirectly, using physician claims. Specifically, the measure algorithm would look for 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. It would then count such physician claims as HOPD "claims".

The problem with this approach is 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. It's not possible to attribute any credibility to a plan that would use POS coding on physician claims as a means of identifying HOPD claims in light of this information.

The practical impact on the measure is this: its plan to rely on POS coding to identify HOPD claims that are missing due to the three-day payment window policy means that a significant number of these missing index HOPD claims *will never be identified*. Yet this is the strategy the measure proposes to use. Any algorithm that relies on using 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.

In this proposed rule, CMS states this concern "relates to the Hospital OQR Program and not the ASCQR Program". However, given that the agency's interest in measures that compare care across settings and their proposal to include the measure in *both programs* and publicly report the results, this concern clearly impacts ASCs in a very direct and palpable way. Unless HOPD claims during the three-day payment window can be accurately identified, the measure routinely disadvantages ASCs by unfairly reporting complete rates for ASCs and incomplete rates for HOPDs. We object in the most strenuous terms to the agency's plan to implement such a fundamentally flawed measure.

C. Measure Rationale and the Three-Day Payment Window Policy

In order to be endorsed, measures must demonstrate meaningful performance gaps. We remain concerned that the three-day payment window policy may also have impacted the data used in the analyses performed to establish the rationale for this measure. These analyses estimated the measure score for both ASCs and HOPDs using 2010 Healthcare Cost and Utilization Project (HCUP) data, and then separately calculated the measure score for HOPDs alone using 2010 data from the Chronic Conditions Data Warehouse (CCW). Both analyses found provider variability. It is unclear how much of this variability may have been a reflection of the three-day payment window policy, which was implemented for dates of service on or after June 25, 2010. Those Medicare claims before June 25 would have included index HOPD visits that occurred within the three-day window; Medicare claims on or after June 25 would not have included index HOPD visits that occurred within the three-day window. It is possible that conclusions reached regarding variability in performance - based entirely on these analyses - are incorrect, and that the variability observed was actually a function of the change in CMS payment policy in the middle of the period analyzed.

D. 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 (for example, the inclusion of physician office claims for colonoscopy in the measure denominator, despite its characterization as a "facility-level measure"). Despite these steps, 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."

Of note, this subpar result 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)."

Since originally submitting the measure to NQF for consideration, the developer has recalculated the reliability testing score using the Spearman-Brown prophecy formula, in order to approximate the ICC for a three-year sample. This resulted in a higher ICC of 0.43, which according to conventional interpretation is "moderate" (though on the very low end of moderate, which ranges from 0.41 to 0.60). Though we believe this is a non-standard application of the Spearman-Brown formula, the NQF's All-Cause Admissions and Readmissions Standing Committee has accepted this ICC score, which provides a reliability estimate for three years of data, as sufficient to meet reliability endorsement criteria.

In our opinion, the reliability of a measure intended for public reporting and accountability purposes should be significantly higher. If facilities are to be judged based on the results calculated for this measure, the reliability of those measure scores should be "substantial" (0.61 to 0.80 per convention), at a minimum. We are also concerned that CMS did not acknowledge the lack of reliability in the measure scores for low volume facilities when issuing these proposals. If the agency determines it will include the measure in the ASCQR Program despite its lack of validity, suboptimal reliability and other issues, the measure score should only be publicly reported for facilities with annual case volumes of qualifying colonoscopies sufficient to generate "substantial" or greater reliability (that is, an ICC of greater than or equal to 0.61) in the measure score.

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

The rates of the outcomes the measure seeks to identify are low. As a result the measure has been specified in ways that generate large case volumes, but that diminish its usefulness. Specifically, the need for volume prevents stratification, meaning the measure score would be reported as a single rate for each facility. This presents challenges for actionability because the measure score provides no insight other than how the facility's rate of hospital visits compared to the expected rate. Because the data used to generate the measure score are not accessible to the facility, it would be impossible for the ASC to determine even basic information, such as which patients were affected, the numbers of ED visits, observation stays or inpatient admissions that occurred, or why any subsequent visit occurred. The measure developer has stated, "CMS agrees that the measure score alone provides limited information for quality improvement since the outcome combines ED, observation stays, and admissions, and that more detailed information on patient outcomes would assist facilities with quality improvement. CMS plans to report patient-level data confidentially to facilities that indicates whether the patient had a hospital visit, the type of visit (admission, ED, or observation stays) if any, and the facility to which the patient is admitted."

