ASC Quality Collaboration

October 5, 2020

VIA ELECTRONIC SUBMISSION

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re CMS-1736-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma:

Please accept the following comments from the ASC Quality Collaboration (ASC QC) regarding CMS-1736-P (85 FR 48772, August 12, 2020) Section XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. The ASC QC is a non-profit organization dedicated to advancing quality measurement and public reporting in ambulatory surgery centers (ASCs) through a collaborative effort of ASC stakeholders. These stakeholders include leaders from ASC management companies, industry associations, professional physician and nursing associations, accreditation organizations, and information technology companies (please see Appendix A to this letter for a complete listing). Collectively, these organizations represent over 1,500 ASCs.

The ASC QC appreciates the ongoing effort the agency devotes to the ASCQR Program, the steps it has taken to make improvements, and its willingness to consider how to balance promoting quality measurement and reporting with the associated administrative and financial burdens.

I. Requirements Regarding QualityNet Account and Security Administrator

Currently, the term "security administrator" refers to the individual(s) who have responsibility for an ASC's QualityNet account management requirements and security. CMS has proposed to use the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. This proposed change in terminology would not change the responsibilities of the individual(s), only the title of the individual(s).

We think the term "security administrator" is sufficient to denote the exercise of authority. The individual who is the administrative leader of an ASC is often called the "Administrator", so this term already conveys exercise of authority to those who work in ASCs. We believe a change would cause more confusion than it is worth.

II. ASCQR Program Data Submission

CMS currently uses the phrases ''data collection period'' and ''data collection time period'' interchangeably in its codified statement of policies regarding the ASCQR Program at 42 CFR 416.310. The agency is proposing to use one consistent phrase to help avoid potential confusion.

We agree that using one consistent phrase, namely "data collection period", would be helpful. We support the change.

III. ASCQR Program Data Submission Deadlines

The ASCQR Program has established submission deadlines but no policy for deadlines falling on nonwork days. CMS has proposed that all program deadlines falling on a nonwork day be moved forward. Specifically, all deadlines occurring on a Saturday, Sunday, legal holiday, or on any other day that is a nonwork day for federal employees would be moved to the first day thereafter which is not a Saturday, Sunday, legal holiday, or a nonwork day for federal employees.

We support this proposal and its codification. However, it would be helpful for the agency to continue to publish the revised deadline when the routinely established deadline falls on a nonwork day.

IV. Proposed Review and Corrections Period for ASCQR Program Data Submitted via QualityNet

ASCs currently submit data for applicable measures to QualityNet from January 1 through May 15 during the calendar year subsequent to the data collection period. (For example, ASCs recently collected measure data from January 1 through December 31, 2019 and submitted this data to CMS from January 1 through May 15, 2020.) ASCs are encouraged, though not required, to submit data early so they can identify errors and resubmit data before the deadline.

CMS is proposing to create a review and corrections period that would run concurrently with the data submission period. During this review and corrections period, ASCs could enter, review, and correct data submitted to CMS. However, after the submission deadline, ASCs would not be allowed to change these data. A similar review and corrections period is being proposed for the Hospital OQR Program.

We support this proposal and its codification. It would allow errors to be readily corrected and give ASCs wishing to review their data prior to a submission deadline an opportunity to do so.

V. Measures for Consideration for Future Inclusion in the ASCQR Program

In this proposed rule, the agency has invited public comment on new measures that address quality of care in ASCs. The agency is also inviting comment regarding additional measures that could facilitate comparison of care provided in ASCs and hospitals.

A. Suspended ASCQR Program Measures Should Be Reinstated

At present, there are four ASCQR Program measures that are suspended pending further action in future rulemaking: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission. CMS is considering updating the data submission method for these measures by moving from the past method of placing Quality Data Codes (QDCs) on individual Medicare claims to having ASCs submit aggregate data to QualityNet.

