

June 25, 2012

VIA ELECTRONIC DELIVERY

Marilyn Tavenner, Acting Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1588-P Room 445-G Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

Re: CMS-1588-P; Proposed Quality Reporting Requirements for Ambulatory Surgical Centers (ASCs)

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-1588-P, Section VIII.E. Proposed Quality Reporting Requirements for Ambulatory Surgical Centers (77 Fed. Reg. 27870, May 11, 2012) and the related ASC Quality Reporting Specifications Manual, Version 1.0. The ASC Quality Collaboration'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 also appreciate the consideration the agency has given to our prior comments on various aspects of the ASC QRP

and are pleased to have this opportunity to provide additional insights, feedback and recommendations regarding the program.

I. ASC Awareness of the Medicare ASC Quality Reporting Program Must Be Improved

We believe, based on our experience at industry meetings and other events, that a significant number of ASCs remain unaware of the Medicare ASC QRP and its requirements. The ASC QC and other ASC industry organizations are committed to continuing our efforts to improve awareness. However, we believe that CMS should also step-up its efforts to inform ASCs about the ASC QRP and its requirements. Traditional outreach methods, such as the Medicare Learning Network's MLN Matters articles, CMS's webpage for ASCs, and its ASC listserv have a limited following in the ASC community as a whole.

On the other hand, ASCs are very likely to be aware of and respond to communications that reach them through their Medicare administrative contractors. We strongly recommend that CMS prepare an ASC communication that would be disseminated through its administrative contractors in order to achieve as wide an educational outreach as possible. This communication should alert ASCs to the imminent implementation of the program and the consequences of non-participation. It should invite ASCs to participate in a CMS-sponsored National Provider Call and direct ASCs to resources for detailed information regarding the ASC QRP. These resources should be accessible online at the QualityNet site. We also believe it would be helpful if CMS created a page on the cms.gov website devoted to the ASC QRP, similar to the Physician Quality Reporting System (PQRS) page it has created within its Quality Initiatives pages. Detailed resources posted here should include an explanation of program requirements and responses to frequently asked questions (FAQs) about the ASC QRP.

We would be happy to provide input and/or feedback on the content of the direct communication and the resources CMS develops to support the ASC QRP. We believe such efforts are crucial and will improve participation rates, in addition to boosting the number of ASCs that achieve, or exceed, the minimum threshold for successful reporting.

II. Proposed Quality Reporting Requirements for ASCs

A. Proposed Minimum Thresholds for Claims-Base Measures Using QDCs

We generally support the agency's proposal to set the threshold for successful reporting for the CY 2014 and 2015 payment determinations at a level of at least 50 percent of Medicare fee-for-service claims. However, an issue has arisen with claims submission testing related to Medicare secondary payer (MSP) claims. Although CMS issued the G-codes for the ASC QRP with the April 2012 HCPCS release, private insurers will not have the files for use until January 1, 2013. We appreciate the agency's plans to exempt ASCs from reporting G-codes on MSP claims from October 1, 2012 through December 31, 2012. We believe these secondary claims should be excluded from the population of claims considered in the determination of data completeness for the CY 2014 payment determination.

B. Data Collection and Processing Period for CYs 2014 and 2015 Payment Determinations

CMS proposes that, in order to be included in the quality reporting data used for the CY 2014 payment determination, claims for services furnished between October 1, 2102 and December 31, 2012 be paid by the administrative contractor by April 30, 2103. As the agency knows, ASCs have up to one year to submit claims for services rendered. While 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, we believe that the proposed period for the collection of claims data may be too abbreviated to capture all pertinent data, particularly 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, CMS could propose that, for the CY 2015 payment determination, claims for services furnished between January 1, 2013 and December 31, 2013 be processed by June 30, 2014, allowing for the capture of as many claims for services as possible.

