



## ASC Quality Collaboration

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September 6, 2013

### VIA ELECTRONIC SUBMISSION

Marilyn Tavenner, Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1601-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: CMS-1601-P; Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals**

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-1601-P, Section XV. Proposed Requirements for Ambulatory Surgical Center Quality Reporting (ASCQR) Program (78 FR 43534, July 19, 2013). 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.

The ASC QC strongly advocates quality reporting. This commitment is reflected in the steps we have taken independently to facilitate quality reporting by ASCs – all without federal incentive or penalty. This includes developing six ASC facility-level quality measures and securing the endorsement of the National Quality Forum (NQF) for each, as well as developing and publishing 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 the consideration CMS has given to our public comments in the past. We

are pleased to have this opportunity to offer additional insights and recommendations.

## **I. Proposed Additional ASCQR Program Measures for the CY 2016 Payment Determination and Subsequent Years**

### **A. 2013 Pre-Rulemaking Report of the Measure Applications Partnership (MAP)**

CMS has relied heavily on the recommendations of the MAP in issuing proposals for measures for future inclusion in the ASCQR Program. While we appreciate the work of the individuals serving on the MAP Coordinating Committee and its various workgroups, the value of the recommendations made for ASCs in the MAP's 2013 Pre-Rulemaking Report were weakened by a lack of relevant expertise and a flawed public comment process.

The MAP should incorporate expert representation for each quality reporting program that CMS administers. It is particularly important that this content matter expertise be included in the workgroup charged with reviewing and making recommendations regarding program quality measures. The MAP's Hospital Workgroup assessed measures for the ASCQR Program, but we were not able to identify a single member of the Hospital Workgroup (or of the MAP Coordinating Committee charged with reviewing the Hospital Workgroup's recommendations) who was directly and routinely involved in the ASC industry, or who, by virtue of past experience or involvement in ASCs, had expertise in ASC matters. This lack of understanding led to the inclusion of inappropriate recommendations for the ASCQR Program in the 2013 MAP Pre-Rulemaking Report submitted to the U.S. Department of Health and Human Services (HHS) earlier this year. Though this does nothing to address the issues with the 2013 ASC recommendations, we are pleased to report that an ASC representative was recently appointed to the MAP Hospital Workgroup. We are confident this inclusion of ASC expertise will improve the MAP's ASCQR Program recommendations in its 2014 and future reports to HHS.

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 - are fundamentally flawed. While MAP agendas currently include opportunities for public comment, these opportunities are scheduled after member discussion and voting on agenda items has been completed. In the specific case of the ASC measures considered by the Hospital Workgroup, key information was not presented and misinformation was not corrected prior to decision-making. Similarly, there was no opportunity for the public to address the Coordinating Committee regarding topics under discussion until after it had completed deliberations. While we appreciated the opportunity provided to comment on the draft of the 2013 Pre-Rulemaking Report, we were disappointed these comments were not considered by the Coordinating Committee and therefore did not result in any revisions to the recommendations in the final report. Public comments were merely summarized in a very general fashion by NQF staff in the body of the final report, and then appended to the report. This lack of consideration is unacceptable.

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.

## **B. Analysis of Cataract Measures Proposed for Inclusion in the ASCQR Program**

CMS has proposed to adopt two clinician-level cataract measures for inclusion in the ASCQR Program. The two measures are as specified in documents on the NQF website and are:

- *Cataracts: Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564)*, which assesses the “[p]ercentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.”
- *Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536)*, which assesses the “[p]ercentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery.”

The *Cataracts: Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564)* measure has not been endorsed by NQF for the ASC setting. CMS indicates that because the measure has been endorsed as a clinician-level measure for the “Ambulatory Care: Clinic” setting it is therefore appropriate for the ASC setting. This appears to equate ASCs with ambulatory clinics, or at least imply that ASCs are a type of ambulatory clinic. This is not the case. As CMS is well aware, per regulation (see 42 CFR §416.2) an ASC is a “*distinct entity that operates exclusively for the purpose of providing surgical services to patients...*” [emphasis added]. An ASC is not an ambulatory clinic, nor a type of ambulatory clinic. In accordance with Federal regulation, it is 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. Nor may ASCs serve as the facility in which pre-operative evaluation and management services are offered, or the site in which the decision for surgery is made in consultation with the patient.