We urge the agency to take action to reinstate the reporting of these four measures via QualityNet.

In the past, other commenters have raised concerns about the burden of QualityNet reporting. However, reporting these measures via QualityNet will not increase burden. Centers that elect to participate in the ASCQR Program already report other measures using QualityNet. Reporting data for additional measures adds very little burden. In truth, reporting aggregate data to QualityNet is far less burdensome than putting QDCs on every Medicare claim – a process which often delays the billing cycle while care outcomes for individual patients are verified. Therefore, we anticipate that reporting ASC-1 through ASC-4 to QualityNet would actually reduce the overall reporting burden for these measures.

In past proposals, CMS has sought comment on the potential adoption of these four measures for the Hospital OQR Program. These measures are straightforward and could readily be applied to other outpatient surgical settings, including Hospital Outpatient Departments (HOPDs). Expanding the adoption of these measures to the Hospital OQR Program would significantly expand the alignment of measures between the Hospital OQR and ASCQR Programs and would allow consumers more opportunities to compare quality and safety across settings of care.

The agency has adopted measures across CMS quality reporting programs on several occasions. In prior rulemaking, CMS identified measures that were not specified for or tested in the ASC setting and finalized them for inclusion in the ASCQR Program. Examples of these actions include the adoption of the Safe Surgery Checklist Use, ASC Facility Volume on Selected ASC Surgical Procedures, Influenza Vaccination Coverage Among Healthcare Personnel, Improvement in Patient's Visual Function within 90 Days of Cataract Surgery, Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients, and Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps measures. Therefore, it's clear CMS is able to take measures not originally specified for the HOPD setting and adopt them for inclusion in the Hospital OQR Program.

Although ASC-1 through ASC-4 are currently specified for the ASC setting, it would not be problematic to modify them so they could also apply to the hospital outpatient setting. As the

measure developer for all four, we can assure you these measures could be readily adapted to allow their application to both types of surgical facilities. In fact, we are aware of HOPDs that already use these measures to collect data for their own internal quality programs.

These four measures address an important Meaningful Measure Initiative quality priority - Making Care Safer by Reducing Harm Caused in the Delivery of Care. All four measures are easy to understand and provide information that healthcare consumers care about. ASC-1, ASC-2 and ASC-3 pertain to serious reportable events and are critical to ensuring patients are protected from harm while receiving care. These measures could be a valuable addition to the Hospital OQR Program, which currently does not include these types of measures, to allow patients better insight into hospital safety. While some cite the low occurrence of these events as an obstacle, the fact remains that they are classified as seriously reportable events and any occurrence should be publicly reported. Further, it has always been the goal of patient safety experts to drive the numbers of these "never events" to zero. ASCs had been publicly reporting these events for several years prior to the recent suspension of reporting. There is no reason that hospitals cannot be similarly transparent.

ASC–4: All-Cause Hospital Transfer/ Admission is a measure that allows stakeholders to better understand how often the patient returns home, as expected, following elective surgical procedures. We believe patients would appreciate the opportunity to understand how often patients admitted to HOPDs for elective outpatient surgery return home, as opposed to being admitted for an observation or inpatient stay. The Hospital OQR Program does not currently include a measure of this type.

There is little burden associated with collecting and reporting data for these measures. The events captured by ASC-1, ASC-2, ASC-3 and ASC-4 are essential to assuring quality and safety in the outpatient surgical setting. Data for these measures is routinely collected in the course of day-to-day clinical operations.

All four measures have been NQF endorsed in the past and had gone through several maintenance of endorsement cycles. As the measure developer and steward, we decided not to submit the measures for additional reconsideration of endorsement cycles. There had not been any changes to the evidence base, scientific acceptability or other NQF criteria, so we felt our limited resources would be better used developing new measures. As a result, the ASC QC allowed NQF endorsement to lapse. Endorsement was not removed because the measures were submitted and failed the endorsement maintenance process. And as you well know, NQF endorsement is not required for the adoption of program measures.

