



ASC Quality Collaboration

September 16, 2021

VIA ELECTRONIC SUBMISSION

Chiquita LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re CMS-1753-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Administrator LaSure:

Please accept the following comments from the ASC Quality Collaboration (ASC QC) regarding CMS-1753-P (86 FR 42018, August 4, 2021) Section XVI. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program and related proposals. 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 improvements the agency has made to the ASCQR Program over time. We also value the agency's willingness to consider how best to balance the benefits of quality measurement and reporting against its burdens. We hope CMS will remain mindful of the profound and ongoing impacts of the Coronavirus Disease 2019 (COVID-19) pandemic on healthcare providers, including ASCs, when making final decisions regarding the proposals set forth in CMS-1753-P.

I. Proposal to Adopt the COVID-19 Vaccination Coverage Among Healthcare Personnel Measure

CMS has proposed to adopt one new measure for the ASCQR Program: the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure. The measure is under

development by the Centers for Disease Control and Prevention (CDC) and would be used to assess the percentage of an ASC's workforce that has received a complete course of vaccination for COVID-19. The same measure has been proposed for other healthcare entities, including Hospital Outpatient Departments (HOPDs).

The agency states it is important for ASCs to report HCP vaccination information in order to determine whether ASCs are taking steps to assess and reduce the risk of spread of COVID-19 among the healthcare workers in their facilities. CMS states the measure would help sustain the ability of ASCs to serve their communities through the public health emergency associated with the virus and into the future. The agency also believes public reporting of the measure results would be helpful to patients - particularly those at high risk for developing serious complications from COVID-19 - as they choose among facilities for treatment.

A. Measure Specifications

As noted above, the proposed measure is still in development and has not been tested. As a rule, we do not support adoption of measures that have not been thoroughly and completely vetted. However, we acknowledge the importance of giving patients an opportunity for insight into the overall COVID-19 vaccination rate of those working in healthcare facilities.

Because we believe the information is important, we hope CMS will make every effort to make the specifications clear. Presently, the denominator is the "[n]umber of HCP that were eligible to work in the healthcare facility for at least one day during the reporting period, excluding persons with contraindications to COVID-19 vaccination." Denominator data are to be collected for three required categories of HCP and can also be collected for a fourth optional category. These categories are:

1. **Employees (required):** This includes all persons receiving a direct paycheck from the reporting facility (i.e., on the facility's payroll), regardless of clinical responsibility or patient contact.
2. **Licensed independent practitioners (required):** This includes physicians, advanced practice nurses, and physician assistants who are affiliated with the reporting facility, but are not directly employed by it (i.e., they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.
3. **Adult students/trainees and volunteers (required):** This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the healthcare facility, but are not directly employed by it (i.e., they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.
4. **Other contract personnel (optional):** Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into the other denominator categories.

Our concern with the denominator results from the fact that the healthcare sector is now embracing more flexible working arrangements and increasingly non-clinical employees are

working remotely, either in a separate business office location or from home. This trend has accelerated during the pandemic. Consequently, we believe it would be possible for there to be confusion about the phrase “eligible to work in the healthcare facility” [emphasis added] in the current denominator statement. It would be helpful for the agency to make sure the intent to collect data for all employees that receive a paycheck is abundantly clear.

It goes without saying that the course of the pandemic cannot be predicted, and the future may bring circumstances that would affect data for the measure specifications. For example, it is possible that what is considered a complete course of vaccination may change in the future. We encourage CMS to be very clear in its communications regarding any updates that impact the measure and to allow sufficient time for the implementation of any changes.

B. Frequency of Data Collection and Submission

CMS is proposing that data submission for this measure would be on a quarterly basis. The agency envisions requiring ASCs to collect the numerator and denominator data for the COVID-19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter. The ASC would then submit the data to the National Healthcare Safety Network (NHSN) Healthcare Personnel Safety (HPS) Component before the quarterly deadline. If an ASC were to choose to submit more than one week of data in a given month, the most recent week’s data would be used to calculate the measure.

The agency is further proposing that the CDC would calculate a single quarterly COVID-19 HCP vaccination coverage rate for each ASC by taking the average of the data from each of the three months submitted for that quarter. CMS would then publicly report this average as the quarterly COVID-19 HCP vaccination coverage rate.

