September 4, 2012

VIA ELECTRONIC SUBMISSION

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1589-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1589-P; Proposed Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

Dear Acting 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-1589-P, Section XVI. Requirements for Ambulatory Surgical Center Quality Reporting (ASCQR) Program (77 FR 45061, July 30, 2012) and the recently released ASC Quality Reporting Specifications Manual, Version 1.0a. 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 the ASC QC's participating 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**. Over 1300 centers, representing more than 20 percent of all Medicare certified ASCs, participated in the most recent report.

We recognize the significant effort the agency has invested in preparing for the implementation of the ASC Quality Reporting Program (ASC QRP). We are grateful to see the

measures we developed included in the program and appreciate the consideration the agency has given to our feedback on implementing a quality reporting system for ASCs. We are pleased to have this opportunity to offer additional insights and recommendations.

I. Educational Materials Regarding the Medicare ASC Quality Reporting Program

In our recent comments to the agency regarding CMS-1588-P, we expressed deep concern regarding the level of awareness surrounding the Medicare ASC QRP in the ASC community as a whole. We are therefore pleased to learn that FMQAI, the CMS support contractor for the ASC QRP, recently sent an educational mailing via FedEx to all Medicare-certified ASCs. This type of direct communication is essential to achieving high levels of initial participation in the program and maximizing the number of ASCs that achieve, or exceed, the minimum threshold for successful reporting. While we were pleased by this direct outreach, we were disappointed that the mailing did not mention the educational webinars regarding the ASC QRP that are scheduled for September 26, 2012. This was certainly a missed opportunity. We urge CMS to take steps to make the webinar available to ASCs that may not become aware of this educational opportunity in time to register and attend. At a minimum, the webinar should be recorded, then posted on both the QualityNet and CMS websites for later viewing.

We are pleased to see the agency has created a page specific to the ASC QRP under the Quality Initiatives section of the cms.gov website. We encourage the agency to continue to expand the resources available at this ASC Quality Reporting webpage, as many in the industry will look to this as a primary source of definitive program information.

We look forward to providing commentary and feedback as CMS continues to expand the ASC QRP resources through additional postings on the QualityNet and CMS websites. We would be happy to provide feedback on these materials prior to their publication.

II. Principles Used in the Selection of Measures for the ASC Quality Reporting Program

A. CMS Principles

CMS has outlined a set of general principles the agency has applied in the selection of measures for inclusion in its other quality reporting programs. While generally sound, we offer the following thoughts on selected items.

The ASC QC supports the alignment of measures across public reporting and payment systems to the extent possible. We believe that the four claims-based outcome measures CMS has adopted under the ASC QRP could be applied to other surgical providers, and encourage CMS to take steps to include these measures in other quality reporting programs. Applying the same facility-level quality measures to all settings offering outpatient surgery expands the comparative data available to Medicare beneficiaries and would represent an important step toward full transparency.

We agree it is important to develop quality reporting programs within the context of national priorities. However, we are concerned by the lack of ASC stakeholder input into the

partnerships that establish priorities and measure applications. ASCs perform approximately 40 percent of *all* surgeries and procedures in the United States – over 22 million each year. Yet there is no direct representation of the industry on either the National Priorities Partnership (NPP) or the Measure Application Partnership (MAP). We believe HHS and CMS should include ASC representation in both partnerships to improve the effectiveness of these entities in formulating priorities for outpatient settings and coordinating efforts across inpatient and outpatient settings.

CMS indicates that it "continuously seek[s] to adopt electronic-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden". We agree that moving toward electronically-specified measures is desirable, but do not believe this is practical for the majority of ASCs in the near term. The use of EHRs in the ASC industry is limited. ASCs were not included in provisions of the American Recovery and Reinvestment Act of 2009 establishing an incentive and penalty program to encourage adoption of health information technology. However, we do strongly encourage CMS to move quickly to allow an EHR reporting option to meet the requirements of the ASC QRP for those ASCs that have implemented EHRs.

Finally, while we support the use of a mix of measure types, we do not believe this should be among the primary considerations for measure selection. We are concerned that a press for measure diversity may lead to the selection of poorly developed measures that have not been adequately tested. For example, the structural measures CMS has selection for inclusion in the ASC QRP – use of a safe surgery checklist and ASC procedure volume – lack carefully developed and tested specifications. Yet their inclusion allows CMS to "check the box" for the structural measure category for the ASC QRP.

B. Additional Principles CMS Should Apply in the Selection of Quality Measures

The ASC QC believes additional considerations should guide CMS in the selection of measures for its quality reporting programs. The following principles are important and should be incorporated into the construct CMS uses: appropriate attribution of accountability, results that are meaningful to the general public, and rigorous measure evaluation and testing prior to implementation. These are described in more detail below.