B. Measures Already Proposed for Inclusion in the ASCQR Program Should Be Adopted

We encourage CMS to adopt two previously proposed measures that have already been through the Measure Applications Partnership (MAP) review process and are eligible for inclusion in the ASCQR Program: the Toxic Anterior Segment Syndrome Measure and the Ambulatory Breast Procedure Surgical Site Infection Outcome Measure. CMS should also consider including these

measures in the Hospital OQR Program.

1. Toxic Anterior Segment Syndrome Measure

The ASC QC is the measure developer and steward for the Toxic Anterior Segment Syndrome (TASS) measure, which assesses the number of patients diagnosed with TASS within two days of undergoing anterior segment surgery in the ASC. The ASC QC developed this measure to fulfill a need to assess complications associated with frequently performed ophthalmic surgeries in ASCs. This measure aligns well with the CMS Meaningful Measures Initiative as a measure of preventable healthcare harm.

The number of anterior segment surgeries performed in ASCs is enormous, numbering in the millions each year, with that number expected to grow as the population ages. Studies in the literature have reported TASS complication rates of 1.8 to 2.1%, pointing to a significant opportunity for improvement.

Eye professionals agree that efforts should be focused on the prevention of TASS. The American Society of Cataract and Refractive Surgery and American Society of Ophthalmic Registered Nurses have published recommended practices for cleaning and sterilizing intraocular surgical instruments aimed at the prevention of TASS. These recommended practices were developed with guidance from AORN, APIC, SHEA, CDC and the FDA. In addition, the American Academy of Ophthalmology (AAO), American Society of Cataract and Refractive Surgery (ASCRS), and the Outpatient Ophthalmic Surgery Society (OOSS) have released recommendations regarding the use of enzyme detergent for cleaning intraocular surgical instruments. Inclusion of the TASS measure in the ASCQR Program will help promote these recommended practices.

The measure has been fully tested in the ASC setting and is currently in use as part of our online public report of ASC quality data. The measure was reviewed by the MAP and received conditional support pending endorsement by the National Quality Forum (NQF). NQF endorsement is not necessary because the statutory requirement that measures reflect consensus among affected parties was met through our collaboration within the ASC industry, as well as our inclusion of the AAO, ASCRS, and OOSS in the review of the measure early in the development process.

Although some have asserted that data for the TASS measure is difficult to collect and that ASCs would not be notified if TASS were diagnosed outside of the facility, the experience of our members indicates this is not the case. Centers performing anterior segment surgery monitor this outcome closely due to its severity. Data regarding TASS outcomes is routinely collected and each of these events is thoroughly investigated. The measure is not difficult to implement because centers performing ophthalmic surgery already collect this data. As noted above, the large number of anterior segment surgeries makes this a very important outcome of which patients should be aware. We encourage CMS to adopt this measure and the submission of aggregated measure data via QualityNet in the next rulemaking cycle.

2. Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure

The Ambulatory Breast Procedure Surgical Site Infection Outcome measure was developed by the Centers for Disease Control and Prevention (CDC). This measure assesses the risk-adjusted Standardized Infection Ratio for SSIs for adult patients following breast procedures conducted at ASCs. The measure compares the reported number of SSIs observed at an ASC with a predicted value based on nationally aggregated data.

The ASC QC and the Colorado Department of Public Health collaborated with CDC in the adaptation and testing of this measure in the ASC setting. It would fill an important gap in the ASCQR Program related to healthcare-associated infections. The measure is fully developed, was tested specifically in the ASC setting, and is currently being used in several State-based quality reporting programs. We support the inclusion of this measure in the ASCQR Program in the future and recommend that CMS adopt the measure in the next rulemaking cycle.