CMS implies the *Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536)* measure is “NQF-endorsed for the ASC setting”, but this is misleading. This measure was never intended to measure facility performance, but rather was developed, tested and NQF-endorsed as a clinician-level measure. During the consensus development process, the NQF specifically requires testing be performed for any level of analysis for which the measure will be implemented in order to assure its acceptability. Review of the measure submission forms and other NQF documentation confirms this measure has not been tested nor endorsed as a facility-level measure for the ASC setting.

While the MAP voted to support these two measures, these recommendations were qualified by its comment that the measures should be tested and NQF-endorsed for the facility level of analysis. In addition, all the public comments the MAP received in response to its draft

2013 Pre-Rulemaking Report were critical of the recommendation to support.

The distinction between clinician-level and facility-level measures is a pivotal one, but was not acknowledged by CMS. The level of analysis has a significant impact on measure specifications. In addition, the level of analysis points to the entity within the healthcare delivery system that generates the data necessary to fulfill measure specifications, and also to the entity that can logically be held accountable for measure results and is best able to take action to meaningfully improve performance. In the case of the proposed cataract measures, that entity is clearly the physician.

These measures rely on data obtained or generated by the physician and recorded in medical records housed in the physician's office at two key points in time: 1) the patient's visit(s) with the physician during which evaluation, examination, and discussion may result in a decision for surgery, and 2) the patient's visit(s) with the physician after surgery during the post-operative 90-day global period. ASCs, as distinct entities that operate in an entirely separate capacity from physician offices [please see 42 CFR §416.2 for the definition of an ASC and the CMS State Operations Manual, Appendix L for detailed guidance on the interpretation of Federal requirements], do not have access to these records.

In addition to these issues, our review of the *Cataracts: Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564)* measure revealed significant problems with the feasibility of implementation in the ASC setting as described below.

First, in order to accurately identify the denominator exclusions for this measure, the ASC would have to determine which of its adult cataract surgery patients had significant pre-operative ocular comorbidities. These pre-existing ocular conditions are specified in a list of denominator exclusions which include: a) a list of ocular comorbidities to be identified using a list of 124 ICD-9-CM diagnosis codes, b) a list of four prior surgeries to be identified through the use of administrative claims, and c) any patient taking tamsulosin (a medication for treatment of benign prostatic hyperplasia). While an ASC would be able to identify patients taking tamsulosin, the ASC would not be able to reliably ascertain the other denominator exclusions without full access to the physician's medical and administrative records for the patient.

Second, to identify the numerator population, the ASC would need to identify those patients who experienced retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment or wound dehiscence within the 30-day period following the index cataract surgery. However, Federal regulations do not permit ASCs to provide post-operative follow-up care, and therefore the patient would not visit the ASC, but rather another site, for post-operative care and identification of complications. Therefore, in order to ascertain whether or not a cataract surgery patient experienced these complications, the ASC would have to request information from the provider responsible for follow-up care. In addition to determining whether or not these specific complications occurred, ASCs would also need to determine if a patient who experienced any of the above-listed complications then underwent any of a list of 39 specified operative procedures (identified by a list of CPT codes) within the 30-day period following the index surgery. Per the Physician Quality Reporting System (PQRS) specifications manual for this measure, the occurrence of any of the 39 operative procedures is to

be identified by reviewing claims. While the physician would clearly have access to his or her own claims for services provided during the 90-day global period, ASCs would only have access to the relevant claims data if it served as the site of service for the subsequent surgery.

The second cataract measure CMS has proposed, *Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)*, would also pose implementation issues for ASCs. This measure relies on the administration of two Visual Functioning VF-8R patient questionnaires, one completed by the patient prior to surgery, and the other completed by the patient during the 90-day period after surgery.

Instructions for administering the survey are included in an implementation guide for this PQRS measure. This guide indicates that both the pre-surgery and post-surgery VF-8R assessments are to be distributed to the patient during the pre-operative and post-operative visits to the physician's office. In both instances, the patient is instructed to return the surveys to a third-party survey vendor in a pre-addressed stamped envelope. The measure requires the use of a third-party administrator in order to prevent the introduction of bias.

Having to hire a third-party administrator to implement this measure would impose a new cost burden for ASCs. In addition, there would be definite logistical issues with having both the physician and ASC arrange for the collection of this data. Asking a patient to complete two sets of identical surveys is unimaginable. We are not sure how this matter would be resolved.