Although CMS has not proposed to do this, given that CMS provides facility-specific reports to hospitals regarding inpatient re-admissions, we are cautiously optimistic that the measure developer is correct in describing the agency's implementation plans. We are also cautiously optimistic that CMS would include the principal discharge diagnosis for the hospital visit, although the measure developer has not indicated that CMS plans to do so. These steps would be helpful, but ultimately they would not be sufficient to support meaningful quality improvement *in ASCs* because the ASC would have such limited insight into why the patient's hospital visit occurred.

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. While it is true that selected hospitals have been successful in reducing readmission rates, 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. Reviews of hospital industry guidance and the case reports of successful hospitals indicate that 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 systems flag patients that are readmitted, allowing staff to review the patient's record in detail and perform root cause analysis to determine what led to the patient's readmission. Many interview selected patients and their families at the bedside during the subsequent admission to learn more about why the patient was readmitted and what, if anything, could have been done to prevent it. This allows the hospital to identify and prioritize improvement opportunities. 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.

What CMS and the measure developer have not recognized is that the ASC setting, as a result of legislation and regulation, is markedly different from the hospital setting in ways that would significantly impact the ability to develop a performance improvement initiative around the results of this measure. In accordance with 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 the information needed to perform the analyses required for effective improvement activities surrounding this measure. 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.

This is why we favor a different approach to the measurement of ED and hospital visits following ASC care and are developing 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.

F. Limited Ability to Make Distinctions Among Facilities

While administrative claims do not impose additional data collection or submission burdens on providers, they are blunt instruments for assessing quality. This measure suffers from very limited discriminatory power. Using the standard 95 percent interval estimate to report the measure score, the developers indicate 99.5% of facilities would be classified as no different than expected, 0.4% of facilities as worse than expected and 0.1% of facilities as better than expected. The overwhelming majority of facilities, 99.6%, would receive a measure score indicating their performance was at, or better than, the expected level – with the implicit indication that no improvement effort would be necessary. The number of underperforming facilities would be miniscule; if we extrapolate 0.4% to the entire universe of approximately 5300 Medicare-certified ASCs (not all of which perform colonoscopies, so this is clearly an overestimate), the number of underperforming ASCs would be very generously estimated at twenty-one facilities. All this expenditure of funds and resources to identify, *at the most*, twenty-one ASCs is hard to rationalize. This also means it would be equally unusual for a consumer to be able to discriminate among facilities using the results of the measure.

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 the proposed criteria for determining when a measure is "topped out" put forth in this rule (and discussed below), if those criteria were to be finalized.

G. Extremely Long Timeframe Means the Measure Score Could Mislead

As a result of the already low rate of the outcomes for this measure, a very long data collection period (3 years) is required in order to generate measure scores that are even moderately reliable. Even if we set aside the issue of the significant lag time from the generation of claims to the reporting of measure results, the measure's extended data collection timeframe means that past performance would continue to impact the measure score for each facility for a long time. The publicly reported measure score would not be a reflection of current, or even recent, performance. In fact, the score would obscure either significant improvement or significant deterioration in recent performance. As a result, consumers could be misled by the lack of timely data. They could mistakenly believe a facility is no different from others, when in fact it has made significant recent improvements and would be a superior choice. Or they could be led to believe a facility is no different from others when in fact the facility has had a recent (and even steep) decline in performance and would be an inferior choice.

H. Incomplete Adaptation to the Outpatient Setting

As noted above, the measure developer has relied heavily on previous work performed to develop a measure of inpatient readmissions in constructing key elements of this outpatient measure, such as the planned admission algorithm and risk adjustment model. Unfortunately, the measure that has been put forth to the NQF retains elements of the inpatient measure that are not appropriate, an indication that the measure has not been thoroughly reviewed and fully adapted for outpatient use. As just one example, certain condition categories (CCs) are not included in risk adjustment if they are only recorded at the time of the colonoscopy, as they are considered to be possible adverse outcomes. Although end stage renal disease (ESRD) would not be a complication

of colonoscopy diagnosed and recorded at the time of the procedure, it was included on the list of CCs.

The measure developer has indicated it will review the list of CCs with their technical experts, though this group is said to have already reviewed the measure details last year. Revised specifications are needed and should be reviewed independently to ensure that outpatient adaptation is complete. If CMS determines it will implement this measure despite it many problems, these revised specifications should be in place and independently reviewed prior to implementation.

II. Proposed Implementation Timeline for the Proposed New Measure for the CY 2017 Payment Determination and Subsequent Years

CMS has proposed to use paid Medicare FFS claims from a 12-month period from July 1 of the year that is three years prior to the payment determination year to June 30 of the following year as the data collection period for this measure. Thus, for the CY 2017 payment determination for this measure, claims from July 1, 2014 to June 30, 2015 would be used. The agency indicates this time period provides for the timeliest data possible while aligning the proposed data submission requirements with its Hospital OQR Program proposals.