If the SSI measure were to be adopted for the ASCQR Program, it is possible measure data would be reported via CDC's NHSN. In the past, ASC measure data submitted to NHSN was collected at the CCN level, whereas all other ASCQR Program measure data is reported to CMS at the NPI level. Implementing NPI level data collection and reporting is needed to fully support consumers in their decision-making. In the past, CDC has indicated its willingness to consider changing from a CCN-based approach to an NPI-based approach. Making this change prior to implementing the Ambulatory Breast Procedure Surgical Site Infection Outcome measure would be helpful. CMS should work with CDC to implement NPI-based data collection in NHSN for ASCs.

VI. Measures for Consideration for Both the ASC and HOPD Settings

In this proposed rule, the agency has also invited public comment regarding additional measures that could facilitate comparison of care provided in ASCs and hospitals.

The ASC QC supports the adoption of additional measures for the ASCQR Program and Hospital OQR Program when types of services overlap and when the measures have been specified in a manner that would allow direct comparisons to be made. With additional development, ASC-1 through ASC-4, ASC-13: Normothermia, ASC-14: Unplanned Anterior Vitrectomy, the Toxic Anterior Segment Syndrome Measure and the Ambulatory Breast Procedure Surgical Site Infection Outcome Measure could be used by both ASCs and hospitals. These measures are all based on clinical data routinely collected by health care facilities.

We also support the use of the OAS CAHPS survey measures for ASC and HOPD settings. The OAS CAHPS survey and measures are specified in a manner that allows direct comparisons to be made. However, because the OAS CAHPS survey is expensive to implement, we encourage CMS to continue to delay adoption of the OAS CAHPS-related measures until the healthcare system has had an opportunity to fully recover from the effects of the COVID-19 pandemic. Please note that, as in the past, our support for the implementation of the OAS CAHPS survey

measures is contingent upon the adoption of options for web and IT based survey modes in addition to traditional mail and telephone survey modes.

On the other hand, there are measures currently in the Programs that cannot be used to make comparisons. CMS has recently characterized certain ASCQR and Hospital OQR Program measures based on data mined from Medicare claims as "aligned". These measures include Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (ASC-19) and Hospital Visits after Hospital Outpatient Surgery (OP-36). As CMS knows, the types of services evaluated by ASC-19 ("general surgery") are not the same as the types of services evaluated by OP-36 ("general surgery", orthopedic surgery and urologic surgery), and therefore the measures are not aligned.

CMS has also characterized Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (ASC-12, OP-32) as "aligned". However, it is precisely because ASC-12 and OP-32 are based on Medicare claims that it is not possible to fully align the two measures. The measure methodology reflects inherent differences in Medicare claims and billing policies for ASCs and HOPDs. When ASC-12 is used to compare ASCs to other ASCs and OP-32 is used to compare HOPDs to other HOPDs, these claims differences do not result in unfair bias. However, these measures do *not* allow comparisons to be made across the two sites of service. This is because the measure methodology systematically undercounts HOPD outcomes vis-à-vis ASC outcomes. Therefore, we *emphatically object* to the use of measures that are based on Medicare claims data as the basis for ASC to HOPD comparisons.

There are a number of reasons that using Medicare claims has a significant impact on the accuracy of measure results in the HOPD setting and precludes valid comparisons between ASCs and HOPDs. These include the following:

A. The Medicare Three-Day Payment Window Policy

Medicare's three-day payment window policy requires that outpatient services provided by a hospital, or any Part B entity wholly owned or wholly operated by a hospital, *on the date of a beneficiary's inpatient admission* must be billed with the inpatient stay. In addition, outpatient services provided by a hospital, or any Part B entity wholly owned or wholly operated by the hospital, *on the first, second, and third calendar days preceding the date of a beneficiary's inpatient admission* are also deemed related to the admission, and must be billed with the inpatient stay. Part B entities affected by this policy include HOPDs, hospital emergency departments and wholly owned physician practices. This policy creates a major obstacle to identifying index HOPD visits, and therefore subsequent "hospital visits" related to HOPD care.