We remind the agency that ASCs are relatively small facilities. In fact, CMS has estimated that approximately 73 percent of ASCs would be classified as small businesses according to the Small Business Administration size standards [72 Fed. Reg. 66901]. The predominance of small facilities is corroborated by CMS data indicating a median of two operating/procedure rooms per facility (mean = 2.5). Smaller facilities have fewer employees and HCP for whom tracking would be required, with data less likely to change over the short periods of time proposed.

Requiring the collection of data at least once monthly - more often than it would be shared with the public - adds burden without enlightening patients any sooner. It is not appropriate for CMS to require healthcare entities to work more frequently to meet government data reporting requirements than the government agencies involved plan to calculate and report results. This is especially true during the current pandemic when healthcare providers and suppliers may struggle with workforce shortages.

We also believe CMS should report the most recent monthly vaccination data rather than the average of the monthly data points. It is important to share the most up-to-date information to support informed patient decision making. The potential for rapid change in the COVID-19 pandemic means the most current data is the most relevant, especially given the inevitable delay between data submission and the quarterly reporting CMS has proposed.

C. Proposed Implementation and Reporting Method

CMS has proposed that ASCs would report the measure through the NHSN web-based surveillance system beginning in January 2022. Specifically, ASCs would use the COVID-19 vaccination data reporting modules in the NHSN HPS Component. In order to submit the required data, ASCs would have to be either already enrolled in NHSN or complete the NHSN enrollment process, which includes registering with CDC's Secure Access Management Services (SAMS), a federal information technology system that gives authorized personnel secure access to non-public CDC applications.

In the past, most ASCs were enrolled in NHSN and registered with SAMS in order to submit data for ASC-8, the Influenza Vaccination Coverage among Healthcare Personnel measure. However, ASC-8 was removed from the ASCQR Program, and most ASCs used NHSN for the last time on or before May 15, 2018. This is relevant because if a NHSN user does not access SAMS in a 12-month period from their last successful login, their SAMS account is terminated, and the user is not able to access NHSN applications via SAMS until they re-register.

Some ASCs currently have an active SAMS account for state-required reporting or other purposes. We note that in March 2019, 642 ASCs were enrolled in and submitting data to NHSN. This represents only a fraction of ASCs; therefore, it appears likely that most ASCs would have to re-enroll in NHSN in order to submit data for the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure. Based on experience we know the registration process can take several weeks to complete. It is possible it may take longer than in the past due to slower mail delivery resulting from the COVID-19 pandemic. Delays may also result from the sheer volume of re-enrollment and registration requests that will be made in a short period of time.

If this measure is adopted, we anticipate it would be finalized in early November 2021, leaving a short period of time for ASCs to become aware of the new requirements for the COVID-19 Vaccination Coverage Among HCP measure and to take the necessary steps to report measure data timely. We are concerned this timeline will prove too aggressive. We urge the agency to delay the implementation if it becomes apparent that ASCs have not been able to complete the enrollment process prior to the first quarterly deadline.

D. Proposed Aggregation of Data by CCN

If finalized as proposed, healthcare facilities would count HCP working in all facilities that share the same CCN. ASCs that share the same CCN would combine data for the COVID-19 Vaccination Coverage Among Healthcare Personnel measure before submission.

We advocate transparent and consumer-centric public reporting of quality measure data, including reporting data in a manner that allows the public to directly correlate quality measure data with an individual facility. CMS should report data for this measure by NPI in order to uniquely identify each individual ASC or other healthcare facility. Combining data makes it

impossible for consumers to understand the performance of an individual facility in cases where multiple facilities share the same CCN.

In the past, CDC has indicated their willingness to consider changing the current CCN-based data collection to an NPI-based approach. CMS should work with CDC to implement data collection under the NPI in NHSN, and then take steps to consolidate reporting around the NPI for all existing and future measures in order to better support consumers.

E. Making Data Available to Consumers on Care Compare

If the agency finalizes the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, we believe it is essential for CMS to take immediate steps to ensure the public has easy access to ASC data. As we discuss in more detail below in Section VII of this letter, it is currently very difficult for consumers to locate ASC quality data through CMS websites. Considering the ongoing public health emergency, this problem must be addressed as a matter of priority.