Even if the ASC could obtain the results of the patient surveys, it is not clear what the facility would do with this information. The physician's decision to recommend cataract surgery is based on more than the potential for functional benefits. Along with other factors, visual acuity and visual impairment are also considerations. We do not know how the ASC, which is not qualified or licensed to evaluate the cataract patient or make these assessments and judgments, is to become involved in professional decision-making in response to the measure results.

Clearly both proposed cataract measures, which CMS characterizes as "chart-abstracted", include data elements intended to be abstracted from the medical records of the ophthalmologist or surveys distributed by their office and processed by a contracted third-party vendor. Because the data are either not available at all, or not consistently available, in the ASC medical record, these measures would impose a significant, and unacceptable, data collection burden.

Both cataract measures are already included in the PQRS for clinician reporting. We do not see the benefit of having both the professional and the facility caring for the same patient collect and report the same measure data. This duplication of effort adds nothing to the advancement of quality in the ASC.

### **C. Endoscopy/Polyp Surveillance Measures Proposed for Inclusion in the ASCQR Program**

CMS has proposed to adopt two clinician-level endoscopy measures for inclusion in the ASCQR Program for the ASC CY 2016 payment determination and subsequent years. The two measures are as specified in documents on the NQF website and are:

- *Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)*, which assesses the “[p]ercentage of patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.”
- *Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659)*, which assesses the “[p]ercentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report.”

CMS states that the two endoscopy measures it has proposed for inclusion in the ASCQR Program are “NQF-endorsed for the ASC setting”, but, as with the cataract measures above, this statement is misleading. Review of NQF documentation reveals the *Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)* was developed, tested and NQF-endorsed as a clinician-level measure. It has not been tested nor endorsed as a facility-level measure for the ASC setting. As noted above, the NQF specifically requires testing be performed for any level of analysis for which the measure will be implemented in order to assure its acceptability.

Since the publication of this proposed rulemaking, the *Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659)* measure lost its Phase 1 time-limited endorsement. This occurred when the measure was not endorsed in Phase 2 of the NQF’s Gastrointestinal / Genitourinary Measure Endorsement Consensus Development Project. As a result, this measure is no longer NQF-endorsed for any level of analysis.

The MAP vote for these two measures was “Support Direction”, indicating the measures were not, in their opinion, ready for implementation in the ASCQR Program. Additionally, the MAP recommended that the measures be tested and NQF-endorsed for the facility level of analysis. Testing in the ASC setting would have revealed significant problems with key measure attributes. Public comment in response to the draft MAP 2013 Pre-Rulemaking Report universally found issue with the recommendation to “Support Direction” for applying these clinician-level measures to the facility setting.

As with the cataract measures discussed above, the critical distinction between clinician-level and facility-level measures has not been acknowledged or addressed by CMS, although in this case the MAP clearly identified the issue.

The *Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)* measure was developed to evaluate the appropriateness of the recommended follow-up interval for a normal screening colonoscopy. This is a recommendation made solely by the physician and does not involve ASC staff. The personnel employed by the ASC - including nurses, technicians, and non-clinical staff - are not trained or licensed to make such recommendations. Therefore, accountability for this measure

logically rests with the physician. Similarly, the measure results are actionable at the physician level.

At its core, the *Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659)* measure evaluates the appropriateness of a physician's decision regarding the timing of follow-up surveillance. This is a decision the physician makes in consultation with the patient, based on information obtained during the patient's visit(s) to the physician's office. It does not involve the ASC or its staff. ASCs are facilities, not medical professionals licensed to practice medicine. Even the clinical staff employed by the ASC - including registered nurses, licensed practical nurses, technicians, and clinical assistants - and are not trained or licensed to evaluate patients for endoscopy. In addition, ASC liability policies do not cover such staff activities.

From a practical standpoint, it is unclear how ASCs are to consistently obtain the information required for this measure. Unless the ASC in question was the site of service for the prior colonoscopy, measure data such as the date of the patient's last colonoscopy, the number, type(s) and location(s) of any polyps detected, and the presence of any extenuating circumstances would not be found in the ASC medical record, and would have to be obtained from other providers. This would represent a significant burden to ASCs.