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. We do not believe it is appropriate to implement physician-level quality measures for non-physician provider types, such as ASCs.

Measures should generate data that is meaningful to the general public. Appropriately selected quality measures must provide information that can be readily understood by the consumer and that can be used in their evaluation of the quality of care offered by the provider. Measures that do not result in clear and helpful data should not be selected.

Whenever possible, measures should be selected from among those endorsed by the National Quality Forum (NQF) through its national multi-stakeholder consensus approval process. While CMS states that consensus among affected parties can be achieved in other ways – including through the measure development process, through broad acceptance and use of the measure, and through public comment – we do not believe these proxies are always equivalent or entirely satisfactory. These alternatives often lack the rigor that characterizes the NQF measure evaluation process and typically bypass the testing that is so essential to the development of a satisfactory quality measure.

III. Measure Topics for Future Consideration

The ASC QC continues to evaluate and develop other potential outpatient surgery quality measures, examining areas such as normothermia, venous thromboembolism, and hospital admission following discharge from an outpatient surgical facility.

We have had a longstanding interest in the development of a patient experience measure for outpatient surgical facilities similar to CAHPS survey tools currently in existence for other providers. We developed a draft survey instrument several years ago, but do not have the resources to complete the necessary testing. We are pleased that CMS has issued a procurement for an ASC CAHPS, and look forward to actively participating in the project.

We are also planning to participate in the Agency for Healthcare Research and Quality's (AHRQ) project that would develop a Surgical Unit-based Safety Program in Ambulatory Surgery (SUSP-AS) to further reduce surgical site infections and other surgical complications. We look forward to providing input regarding several aspects of the project, including the surgical safety checklist and the survey that would assess the culture of safety.

IV. Process for Making Updates to Measures

In its other quality reporting programs, CMS has adopted a subregulatory process for making updates to the measures adopted for each program. We agree that when a national consensus building entity (such as the NQF) updates the specifications for a measure adopted under the ASC QRP that CMS should update its specifications accordingly. These NQF updates typically occur as a result of a measure maintenance process that occurs every several years, although there is an ad hoc process for annual updates. We believe CMS should also look to specification changes made by measure developers/stewards, as these changes can occur any time a change in evidence, consensus standards or other factors merits an update.

For measures that are not endorsed by a national consensus building entity, CMS currently determines when changes are needed, in part, through an internal measure maintenance process involving Technical Expert Panels. We believe relevant ASC clinical and operational expertise should be brought to bear in the review and update of any measures CMS adopts for the ASC QRP that are not endorsed by a national consensus building entity. CMS should ensure the Technical Expert Panel used in its internal, subregulatory maintenance process for such ASC measures includes substantial representation from the ASC industry.

V. Form, Manner and Timing for Claims-Based Measures for Payment Determination for CY 2015 and Subsequent Years

A. Data Completeness Requirements for Payment Determinations for CY 2015 and Subsequent Years

We support the agency's proposal to determine data completeness for claims-based measures for the CY 2015 and subsequent payment determination years by comparing the number of Medicare claims (including Medicare secondary payer claims) meeting measure specifications that contain the appropriate quality data codes (QDCs) with the number of Medicare claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims. With the exception of the inclusion of Medicare secondary payor claims, this is the same method CMS will use to determine data completeness for the CY 2014 payment determination.

B. Data Collection and Processing Period for Payment Determinations for CY 2015 and Subsequent Years

CMS proposes that, in order to be included in the quality reporting data used for the CY 2015 payment determination, claims for services furnished between January 1, 2013 and December 31, 2013 be paid by the administrative contractor by April 30, 2014. As the agency knows, ASCs have up to one year to submit claims for services rendered. We understand the agency's need for lead-time in order to process and analyze quality data, make payment determinations, and supply payment information to administrative contractors, but continue to believe that the proposed period for the collection of claims data is too abbreviated to capture all pertinent data, especially for the outcome measures.

We believe that as the agency gains experience with ASC quality data analysis, and the determination and implementation of any payment adjustments over time, it should seek ways to push the date by which claims must be processed back as close to the one-year mark as possible. For example, for the CY 2016 payment determination, the deadline for claims for services furnished between January 1, 2014 and December 31, 2014 should be pushed back to June 30, 2015, allowing for the capture of as many claims as possible.

VI. ASC Quality Reporting Specifications Manual Version 1.0a

We appreciate the agency's willingness to accept feedback regarding its specification manual for the ASC QRP. We are pleased to see several significant improvements in Version 1.0a, but encourage CMS to make additional changes to improve the clarity and usefulness of the manual as soon as possible.