The principal difficulty with this proposal is that, as noted above, this measure requires three years of data to achieve even modestly reliable measure scores for high volume facilities. The two-year reliability of the measure was reported to be just "fair" and therefore the one-year measure reliability score would be even lower due to the small number of observations. One year of data collection would not be sufficient and is not something we can support. If the agency adopts the proposed measure, it should extend the data collection period to three years in order to remain consistent with timeframe of reliability data submitted to NQF for consideration of endorsement, and in order to ensure at least some semblance of reliability in the measure scores it would plan to report to the public.

In summary, the proposed time period of July 1, 2014 through June 31, 2015 is of significant concern to us. Further, we are not supportive of retroactive implementation dates. If this measure is implemented, data should be collected over a three-year period beginning July 1, 2015 and continuing through June 30, 2018, making the data available for the CY 2020 payment determination.

III. Delayed Data Collection and Proposed Exclusion for ASC-11 for the CY 2016 Payment Determination and Proposed Voluntary Data Collection for ASC-11 for CY 2017 and Subsequent Payment Determination Years

CMS finalized ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) for inclusion in the ASCQR Program despite overwhelming public opposition to the measure, which was based primarily on its lack of feasibility in the ASC setting. Since then, the agency has "come to believe that it may be operationally difficult at this time for ASCs to collect and report this measure." As a result, implementation of the measure has been delayed twice, most recently until January 1, 2015 for the CY 2016 payment determination. CMS is now proposing to exclude ASC-11 from the CY 2016

payment determination measure set, saying it would not subject ASCs to a payment reduction with respect to this measure for the CY 2016 payment determination. We agree with this proposal.

CMS further proposes to continue to include this measure in the ASCQR Program measure set for the CY 2017 payment determination and subsequent years on a strictly voluntary basis. ASCs would not be subject to a payment reduction for failing to report this measure. Any data submitted voluntarily would be publicly reported by CMS.

It is our belief that the number of ASCs that would voluntarily report this measure would be very small indeed. This belief is based on very low levels of participation for the corresponding PQRS measure - 215 of the more than 7,300 cataract physicians in the US - in 2013. Given that the measure is very challenging and expensive for ASCs to implement, we anticipate the number of ASCs that would voluntarily participate would be much lower than the number of physicians that have participated. However, if any ASCs do report measure data, CMS contractors will still have to perform all the tasks necessary to develop and maintain the means to collect and publicly report the information. We question the value of this effort and do not believe it would have any appreciable impact on ASC performance or provide enough consumer information to warrant the effort. We believe taxpayer dollars would be more wisely expended in the support of other agency objectives. Therefore, we recommend the removal of the measure from the Program.

IV. Data Submission Requirements for ASC-8 (Influenza Vaccination Coverage Among Healthcare Personnel) Reported via the National Healthcare Safety Network (NHSN) for the CY 2016 Payment Determination and Subsequent Years

Last year, CMS proposed that ASCs would have until August 15, 2015 to submit their 2014-2015 influenza season data to NHSN, this being the latest date possible that would allow sufficient time for the agency to make the CY 2016 payment determinations. August 15 is also the data entry deadline for the ASCQR Program structural measures entered via QualityNet. Some commenters supported this proposal, while others expressed disagreement, and ultimately the agency did not finalize the August 15, 2015 deadline.

This year CMS is proposing that the deadline for data submission be on May 15 of the year in which the influenza season ends, similar to the Hospital IQR and OQR Programs. For example, for the CY 2016 payment determination, ASCs would be required to submit their 2014-2015 influenza season data by May 15, 2015. This proposal would align the ASC submission deadline with the May 15 deadline used in the Hospital IQR and OQR Programs for this measure.

As we stated last year, though 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 well beyond the close of the 2014-2015 influenza season, we support the August date. Although it is in its infancy, the ASCQR Program is already complex, featuring different data collection time frames, data submission deadlines and data submission methodologies. The Program is already more complicated than is strictly necessary. Any steps that can be taken to simplify and streamline program requirements would be helpful toward reducing the burden of keeping track of, and complying with, the already numerous requisites. If the agency desires a consistent data submission deadline across settings, it should consider the August 15 date for the Hospital IQR and OQR Programs, as well.

V. Proposals for the Removal of Quality Measures from the ASCQR Program

In this proposed rule, CMS has offered several proposals around the removal of previously adopted ASCQR Program measures.