Finally, physicians already report both measures under the PQRS. We do not see any value in having data for the same measure collected and reported for the same patient by both the physician and the ASC. This potential for duplicate reporting would increase provider burden without adding new information to the pool of quality data available to the public. Because this has been developed, tested and NQF-endorsed as a clinician-level measure, physicians, not facilities such as ASCs, are the appropriate submitters of the data for this measure.

#### **D. ASC QC Recommendations Regarding Measures CMS Proposed for Inclusion in the ASCQR Program**

Based on our analyses and on the feedback we have received from ASCs across the nation, the ASC QC does not support any of the four measures CMS has proposed for inclusion in the ASCQR Program. In our opinion, CMS has not met its statutory requirement that measures "reflect consensus among affected parties." As noted above, one of the measures did not achieve NQF endorsement, and the NQF endorsement for the three remaining measures was solely as clinician-level measures. In addition, there is no other form of consensus around the use of these measures at the facility level.

All four measures have already been implemented in the quality reporting program for which they were intended: the PQRS. Under the PQRS, these measures have varying thresholds for successful reporting, at most requiring the collection and submission of data for 80 percent of eligible Medicare beneficiaries. Yet CMS has proposed that ASCs collect data on these measures for all specified ASCs patients. To suggest ASCs make more extensive data collection and submission efforts than the physicians for whom these measures were intended is unreasonable.

It is well established that performance improvement activities are meaningless if applied to outcomes or processes over which an entity has no control, yet every one of these measures

evaluates actions and outcomes that are outside the control of the ASC. Asking ASCs to expend resources engaged in quality reporting activities that would have no direct impact on facility performance improvement efforts is not only wasteful, it reduces the time and resources that otherwise would have been available for measuring and advancing quality in areas where the ASC has the ability to drive improvement.

We recognize CMS wishes to align measures across programs, but these efforts must not result in duplication of effort, additional burden and expense, and lost opportunity for meaningful quality improvement. According to the NQF, alignment across settings works well when measures “produce meaningful information without creating extra work for those responsible for the measurement.” We agree with the NQF and suggest that the agency seek to create alignment through measures that may be reasonably applied across facility-level providers where services are comparable.

The agency should seek to propose measures that evaluate some relevant aspect of the ASC’s contribution to the care of the patient. By selecting measures that gauge what a facility could be doing better, the ASCQR Program could provide opportunities for additional advances in quality that are complementary to clinician-level performance improvement efforts.

#### **E. Implementation Timeline for Proposed Additional Measures for the CY 2016 Payment Determination**

As noted above, we do not support the adoption of any of the four proposed measures for inclusion in the ASCQR Program. However, should the agency choose to finalize any of the measures over the objections of so many stakeholders, we would be very concerned about the limited amount of time that ASCs would have to respond to and prepare for any new measures finalized in the rulemaking process. Specifically, CMS has proposed that, for any finalized measures, ASCs begin to collect quality data on January 1, 2014 for the CY 2016 payment determination. We anticipate CMS will issue the ASC/OPPS final rule at the end of October or the beginning of November 2013. This would give ASCs approximately two months to become aware of and versed in the new quality measures finalized in the rule, to develop and implement the changes in daily processes and operational systems needed to collect the required data, to educate staff regarding the new measures and the new processes for collecting the required data, and to initiate data collection. The proposed timeline is entirely inadequate.

Placing this proposal in the context of the timeframe CMS allows for updating or making changes to existing ASCQR Program measures highlights how inappropriate it would be to provide such limited advance notice for implementation of a newly adopted measure. In the CY 2012 OPPS/ASC final rule with comment period, CMS finalized a subregulatory process for technical specification updates to existing measures under the ASCQR Program. At least 3 months advance notice is allowed for non-substantive changes (such as changes to ICD-9, CPT, NUBC, and HCPCS codes) and a period of at least 6 months of advance notice is provided for substantive changes to data elements that would require significant systems changes. [See 76 FR 74513 through 74514].

The adoption of a new measure is a substantive change in the ASCQR Program requiring significant system changes. In our experience, implementing a new measure is more challenging



than revising an existing measure. As such, new measure implementation is deserving of at least as much time as, and certainly no less time than, the minimum of 6 months of advance notice extended when specifications for existing measures require a substantive change.