In addition, there is essential information regarding successful claims-based reporting that has not been included in the manual. We note that for its other quality reporting programs, CMS has used a separate implementation guide to convey this type of information. While the enclosure in the FMQAI letter mentioned above was helpful, we believe CMS should include

this information in the specifications manual, or, if this is not feasible, prepare an ASC implementation guide explaining the mechanics of claims-based reporting and the use of the QualityNet website. ASCs should not have to search through a list of FAQs to try to piece together this essential information. If this information is incorporated into a separate implementation guide, that guide should be posted online at both the QualityNet website and the CMS website.

A. Claims-Based Reporting for Medicare Secondary Payer Patients

Although CMS issued the G-codes for the ASC QRP with the April 2012 HCPCS release, private payers will not have the HCPCS data files for use until January 1, 2013. As a result, private payer claims with QDCs received prior to January 1, 2013, can be rejected for having invalid codes. Recognizing this, CMS determined that only claims where Medicare is the primary payer would be used in the calculation of data completeness for the CY 2014 payment determination. Claims where Medicare is the secondary payer will not be included.

The current specifications manual indicates that data for claims-based measures are to be reported for all Medicare Part B fee-for-service patients, including Medicare Secondary Payer (MSP) patients. To avoid confusion, we believe it is essential CMS clarify the finalized status of MSP claims by explicitly stating that MSP claims will not be included for the October 1, 2012 through December 31, 2012 reporting period. This statement should be included in the "Data Collection and Submission" discussion on page 4 of the manual. This information should also be explicitly stated in the "Reporting Period" section for each of the claims-based measures. This type of information should also be included in the suggested implementation guide referenced above.

B. Instructions for the Use of QDCs G8907 and G8916

CMS has included a page of information regarding the use of QDCs 8907 and G8916 on page 5 of the specifications manual. For those who are not well acquainted with the measures and their corresponding codes, this section of the manual is confusing. More explanatory context is needed for this information to be as helpful as possible. First-time users are likely to be confused by the references to measure numbers without their corresponding titles, by statements that reference outcome measures without stating what those outcome measures are, and by references to "four of the five claims-based outcomes measures" (there are only four claims-based outcome measures).

Users are also likely to be confused by seemingly contradictory statements regarding the use of G8918. In one sentence the manual states, "CMS requires all facilities to report on the ASC-5 measure for all Medicare fee-for-service patients, *even if there is no indication for or order for perioperative antibiotics* (G8918)" (emphasis added). In the very next sentence the manual states, "IMPORTANT: *For surgical patients with an order for prophylactic antibiotics*, information on the fifth measure, Prophylactic IV Antibiotic Timing, will be reported separately" (emphasis added).

C. Prophylactic Intravenous (IV) Antibiotic Timing (ASC-5)

The ASC QC developed five of the measures that have been adopted for claims-based reporting. For each of the four claims-based outcome measures, CMS has included a statement following the "Clinical Recommendation Statements" that directs the user to the ASC QC website for additional information: "Additional information and resources, such as sample data collection forms and frequently asked questions (FAQs) about the measures, can be found on the ASC Quality Collaboration website at **www.ascquality.org**." We believe it would be helpful to include the same statement in the specifications for this process measure.

D. Safe Surgery Checklist Use (ASC-6)

In our comments to the agency regarding CMS-1588-P, we noted that Version 1.0 of the Specifications Manual for the Safe Surgery Checklist Use measure indicated ASCs were to report whether a safe surgery checklist based on accepted standards of practice was used "*at any time during the designated period*" (emphasis added). This was a change from the agency's previous statement finalizing the measure in CMS-1525-FC, which indicated "an ASC would report whether their facility employed a safe surgery checklist that covered each of the three critical perioperative periods *for the entire calendar year of 2012*" (emphasis added). CMS staff advised that it was the agency's intent to measure use of a safe surgery checklist at any time during the performance period. We note that Version 1.0a of the manual now indicates that ASCs are to report whether a safe surgery checklist based on accepted standards of practice was used "*during the designated period*" (emphasis added), a change which deletes the phrase "at any time".

We are pleased CMS has confirmed that, for the initial year of data collection, an ASC may answer "Yes" if the checklist is used at any time during calendar year 2012. In subsequent years the checklist must be utilized for the entire year in order to answer affirmatively. This incremental implementation is a fair approach given that many ASCs are just now becoming aware of ASC QRP requirements. Given that this information is essential to correct interpretation and reporting for this measure, we believe it must be included in the specifications manual itself, not just in a list of questions and answers on the QualityNet website. We urge the agency to ensure the specifications manual is updated timely to include this information.

E. ASC Facility Volume on Selected ASC Surgical Procedures (ASC-7)

CMS finalized the structural measure ASC Facility Volume Data on Selected ASC Surgical Procedures for the CY 2015 payment determination. When originally proposed, this measure was poorly specified. Although improvements were made in Version 1.0 of the Specifications Manual, we noted in comments to the agency regarding CMS-1588-P that there were still many pertinent details lacking. We hoped to see further clarification in this revision of the manual, but none are apparent. We believe it is essential for CMS to take steps to offer the necessary clarification as soon as possible.