C. Proposed Reconsideration Timeline

CMS proposes to implement a reconsideration process for the ASC Quality Reporting Program that is modeled on the reconsideration process it has implemented for its hospital quality reporting programs. Included is a proposal that ASCs submit a reconsideration request by March 17 of the affected payment year. This proposal is based on claims processing guidelines that allow Medicare administrative contractors 30 days to process clean claims, and 45 days to process claims other than clean ones. March 17 was chosen because it falls 45 days after January 31.

We do not believe this is a sufficient period of time for a number of reasons. First, the proposed March 17 date appears to assume that all ASC claims are submitted on the same day as the date of service. While this sometimes happens, it is more often the case that the claim is submitted within a period of several days following the date of service. In addition, the month of January already brings other reimbursement changes that result from the Medicare ASC payment update for each calendar year. The proposed timeframe allows very little time for ASCs to analyze the full complement of their January payments from Medicare and determine the cause of any deviation from the expected payment (there are other issues that could universally drop payments, such as a downward adjustment of a local wage index), and subsequently prepare the reconsideration request, including copies of all the claims at issue – which could be a substantial number of claims depending on the Medicare beneficiary volume at the ASC.

We strongly recommend CMS allow ASCs until April 15 of the affected payment year to submit a request for reconsideration. This timeframe allows a number of days to pass between the beneficiary date of service and claim submission, allows sufficient time for ASC analysis of January claims, and allows a more reasonable amount of time for the preparation of the request

for reconsideration, including gathering and copying the necessary supporting claims documentation.

III. ASC Quality Reporting Specifications Manual

A. Prophylactic Intravenous Antibiotic Timing Measure (ASC-5)

As we have stated in comments to the agency in the past, case mix across ASCs is very diverse and should be considered when establishing reporting requirements for individual measures. The Prophylactic Intravenous (IV) Antibiotic Timing measure is an example of a measure that would not apply to all ASCs. For example, single specialty ASCs that provide gastrointestinal endoscopies do not administer IV prophylaxis for the prevention of surgical site infection (SSI). In addition, 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 these ASCs and plans to require those facilities to submit G8918 on all their claims. We continue to believe that this approach imposes unnecessary burden for ASCs that do not administer prophylactic IV antibiotics for SSI. We recommend CMS reconsider the issue of "no volume" exemptions for this measure. The agency could develop a G-code to be submitted once annually by ASCs that do not administer intravenous antibiotic prophylaxis for SSI. This code would allow the ASC to claim an exemption from data submission for this measure. Another alternative would be to allow ASCs that do not administer IV antibiotic prophylaxis for SSI to claim an exemption through their QualityNet account.

Absent the creation of such an exemption, we recommend that CMS clarify the need for all centers to report on this measure through explicit statements in the Specifications Manual. We believe it would be helpful to develop a heading (similar to the existing "Reporting Mechanism", "Description", and "Denominator" headings, for example) titled "Who is Required to Report", or some similar phrase. Under this heading, CMS would indicate that all ASCs are required to report. In addition, we believe it would be helpful to include a statement under the coding options heading that makes it explicit that G8918 should be used to report on this measure when the patient is excluded from the measure denominator.

B. Safe Surgery Checklist Use (ASC-7)

We note that the Specifications Manual for the Safe Surgery Checklist Use measure asks ASCs to indicate whether the center used a safe surgery checklist based on accepted standards of practice "at any time during the designated period" (emphasis added). This is a change from the agency's previous statement finalizing the measure in CMS-1525-FC, in which it 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). We appreciate the flexibility the agency has shown in relaxing the requirements for this measure for the initial year of reporting.

As we stated in previous comments, it is our understanding that the agency intends to apply this measure to all ASCs, including centers that perform procedures. We continue to believe the agency should revise the descriptive statement of the measure so this intent is clear. We suggest the agency refer to the checklist as a "safe surgery/procedure checklist" and modify its statement of the measure's purpose to make explicit that the purpose is to assess whether ASCs are using a safe surgery/procedure checklist that addresses effective communication and helps ensure that safe practices are being performed at three critical perioperative *or* periprocedural periods: prior to the administration of anesthesia or sedation, prior to incision or the beginning of the procedure, and prior to the patient leaving the operating or procedure room.