In short, the proposed time period of January 1, 2014 through December 31, 2014 is of significant concern to us and is not something we can support, as it does not allow sufficient time to prepare following the publication of the OPPTS/ASC final rule. If the agency adopts any of the four proposed measures, it should modify the data collection period to January 1, 2015 through December 31, 2015, delay the data submission period until 2016, and use the data for the CY 2017 payment determination.

#### **F. Measure-Level Exemptions for Proposed Additional Measures for the CY 2016 Payment Determination**

As noted above, we do not support the adoption of any of the measures proposed for inclusion in the ASCQR Program for CY 2016. However, should the agency finalize any of these measures, CMS should take additional steps to address burden in those ASCs that do not perform cataract surgery or colonoscopy.

In ASCs where a measure would never apply, CMS should allow measure-level exemptions. ASCs that do not offer cataract surgery and/or colonoscopy services should be offered a single-step method of claiming an exemption based on no volume. This could be as simple as requiring the ASC to check a single box on the QualityNet site indicating they do not offer the type of service specified by the measure. This would require fewer steps and therefore be preferable to requiring ASCs to enter zeros for the measure in question.

Although CMS has not offered a measure-level exemption for ASC-5, Prophylactic Intravenous (IV) Antibiotic Timing, such an exemption would be appropriate. Single-specialty ASCs that provide gastrointestinal endoscopies do not administer IV prophylaxis for the prevention of surgical site infection (SSI). Many single-specialty ophthalmic ASCs administer topical, rather than IV, antibiotics for SSI prevention. The collection of this data in centers that do not administer IV antibiotic prophylaxis does not generate any information that can be used in performance improvement or to inform consumer decision-making. As a result, this policy imposes an unnecessary burden for such ASCs. ASCs that do not administer IV antibiotic prophylaxis for SSI could claim an exemption by checking a single box next to an attestation on the QualityNet site. Alternatively, CMS could develop a G-code (e.g., Gxxxx – This facility does not administer IV antibiotic prophylaxis for surgical site infection) that ASCs could submit on a one-time basis on a claim to notify the agency of their claim for an exemption.

Use of either suggested method – an exemption check box on QualityNet or a one-time submission of an exemption G-code - could be readily audited by reviewing Medicare claims. For example, an ASC that claims an exemption for ASC-5 but that submits codes for services typically requiring antibiotic prophylaxis could be flagged for an in-depth review.

## **II. Considerations in the Selection of ASCQR Program Quality Measures**

CMS has outlined a set of general considerations it applies in the selection of measures

[see 77 FR 68493 through 68494] for the ASCQR Program. Additional principles are needed to guide the selection of appropriate and meaningful measures. These include the following concepts:

- Selection of quality measures should be guided by appropriate attribution of accountability. Measures selected for use in outpatient surgical facilities should reflect aspects of patient care that are attributable to the facility itself - its staff, equipment, environment of care, and its roles in the delivery of patient care - and for which the facility, by virtue of its specific functions in patient care, may reasonably be held accountable.
- Measures should be fully vetted for the intended level of analysis - including assessments of validity, reliability, feasibility and usability - before being considered for inclusion in a federal quality reporting program. Rigorous evaluation and testing is essential to the development of meaningful quality measures.
- Measures should generate data that is useful to the general public. Appropriately selected quality measures must provide information that can be readily understood by the consumer and used in their evaluation of the quality of care offered by the provider.

### **III. ASCQR Program Measure Topics for Future Consideration**

The ASC QC continues to evaluate and develop other potential outpatient surgery quality outcome measures such as normothermia, which we are preparing to pilot test. We are also working on outcome measures for venous thromboembolism and hospital admission following discharge from an outpatient surgical facility. We remain interested in a surgical site infection outcome measure, and hope to resume our collaboration with the Centers for Disease Control and Prevention (CDC) in this area soon.

In addition, we have had a longstanding interest in the development of a patient experience measure for outpatient surgical facilities similar to the Consumer Assessment of Health Providers and Systems (CAHPS) survey tools currently in existence for other providers. As you know, CMS has issued a procurement for an ASC/HOSD CAHPS, and we are actively participating in the project, along with other stakeholders.

We are also participating in the Agency for Healthcare Research and Quality's (AHRQ) project to develop a Surgical Unit-based Safety Program in Ambulatory Surgery (SUSP-AS) to reduce surgical site infections and other surgical complications. We continue to provide input regarding several aspects of the project, including the survey that would assess the culture of safety, as well as measures that would evaluate the impact of implementing a surgical safety checklist. These measures may be topics for further development, but we do not yet have enough information to determine if there is a performance gap in these areas.