Simply stated, CMS does not permit HOPDs to generate a claim when there is an inpatient admission during the three-day window following the HOPD service, except in cases where the service was therapeutic and the hospital attests that the subsequent admission was unrelated. *HOPD claims that do not exist cannot be counted*. As a result, these measures cannot directly identify inpatient admissions that may have resulted from services performed in the HOPD setting when those unplanned admissions occur on the date of the service, or during the three

days subsequent to the service. The measures can only directly identify hospital visits occurring on days 4, 5, 6 and 7 following the index HOPD visit; index claims for days 0, 1, 2 and 3 *would not be created*, and therefore cannot be counted.

B. Attempts to Count HOPD Measure Outcomes Indirectly on Days 0-3 Are Flawed

ASCs are not subject to the three-day payment window policy. Identifying ASC Medicare claims is straightforward. As a result, ASC-12 and ASC-19 identify ASC facility services *directly*, using ASC facility claims. HOPD services for OP-32 and OP-36 during the three-day payment window are identified *indirectly, using physician claims.* Place of service (POS) coding on these physician claims is used to establish the HOPD site of service. Specifically, the measure algorithm looks for physician claims with POS coding indicating an HOPD setting that 1) also have an inpatient admission within three days and 2) lack a corresponding HOPD facility claim.

Unfortunately, POS coding on physician claims has a long history of high error rates. The Department of Health and Human Services Office of Inspector General has performed repeated audits of physician POS coding that consistently demonstrate that physician claims underrepresent the hospital site of service. These errors result in physician claims that indicate the service was performed in the physician's office, when in fact the service was actually performed in a hospital outpatient department or an ASC. See, as some examples of many such OIG reports over the years: A-02-04-01010 (error rate 88%), A-05-04-00025 (error rate 79%), A-06-04-00046 (error rate 76%), A-01-06-0052 (error rate 81%), A-01-09-00503 (error rate 90%) and A-01-10-00516 (error rate 83%). *Errors in POS coding are not an isolated, infrequent or insignificant problem*. As a result, HOPD measure outcomes during the three-day payment window are systematically undercounted.

It's also important to realize that those physicians whose practice is wholly owned by a hospital are also bound by Medicare's three-day payment window policy as noted above. This means that in cases in which the physician who performs an HOPD service is in a practice wholly owned by the hospital, there will not be a physician claim if there is an inpatient admission on days 0-3. When the physician claim does not exist, there is absolutely no possibility of identifying the HOPD service. Many physicians are employed by hospitals and hospital systems, which means the absence of a physician claim is not an isolated, infrequent or insignificant occurrence either.

C. Denominator Exclusions Are Not Applied to Both Settings

OP-32 and OP-36 exclude HOPD services for patients who have an ED visit on the same day but billed on a separate claim, unless the ED visit has a diagnosis indicative of a complication of care. The measures also exclude HOPD services that are billed on the same hospital outpatient or inpatient claim as an ED visit, unless the ED visit has a diagnosis indicative of a complication of care. This is because the sequence of events in these cases is not clear. However, no exclusion is made in ASC-12 and ASC-19 when an ASC visit and an ED visit are billed on the same day although the sequence of events is also unclear.

D. Different Claim Forms Impact the Data Available for Risk Adjustment

ASCs submit claims using the CMS-1500 while HOPDs submit claims using the UB-04. Among their differences, the two forms vary in the total number of fields available for the submission of diagnosis codes and in the types of fields associated with diagnosis coding. Importantly, the CMS-1500 used by ASCs requires a pairing of each procedure code with a diagnosis code supporting its medical necessity. As a result, ASCs do not have a method for coding additional underlying comorbidities that could impact the measure's risk adjustment methodology. When risk adjustment is not applied equally to both settings, the measure results cannot be used for comparative purposes.