Absent this suggested revision, we recommend that CMS clarify the need for all centers to report on this measure through explicit statements in the Specifications Manual. As we have suggested above for the Prophylactic Intravenous Antibiotic Timing Measure, we believe it would be helpful to develop a heading titled "Who is Required to Report", or a similar phrase. Under this heading, CMS should indicate that all ASCs are required to report.

C. ASC Facility Volume on Selected ASC Surgical Procedures (ASC-6)

CMS has 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. We appreciate the improvements that the current Specifications Manual has made as compared to the original description of the measure, but find that there are still many pertinent details lacking.

There is a good deal of legitimate confusion surrounding how ASCs are to develop the "aggregate count" of selected procedures in each of the categories and subcategories that CMS has specified for the measure. The measure specifications are not sufficiently detailed to allow for consistent preparation of procedure counts for reporting. There are several questions CMS should address in order to create clear specifications and ensure consistent data collection 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 either before or after the administration of anesthesia (e.g., those services that are submitted using a -73 or -74 modifier appended to the service code)? These types of questions should be addressed as soon as possible to allow ASCs to prepare for implementation.

D. Appendix A

The last paragraph of Appendix A to the Specification Manual states, "Additional information and resources, such as sample data collection sheets or logs and frequently asked questions (FAQs) about the measures, can be found on the ASC Quality Collaboration website at www.ascquality.org." While the reference to the ASC QC is appreciated, this implies that the ASC QC is a source of this type of information for **all** of the measures presented in the Manual, when in fact, we are only in a position to provide supplemental materials and information for the

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measures we have developed and for which we serve as the measure steward. Accordingly, we request that this statement be removed from Appendix A and that the agency instead include a similar statement at the end of each of the sections of the Manual that address measures developed and maintained by the ASC QC:

- 1. Measure Title: Patient Burn
- 2. Measure Title: Patient Fall
- 3. Measure Title: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- 4. Measure Title: Hospital Transfer/Admission
- 5. Measure Title: Prophylactic Intravenous (IV) Antibiotic Timing.

We suggest the statement be a minor modification of the one now included at the end of Appendix A: "Additional information and resources, such as sample data collection sheets and/or logs, and frequently asked questions (FAQs) about this measure, can be found on the ASC Quality Collaboration website at www.ascquality.org."

IV. 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. We anticipate providing additional feedback on a broader range of topics in response to the upcoming CY 2013 OPPS/ASC proposed rule.

A. Alternative Reporting Mechanisms

As stated in the past, the ASC QC believes 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 in developing an ASC-specific registry. While we do not have a definitive timeline for a 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 have the potential for use in data collection and reporting from selected GI and ophthalmic ASCs as well.

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

B. Publication of ASC Quality Reporting Program Data

The ASC QC supports transparency and welcomes a fair presentation of ASC quality and cost information 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.

CMS should provide ASCs an opportunity to preview any data to be made public, in addition to providing 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 regarding its interpretation and use in decision-making. For example, the ASC QC's webpage presenting the public report of quality data for the ASC QC's measures includes the following information regarding the Hospital Transfer/Admission measure (ASC-4):

"Hospital Transfer/Admission

ASCs provide surgical services to patients not requiring hospitalization. Therefore, ASCs screen patients referred to their facilities to ensure they can be safely cared for as an outpatient.

The frequency of ASC admissions experiencing a transfer or admission to a hospital upon discharge from participating ASCs is shown below as a rate per 1000 admissions. Not all conditions requiring a hospital transfer or admission result from the care the patient received in the ASC, nor can all medical conditions requiring a hospital transfer or admission be anticipated in advance. Therefore, some level of hospital transfer or admission is expected."

We believe that a similar narrative should be provided for each measure that is presented for public reporting.

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.

C. 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

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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.

Thank you for considering these comments. In closing, we wish to emphasize what we believe is a critical need for CMS educational outreach to all ASCs in order to encourage participation in the ASC QRP.

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