Finally, we are expanding our efforts to collaborate with specialty professional and nursing societies and other stakeholders in single-specialty ASCs to explore options for specialty-specific measures.

### **IV. Alternative Data Collection Mechanisms**

CMS has indicated it is seeking 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. CMS has provided physicians with several data reporting options under PQRS. This flexibility 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 propose 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 development 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 at its earliest opportunity.

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.

## **V. Technical Specification Updates**

As in its other quality reporting programs, CMS has adopted a subregulatory process for making non-substantive updates to the measures adopted for the ASCQR Program. For measures that are not endorsed by a national consensus building entity, such as the Safe Surgery Checklist Use (ASC-6) and ASC Facility Volume on Selected ASC Surgical Procedures (ASC-7) measures, CMS currently determines when changes are needed, in part, through an internal measure maintenance process involving Technical Expert Panels. We continue to believe relevant ASC clinical and operational expertise should be brought to bear in the review and update of these measures.

We have repeatedly voiced concerns regarding the lack of rigorous specification for the ASC Facility Volume on Selected ASC Surgical Procedures (ASC-7) measure. When originally proposed, this measure was poorly specified. Although improvements were made in Version 1.0 of the Specifications Manual, there were still many pertinent details lacking. We hoped to see further clarifications over time, but none are apparent in Version 3.0. There are several questions CMS should address *in the Specifications Manual* in order to ensure consistent data preparation and reporting. For example, are aggregate procedure counts to be prepared for the nine categories alone, or are aggregate counts to be prepared for the 34 subcategories, or by CPT code? In

preparing the aggregate counts, are secondary procedures to be counted in addition to the primary procedure? How are bilateral procedures or those performed on multiple spinal levels to be counted? How should ASCs count cases that are cancelled or otherwise discontinued after the patient has been admitted? In addition, the categories outlined in the manual do not align with the data entry screens in QualityNet. It is essential that CMS take steps to correct these problems as soon as possible in order to facilitate consistent data reporting across ASCs.

## **VI. Proposed Minimum Threshold for Claims-Based Measures Using Quality Data Codes (QDCs) for the CY 2016 Payment Determination and Subsequent Years**

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. The agency proposes to continue this 50 percent minimum threshold for the CY 2016 payment determination and subsequent years, though stating it intends to propose increasing this percentage for future payment determinations.

We appreciate the consideration the agency has shown by proposing to continue the 50 percent threshold for the CY 2016 payment determination, as there may be isolated instances where ASCs, administrative contractors and billing clearing houses are not familiar with ASCQR Program reporting requirements, or are still working toward full implementation. We anticipate these issues will be short-lived, and therefore recommend CMS increase the minimum threshold for the CY 2017 payment determination in future rulemaking.

## **VII. Proposed Minimum Case Volume for Claims-Based Measures Using QDCs for the CY 2016 Payment Determination and Subsequent Years**

CMS has proposed a program exemption for ASCs with low Medicare volume to minimize the burden of reporting for these facilities. Specifically, ASCs with fewer than 240 Medicare claims per year during a reporting period would not be required to participate in the ASCQR Program for the subsequent reporting period. The proposed exemption would begin with the CY 2016 payment determination and extend to subsequent years, as long as the ASC's volume of Medicare claims remained below the 240-claim threshold. We understand this exemption, though proposed under the "Proposed Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs" section, would provide an exemption from all program requirements, not just an exemption from reporting measures using QDCs.

CMS states the volume threshold of 240 Medicare claims per year translates to an exemption for roughly 10 percent of ASCs. We support the concept of an exemption for the 10 percent of ASCs with the lowest volume of Medicare claims. However, it is not clear how the 240-claim threshold correlates to the 10 percent of ASCs submitting the lowest volume of Medicare claims. Review of the CMS Limited Data Set file accompanying this proposed rulemaking suggests the 10 percent target would be reached with a lower claim threshold.

We do agree it would be important to implement this policy by indicating a specified number of claims in order to allow ASCs to independently determine their need to participate from year to year. ASCs with Medicare volumes near the threshold may well experience an "on

again, off again” requirement to participate in order to qualify for a full payment update, so we encourage the agency to issue annual reminders of this policy. We also believe any ASC eligible for the exemption that wishes to report for reasons other than receiving a payment update should be able to do so.