F. Newly Announced COVID-19 Vaccination Mandate for ASCs and Other Healthcare Facilities

When this proposed rule was issued, CMS had emphasized in other rulemaking that the proposed COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure was not a mandate for vaccination. However, the Biden-Harris Administration has subsequently announced that it will require COVID-19 vaccination of staff within all Medicare and Medicaid-certified facilities, including ASCs. To implement this mandate, CMS is developing an Interim Final Rule with Comment Period that will be issued in October. As CMS drafts its revisions to the ASC Conditions for Coverage and updates the associated survey tools used to assess compliance with the new requirements, we ask the agency to be as clear as possible about when ASCs would be expected to meet the new requirements, and what CMS would require ASCs to do in the event any staff member were to decline vaccination.

II. Proposal to Require Previously Suspended ASCQR Program Measures ASC-1 through ASC-4 Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and Subsequent Years

ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/ Admission were adopted into the ASCQR Program beginning with the CY 2014 payment determination. In the past, data for these measures were reported via quality data codes (QDCs) that ASCs submitted on individual Medicare claims. Beginning with the CY 2019 reporting period, CMS suspended these measures while considering changes to the data submission methodology. CMS is now proposing to resume requiring data for these four measures but changing the submission method to the Hospital Quality Reporting (HQR) System (formerly known as QualityNet). Reporting would resume beginning with the CY 2023 reporting period for the CY 2025 payment determination.

A. Reinstatement of Reporting Requirement

We support resuming the requirement to report these measures for the ASCQR Program. As serious reportable events, ASC-1, ASC-2, and ASC-3 are essential to efforts to help ensure patients are protected from harm while receiving care. Monitoring and publicly reporting these events helps maintain the focus on efforts to prevent their occurrence. These events are rare, and fortunately so. Incorporating these patient safety measures into the ASCQR Program allows the agency and other stakeholders to continue to support the goal of driving toward and eventually sustaining zero harm.

All four measures are of enduring interest to patients because they help answer some of the most common questions consumers have around personal safety when in the care of the facility and about how likely they are to be transferred or admitted to a hospital instead of going home as anticipated.

All four of these measures are also crucial because they are applicable to all ASCs. Other than the proposed COVID-19 Vaccination and OAS CAHPS-based patient experience measures, there are no other measures in the ASCQR Program that can be reported by all centers. Without these measures, patients would only have access to quality data for specific procedures that may or may not be pertinent to their planned procedure. Giving patients access to data for all participating ASCs is valuable.

It is important to note that although the ASC QC allowed National Quality Forum (NQF) endorsement for these measures to lapse, endorsement was not removed because the measures were submitted and failed the endorsement maintenance process. As the measure developer and steward, we made the decision not to submit the measures for reconsideration of endorsement given that all four measures had been endorsed and re-endorsed by the NQF in previous cycles. Despite the absence of current NQF endorsement the measures continue to meet the statutory requirement of consensus among affected parties as evidenced by the ongoing support of the ASC community and their continued submission of data for these measures to the ASC QC's public reporting project at ascquality.org.

B. Measure Reporting Method

We support the proposal to use the HQR System for reporting for ASC-1, ASC-2, ASC-3 and ASC-4. There are several advantages to this reporting method. Most important, this approach would promote greater transparency by allowing the opportunity for ASCs to share aggregated data for all patients instead of only Medicare fee for service (FFS) patients as in the past. Using the HQR System would also:

- allow ASCs to avoid the delay in submitting claims that resulted while centers gathered quality data so the appropriate QDC(s) could be applied,

- allow ASCs to make corrections during the data submission period (which was not possible in the past if an ASC identified an erroneous or missing QDC on a claim that had already been submitted and processed),
- reduce the amount of time and resources required to submit measure data, and
- simplify the requirements of the ASCQR Program by streamlining the number of methods required for quality measure data submission.

Although reporting this data for all patients would be best, it is not clear to us whether the agency plans to implement the measures for all patients, or instead require ASCs to continue data collection and submission for Medicare FFS patients only. Clarification on this matter is requested.

On a related matter, there have been problems with the batch submission function for reporting measure data on the HQR platform, which we shared with you earlier this year. We trust the agency will take steps to promptly rectify these issues to allow use of this valuable, streamlined reporting option.

C. Measures Should Be Reported Across Surgical Settings of Care

We are disappointed to see that the agency did not propose to adopt ASC-1, ASC-2, ASC-3 and ASC-4 for the Hospital OQR Program. In CMS-1717-P, CMS sought public comment on the potential future adoption of these measures for the Hospital OQR Program, which does not include measures of this type. As we have shared with CMS in past comments, moving to adopt these measures would increase the alignment of measures between the Hospital OQR and ASCQR Programs and, most importantly, would allow consumers more opportunities to compare quality and safety across settings of care.