In summary, the above factors impact the calculation of measure results to such a degree as to preclude valid comparisons across sites of service. The measure developer has stated, "the rates calculated separately for HOPDs and ASCs… should not be compared directly" in their report titled "2019 Measure Updates and Specifications Report Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy– Version 5.0." This information is included in a 39-page technical report that consumers are unlikely to read. Yet the agency has made no effort to clarify the appropriate use of results of these measures and continues to refer to them as "aligned".

CMS has an obligation to present accurate information to consumers. To ensure consumers are not misled, the agency should take immediate action to differentiate the measures and to make it clear that the measure results cannot be used to compare ASC care to HOPD care. We suggest the agency revise the names of the measures to make them distinct and add interpretive guidance clarifying that the measure results cannot be compared across the two settings. Additionally, CMS should not refer to the measures as aligned, because to the layperson this language implies the measures can be used to make comparisons.

Claims should not be the basis for measures comparing quality of care in ASCs and HOPDs. We encourage the agency to focus any future measure development for comparative purposes along different lines.

VII. Public Reporting of ASCQR Program Data

While the ASC QC was pleased to see that CMS invested in a new CMS Care Compare site, we were disappointed that ASCs were not among the providers included in the project. We urge the agency to make the addition of ASCs a priority.

The current method of displaying ASCQR Program data is unsatisfactory. ASC quality data is presented on the Hospital Compare website. The name of the website implies it is a location for hospital information, not ASC information. In addition, the current link to ASCQR Program data on the Hospital Compare homepage is not prominently displayed, rather just one of several in a list of quality programs and other related links. For those few consumers who find the link to the ASCQR Program, the display of the data is not as helpful as it should be. It is difficult to understand the measure data being presented and what it means. It is also hard to find a specific facility, and there is no easy way to compare measure data from various centers. Many

improvements are needed to support consumers and moving the data to CMS Care Compare would be a welcome step in the right direction.

VIII. The Measure Applications Partnership (MAP)

The ASC QC appreciates the work of the individuals serving on the MAP Coordinating Committee and its various workgroups and we are grateful for the process improvements that have been made over the years. However, the ongoing absence of any meaningful ASC representation on the Hospital Workgroup of the MAP remains a serious concern. We bring this issue to your attention because CMS is responsible for convening the MAP.

The Hospital Workgroup of the MAP is charged with developing recommendations regarding the ASCQR Program. ASC representation on the Workgroup is crucial, yet for the last five years the workgroup has not had any individual or organization able to provide the ASC industry expertise needed to ensure sound recommendations for the ASCQR Program. Ongoing ASC organizational or subject matter expert presence on the MAP Hospital Workgroup is crucial to informed decisions. CMS should work with the National Quality Forum to ensure this deficiency is corrected with the next cycle of appointments in 2021.

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Thank you for considering these comments. We look forward to continuing our dialogue with CMS regarding the ASCQR Program and would be happy to assist with questions or provide additional information at your request.

Sincerely,

Ann Shimek

Ann Shimek, MSN, BSN, RN, CASC
Executive Director
ASC Quality Collaboration

Appendix A:
Current Participants in the Activities of the ASC Quality Collaboration

Accreditation Association for Ambulatory Health Care
Ambulatory Surgery Center Association Foundation
AmSurg
Association of periOperative Registered Nurses
California Ambulatory Surgery Association
Covenant Physician Partners
Florida Society of Ambulatory Surgery Centers
HCA Healthcare, Ambulatory Surgery Division
HST Pathways
Kaiser Permanente
Merritt Healthcare
New Jersey Association of Ambulatory Surgery Centers
Outpatient Ophthalmic Surgery Society
Physicians Endoscopy
Practice Partners in Healthcare, Inc.
Regent Surgical Health
Surgery Partners
Surgical Care Affiliates
The Joint Commission
United Surgical Partners International
Value Health
Visionary Enterprises, Inc.