### **VIII. Proposed Requirements for Data Submitted Via QualityNet**

For the CY 2016 payment determination and subsequent years, CMS has proposed to alter the data collection and submission time periods for measures submitted through Quality Net, including the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures measures. Under this proposal, the data collection period would be the calendar year occurring two years prior to the payment determination year. In addition, the proposal would also extend the data submission period, which is currently finalized in rulemaking as July 1 through August 15, to a more generous period extending from January 1 to August 15 in the year prior to the payment determination. If implemented for the CY 2016 payment determination, the data collection time period for these measures would be dates of service from January 1, 2014 to December 31, 2014, and the data submission time period would be January 1, 2015 to August 15, 2015.

We fully support a significantly longer data submission period for these measures. CMS has currently set the data collection period from July 1 through August 15, and extending this to January 1 through August 15 of each calendar year would be very helpful.

We also agree there is benefit to aligning the data collection time periods for the claims-based and Web-based measures. As it currently stands, the data collection timeframe for the web-based measures is three years prior to the impacted payment determination year, while the data collection timeframe for claims-based measures is two years prior to the impacted payment determination year. Ideally, the quality data collected during a given time period would impact only one payment update determination.

While we support the proposal to shift the data collection time period, we believe this alignment will result in a significant amount of confusion. To help remedy this, CMS must invest in extensive educational outreach and must ensure timely delivery of this information via all available avenues of communication.

### **IX. Proposed Data Submission Requirements for a Measure Reported via the National Healthcare Safety Network (NHSN)**

In earlier rulemaking, CMS finalized the inclusion of the Influenza Vaccination Coverage among Healthcare Personnel measure (NQF #0431) for the CY 2016 payment determination and specified that data submission would be via the NHSN during the period from October 1, 2014 to March 31, 2015. CMS is proposing to use the data submission and reporting procedures that have been set forth by CDC for NHSN participation and for submission of data.

CMS has stated “that ASCs would know and be comfortable with these procedures because these procedures are already used by many ASCs to fulfill State-mandated reporting of healthcare-associated infection (HAI) data through the NHSN in at least 17 States.” While it is

true that a number of States have mandated NHSN reporting, many of those State requirements do not include ASCs. And although some of the States that mandate SSI reporting have a large number of ASCs, the procedures that they require to be monitored are not often performed in the ASC setting. As a result, most ASCs in those States still are not covered under the SSI mandates. CDC estimates there are currently only about 285 ASCs enrolled and reporting in NHSN, most of these only for specific SSI reporting. Consequently, the vast majority of ASCs are entirely unfamiliar with NHSN. CMS and CDC should plan to make significant investments of time, personnel, and other resources to support the initial enrollment and reporting process to ensure a smooth implementation.

### **A. NHSN Processes, Guides and Other Materials**

The CDC NHSN website includes detailed enrollment, set-up, and reporting guides and procedures designed for hospitals. We are concerned that this hospital orientation will lead to unnecessary confusion and burden if NHSN materials are not appropriately adapted for ASC users prior to the enrollment process.

For example, the NHSN enrollment webpage for ASCs titled “5-Step Enrollment for Ambulatory Surgery Center Facilities” includes the “NHSN Facility Administrator Enrollment Guide” at <http://www.cdc.gov/nhsn/PDFs/FacilityAdminEnrollmentGuideCurrent.pdf>. This guide references hospitals, hospital organizational structure, hospital administrators, hospital American Hospital Association (AHA) ID numbers, VA hospital station codes, and the Hospital Inpatient Quality Reporting Program. There is even a reference to an outpatient dialysis center. Yet there is not a single reference to an ambulatory surgery center included in the entire document. An ASC could appropriately wonder if the document was inadvertently linked to the ASC page in error. The document could be made suitable for use by all facility types by using the more general term “facility” instead of the word “hospital”, and by including references to specific provider types where appropriate.

Additionally, certain CDC NHSN materials are, from the ASC perspective, unnecessarily complex. For example, the NHSN set-up process requires facilities to map patient care locations within the facility. The “CDC Locations and Descriptions and Instructions for Mapping Patient Care Locations” (located at [http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions\\_current.pdf](http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions_current.pdf)) is a comprehensive 45-page document that would be useful to a complex facility with multiple locations to set-up and track, but would represent a burden to an ASC trying to locate the handful of CDC Location Codes relevant to an ASC. A significantly abridged version is needed for ASC use.