These measures are straightforward and could readily be applied to other outpatient surgical settings, including HOPDs. These measures are currently specified for the ASC setting but could easily be modified to allow use by additional facility types. There is little burden associated with collecting and reporting the data. 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, so most HOPDs are likely already collecting this type of information for their internal use.

As you know, CMS has adopted measures across programs before. In the past, CMS has selected measures that were not specified for the ASC setting and finalized them for inclusion in the ASCQR Program without hesitation. Examples include 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. Given these precedents, it is clear CMS could take measures not originally specified for the HOPD setting and propose them for inclusion in the Hospital OQR Program.

Therefore, we encourage the agency to propose these measures for inclusion in the Hospital OQR Program in the next rulemaking cycle.

III. Proposal to Require ASC-11: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination

ASC-11 assesses the percentage of patients aged 18 years and older who had cataract surgery and experienced improvement in visual function within 90 days following surgery. The results of the measure are based on patients’ completion of both pre-operative and post-operative visual function surveys.

In the CY 2014 OPPS/ASC final rule, CMS finalized the adoption of ASC–11 for inclusion in the ASCQR Program over many objections regarding the implementation burden and concerns regarding the feasibility and actionability of the measure. Shortly after adopting the measure, the agency delayed implementation twice before deciding to make reporting strictly voluntary. Under this voluntary status, ASCs are not obligated to report on the measure in order to be eligible to receive their annual payment update. However, any data submitted to the agency has been subject to public reporting.

CMS states it made ASC-11 voluntary for a few reasons. First, the agency understood it was “operationally difficult for ASCs to collect and report on the measure” because the results of the surveys were collected by clinicians during office visits, “making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery” (79 FR 66984). As CMS has indicated, ASC-11 relies on data obtained by the clinician and recorded in the clinician’s medical records during the patient’s pre-operative visit(s) and additional postoperative visit(s). 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.

The agency also acknowledged the collection and reporting burden and subsequently applied a sampling scheme and a low case threshold to address these concerns. The agency now believes all issues are resolved and that the measure is now appropriate as mandatory. The agency further states the measure provides opportunities for care coordination as well as direct patient feedback.

A. ASC-11 Remains Impractical as a Mandatory Measure

The ASC QC does not support implementing ASC-11 as a mandatory measure. We believe ASC-11 would continue to pose data collection and reporting challenges, notwithstanding the changes CMS has made. While it is true that a small number of ASCs have voluntarily reported the measure, we think it is unlikely that additional ASCs would be able to join their ranks. Implementation of the measure would require ASCs to obtain the preoperative and postoperative survey data from the ophthalmologists performing the surgery. You will recall that in previous comments we shared our concern about the low number of physicians reporting on the measure

under the (then) Physicians Quality Reporting System. Specifically, in 2013 only 215 of the more than 7,300 cataract physicians in the US reported on the measure.

Fast forwarding to the present, our research indicates that, as of 2021, the physician measure corresponding to ASC-11 - the Quality ID #303: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure - is still in use under the current Merit-based Incentive Payment System of the Quality Payment Program for clinicians. Under the ophthalmology track for the program, clinicians choose six measures to report. There is no requirement that clinicians choose Quality ID #303 when selecting which measures to report.

We have discovered there are no publicly reported results available in 2021 for Quality ID #303: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure from the PY 2019 reporting period. According to the Quality Payment Program support contractor, this is because the standards for publicly reporting the measure were not met. Reporting standards were not met because fewer than 20 reporters submitted data.

In light of this, we think it unlikely that additional ASCs beyond those already reporting voluntarily will be able to get survey results from surgeons because it appears that fewer than 20 are collecting and reporting the survey data ASCs would need. Therefore, we strongly urge CMS set aside the proposal for mandatory reporting and continue with voluntary reporting of the measure.

B. An Alternative Measure Addresses the Topic of Ophthalmic Surgery

We note CMS states that another reason it proposed the measure was to address a high-impact condition that is not otherwise adequately addressed in the current ASC measure set. We suggest, as we have done in years past, that the agency propose 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, including cataract surgery, in ASCs.

The number of anterior segment surgeries performed in ASCs is substantial, 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.