As we noted in the past, the measure specifications are not sufficiently detailed to allow consistent preparation of procedure counts across different ASCs. There are several questions CMS should address 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 thirty-four (34) subcategories, or both? 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? These types of questions should be addressed as soon as possible to allow ASCs to prepare for data reporting.

VII. Additional Considerations

CMS has stated its intent to issue proposals pertaining to other aspects of the ASC QRP in future rulemaking. We offer the following comments regarding selected topics as the agency develops these additional proposals and refines existing policies.

A. Exemptions for Low Volume or No Volume

Case mix across ASCs is very diverse. As a result, situations arise when selected measures are not applicable to the case mix of an individual ASC. In circumstances where a measure would never, or very rarely, apply to an ASC, CMS should create appropriate low volume or no volume exemptions to reduce provider burden. Measure ASC-5, Prophylactic Intravenous (IV) Antibiotic Timing, is an example of a measure that does not apply to all ASCs. 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.

CMS has determined that it will not offer an exemption for this measure. 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 unnecessary burden for ASCs that do not administer prophylactic IV antibiotics for SSI. We strongly recommend CMS reconsider the issue of exemptions for this measure. ASCs that do not administer IV antibiotic prophylaxis for SSI could claim an exemption through their QualityNet account.

B. Alternative Reporting Mechanisms

The ASC QC remains convinced CMS should allow ASCs to meet the quality data reporting requirements under the ASC QRP using registry-based reporting as an alternative to the other mechanisms CMS has outlined for ASC use through CY 2016. We note that CMS has provided physicians with several data reporting options under PQRS and believe this flexibility should be extended to ASCs as well.

The ASC QC has a strong interest is developing an ASC-specific registry. It would be very helpful to our progress if CMS would provide some guidance as to whether or not registry-based reporting will be an option for ASCs in the future. It is our intent that the registry would collect data from participating ASCs on a broad variety of quality measures, including measures

CMS has adopted under the ASC QRP. We anticipate this registry would collect quality measure data for all patients, regardless of payment source.

While we do not have a definitive timeline for our registry development project at this time, we are aware of other registries already in operation. Examples include the GIQuIC and Ophthalmic Patient Outcomes Database registries, which may currently be used to satisfy PQRS reporting requirements. We believe these registries are potential avenues for ASC registry-based reporting if this alternative becomes available under the ASC QRP.

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. Absent an indication from CMS that it will accept EHR-based reporting, there is little incentive for EHR vendors to incorporate ASC measures into their products.

C. Publication of ASC Quality Reporting Program Data

The ASC QC supports transparency and welcomes a fair presentation of ASC quality data that could assist consumers in making informed health care decisions. Consumers should be able to access this information on websites that are organized to allow easy comparisons across facilities that offer outpatient surgical services, while also protecting the rights of providers by assuring that the information made available is correct, current, and clearly presented.

ASCs should have an opportunity to preview any data before they are made public. In conjunction with the preview materials, CMS should provide contact information for program content areas experts that ASCs can contact to ask questions or raise concerns with any information prior to its publication. There should also be a provider narrative section for each provider-specific item presented to the consumer. This narrative box would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented. In addition to reporting quality data, other useful information such as facility accreditation status should be made available to the consumer.

In addition, the site displaying ASC quality data should provide the consumer with basic information regarding each measure, including guidance that would assist the consumer with interpretation of the measure data and its appropriate use in decision-making.

We look forward to the more detailed proposals on the publication of ASC quality program data in later rulemaking. We are particularly interested in the agency's plans for determining the threshold at which data for centers with low Medicare volume should be deemed unreliable, and therefore unsuitable for public reporting.

D. Feedback and Benchmarking

Following the end of each the reporting periods, CMS should provide confidential feedback reports based on the quality measures reported by individual ASCs for services

provided during the reporting period. These reports should address topics such as measure participation, data completeness, QDC submission errors and measure performance detail.

In addition to its use for public reporting purposes, the data collected through the ASC QRP should also be made available to participating ASCs for benchmarking purposes. We urge CMS to develop a process for establishing ASC benchmarks on a measure-by-measure basis. This information would be valuable as individual ASCs assess their performance relative to their peers and determine if performance improvement activities are needed. The Hospital-Specific Reports (HSRs) CMS currently prepares for individual hospitals participating in the Hospital IQR program could serve as a model.

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Thank you for considering these comments. We look forward to continuing our dialogue with the agency regarding the ASC QRP. 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
Health Inventures
Hospital Corporation of America, Ambulatory Surgery Division
Nueterra Healthcare
Outpatient Ophthalmic Surgery Society
Surgical Care Affiliates
Symbion
The Joint Commission
United Surgical Partners International