A. Proposed Criteria for Immediate Removal of Measures

In circumstances where evidence arises that the continued use of a measure as specified raises patient safety concerns, CMS proposes to immediately remove said measure, notifying ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the QualityNet website. The agency would subsequently confirm the removal of said measure in the next OPPS/ASC rulemaking cycle. This is the same process the agency has implemented and/or proposed to adopt for other of its quality reporting programs. We support this proposal, but recommend that the agency notify providers by mail and also post notification on the CMS website on the ASC Quality Reporting webpage under the "Announcements" heading.

B. Proposed Criteria for Removal of Measures Through Regular Rulemaking

For situations in which continued use of a measure does not raise specific safety concerns, the agency is proposing to use the regular rulemaking process to remove a measure. CMS is proposing to use the same list of the criteria it uses to determine whether to remove measures from the Hospital IQR Program as the basis for determining whether to remove measures from the ASCQR Program. These criteria are: (1) measure performance among facilities is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped out" measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

There appears to be an error in the list of criteria in the ASC section of this proposed rule, wherein criteria (2) and (6) are essentially duplicative. We referenced both the Hospital IQR criteria and Hospital OQR proposals, and have determined CMS likely intended item (2) to read as follows: "(2) performance or improvement on a measure does not result in better patient outcomes."

We support the following criteria for application to all measure types: (3) a measure does not align with current clinical guidelines or practice; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. The remaining criteria should be applied more selectively on a measure-by-measure basis, and with consideration of the value of the information the measure provides to the consumer and the provider community affected by the measure.

C. Proposed Criteria for Identification of "Topped-Out" Measures

A measure is considered "topped-out" when performance among entities is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. CMS believes these measures should be considered for removal from the ASCQR Program because their reporting burden may outweigh the value of the quality information they provide. The agency is proposing that a measure under the ASCQR Program would be considered "topped-out" when it meets both of the following criteria:

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- A truncated coefficient of variation less than or equal to 0.10

To identify if a measure has statistically indistinguishable performance at the 75th and 90th percentiles, CMS would determine whether the difference between the 75th and 90th percentiles for a measure is within two times the standard error of the full dataset. The coefficient of variation (CV) measures the standard deviation as a percentage of the sample mean; this provides a statistic that is independent of the units of observation. A large CV would indicate a broad distribution of individual ASC scores, with large and potentially meaningful differences in performance. A small CV would indicate the distribution of individual scores is tightly clustered around the mean, suggesting the measure is not useful for drawing distinctions regarding performance. The truncated CV excludes observations whose rates are below the 5th percentile and above the 95th percentile. Use of this value would remove the highest and lowest outliers, which could widen the distribution of scores. These same criteria have been proposed for adoption in the Hospital VBP and IQR Programs.

We believe this approach is too simplistic, and could prompt the removal of valuable program measures. Examples would include patient safety measures, whose goal is to drive toward and sustain zero harm, critical outcome measures such as surgical site infection rates and patient experience measures. These types of measures could, over time, develop performance scores with the statistical characteristics enumerated above, but we believe they would have enduring value to consumers and providers despite this. Consequently, we cannot support the criteria CMS has proposed.

VI. 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 more. 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. The ASC QC has a strong interest in developing an ASC-specific registry. It is our

intent that the registry will collect data from participating ASCs on a broad variety of quality measures, including all the measures CMS has adopted under the ASCQR Program. We further anticipate this registry would collect patient-level quality measure data, regardless of payment source.

While the ASC QC's registry project remains in the planning stages, other registries 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.

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

The current minimum threshold for successful reporting for measures submitted using 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. Measure Applications Partnership (MAP) Process Improvements Are Needed

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 completely unsatisfactory, treating public input as an afterthought that is not worthy of consideration. Although MAP agendas currently include opportunities for public comment, these opportunities 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 should 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 received in response to its draft report and then make any appropriate revisions to its recommendations prior to issuing a final report.

As a measure developer, we find the agency's practice of asking the MAP to consider and 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 developing a habit of advancing incomplete ideas in an apparent rush 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. The MAP's decisions carry significant weight. With so much at stake, it is not reasonable to issue recommendations based on measure concepts or measure drafts. When "concepts" are presented, MAP should determine whether the measure concept/draft would fill a measure gap but reserve further judgment for the completed measure.

Further, the inclusion of measure "concepts" results in an unreasonably large number of items for the MAP to consider. 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 HealthCare
Ambulatory Surgery Foundation
Ambulatory Surgical Centers of America
American College of Surgeons
American Osteopathic Association, Healthcare Facilities Accreditation Program
AmSurg
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
Symbion
The Joint Commission
United Surgical Partners International