The instances detailed above are examples of current issues, not a comprehensive list of materials requiring adaptation for the ASC audience. We are aware of, and grateful for, CDC’s progress in creating an annual outpatient facility survey form for NHSN. Similar efforts are needed to adapt other existing NHSN resources and protocols for ASC use. It is essential that all other existing NHSN materials be reviewed and adapted as needed for ASC use *prior* to new ASC enrollment in NHSN.

### **B. NHSN Enrollment Requires Installation of a Digital Certificate**

Another area of concern is the current requirement for a digital certificate as part of the NHSN enrollment process. ASCs currently using NHSN to meet various State reporting requirements have consistently experienced difficulties with installation of the digital certificate, as the vast majority do not have an information technology department to provide the needed technical support. It is our understanding that CDC plans to transition to a new Secured Access Management System (SAMS), which does not require a digital certificate, prior to beginning enrollment of ASCs new to NHSN following the January 2014 NHSN release. We are pleased to learn of this. However, we remain concerned that various other security requirements flowing from the Federal Information Security Management Act, as amended by the Cybersecurity Act of 2012, and the National Institute of Standards and Technology for accessing government systems, might add their own set of challenges to the enrollment process. These effects have been seen during the recent ASC registration for the Secure QualityNet Portal.

In short, we urge CMS and CDC to allow a generous amount of lead-time combined with extensive education and ample technical support to ensure the success of this step in the process.

### **C. Additional Efforts are Needed Prior to ASC Enrollment in and Use of NHSN**

In light of the many challenges that ASCs faced in registering for and reporting into the QualityNet site this summer, CMS should take the following steps to provide a smooth NHSN enrollment and set-up process for approximately 5000 ASCs:

- Ensure all enrollment, set-up and reporting forms and guidance are appropriate to ASCs to avoid confusion and unnecessary burden
- Ensure all educational materials are ASC-appropriate and available well in advance to ensure that ASCs are prepared to meet all CMS and CDC NHSN requirements
- Ensure all training materials and educational webinars are consistent and accurate to avoid misinformation and confusion
- Allow a generous amount of time for education, enrollment and set-up before the data submission period begins
- Ensure the availability of adequate technical support for ASC users so delays in responding to calls from ASCs for assistance are avoided

The ASC QC has already worked closely with CDC in developing ASC-appropriate materials on other projects, and would be willing to provide assistance with the first two items suggested above.

### **D. Proposed NHSN Data Submission Deadline**

CMS has also proposed that ASCs have until August 15, 2015 to submit their 2014-2015 influenza season data to NHSN. This August 15 deadline is the same as the deadline for the structural measures ASCs must enter via QualityNet. While we recognize this date is not consistent with the deadline for other quality reporting programs that enter data for the influenza vaccination measure via NHSN, and that the proposed date is well beyond the close of the 2014-2015 influenza season, we support the August 15 date. Although it is in its infancy, the ASCQR Program is already quite complex, featuring three different data submission methods for the CY 2016 payment determination. Given this, a consistent data submission deadline could help

minimize potential confusion across the NHSN and QualityNet data entry systems.

**X. Proposed Additional Criterion for Extraordinary Circumstance Waivers or Extensions for CY 2014**

The agency has already established procedures for extraordinary circumstance extension or waiver requests for the submission of information required under the ASCQR Program. CMS is now proposing that, beginning in CY 2014, the agency may grant a waiver or extension to ASCs for data submission requirements if it determines that a systematic problem with one of its data collection systems directly or indirectly affected the ability of ASCs to submit data. CMS is further proposing that, if it makes the determination to grant a waiver or extension, the agency would communicate this decision through a listserv notice and posting via the QualityNet web site. We support these proposals.

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Thank you for considering these comments. We look forward to working with the agency regarding the ASCQR Program. We 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  
Florida Society of Ambulatory Surgery Centers  
Hospital Corporation of America, Ambulatory Surgery Division  
Nueterra Healthcare  
Outpatient Ophthalmic Surgery Society  
Surgery Partners  
Surgical Care Affiliates  
Symbion  
The Joint Commission  
United Surgical Partners International