There is consensus among eye professionals that prevention of TASS is important. 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 the ASC QC's online public report of ASC quality data. The measure was reviewed by the MAP in the past and received conditional support pending endorsement by the NQF. As you know, NQF endorsement is not always necessary. The statutory requirement that quality 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 TASS 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. In fact, ASCs performing ophthalmic surgery monitor this outcome closely due to its severity. Data regarding occurrences is routinely collected and each event is thoroughly investigated. As noted above, the large number of anterior segment surgeries makes this a very important outcome for patients to be aware of. We encourage CMS to propose adoption of this measure and the submission of aggregated measure data via the HQR System in the next rulemaking cycle. It would also be desirable for CMS to propose adoption of this measure for the Hospital OQR Program.

IV. Proposal to Require ASC-15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

CMS previously adopted five survey-based measures derived from the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) but delayed implementation due to “lack of sufficient operational and implementation data.” These survey-based measures are intended assess patient experience with care following a procedure or surgery in an ASC or hospital outpatient surgery department (HOSD). Specifically, for ASCs, these five measures are: ASC-15a: OAS CAHPS – About Facilities and Staff; ASC-15b: OAS CAHPS – Communication About Procedure; ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery; ASC-15d: OAS CAHPS – Overall Rating of Facility; and ASC-15e: OAS CAHPS – Recommendation of Facility.

The equivalent Hospital OQR Program measures are OP-37-a-e. Since January 2016, ASCs and HOPDs have had the option of reporting survey data via the National OAS CAHPS voluntary reporting program.

We appreciate the investment CMS has made in developing the OAS CAHPS survey. We fully support use of a standardized survey of the patient's experience of care and are pleased the OAS CAHPS survey addresses the experience of surgical care received in both HOSDs and ASCs, increasing opportunities for consumers to make comparisons across outpatient surgical facilities.

CMS is now proposing to resume implementation of the five measures, ASC-15a–e, beginning with voluntary data collection and reporting to the ASCQR Program during the CY 2023 reporting period. CMS is proposing to follow this voluntary period with mandatory data

collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. The same voluntary and mandatory time frames have been proposed for the Hospital OQR Program.

We note that if the agency finalizes its proposal, ASCs that voluntarily report the OAS CAHPS survey-based measures during the CY 2023 reporting period would do so as part of the ASCQR Program until mandatory reporting begins. ASCs would not submit survey data to both the ASCQR Program and the above-mentioned National OAS CAHPS voluntary reporting program.

A. Duration of the Voluntary Data Collection and Reporting Period

CMS states it initially considered a 2-year voluntary period - both the CY 2023 and CY 2024 reporting periods - for OAS CAHPS data collection and reporting. We believe this initial plan was a prudent one and urge the agency to extend the voluntary period to two years. Many ASCs have experienced and continue to experience challenges due to the COVID-19 pandemic and we believe extended preparation time for OAS CAHPS implementation is warranted due to these extraordinary circumstances.

In addition, the experience of those ASCs that are already voluntarily using the OAS CAHPS survey points to some difficulties that took time to overcome. These challenges may be more than many ASCs can easily take on at this time. For example, making provision for the patient populations excluded from the measure, namely patients who cannot be surveyed because of state regulations, patients whose address is not a U.S. domestic address, patients who request that the ASC not release their name and contact information to anyone other than facility personnel (“no-publicity” patients), prisoners, nursing home residents, patients discharged to hospice and deceased patients will require a good deal of effort. Adding this capability to the functionality of ASC operating systems has been complicated, time-consuming and costly. In addition, ASCs must pay for the creation of an electronic interface between their billing systems and their survey vendor to communicate patient information. There is significant expense – thousands of dollars of additional charges – associated with these steps in implementation. Some ASCs are fortunate to have rich IT resources at their disposal, but we are concerned many ASCs without this luxury will find these issues time-consuming and expensive to address.

In short, an additional year of voluntary collection and submission is warranted, and we urge the agency to adopt the two-year time frame it initially considered.

B. Modes of Survey Administration

The data collection for the OAS CAHPS survey currently has three administration methods: (1) mail-only; (2) telephone-only; and (3) mixed mode (mail with telephone follow-up of non-respondents). We are pleased to see the proposal that would allow two additional survey administration modes taking advantage of web-based technology: web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents.

CMS should also allow a web-only survey administration mode. Data shows that web-only administration has a superior response rate compared to telephone-only. Specifically, the mode experiment CMS conducted evaluated five administration modes: mail-only, telephone-only, web-only, web with mail follow-up and web with telephone follow-up. Response rates were 35 percent for mail-only, 19 percent for telephone-only, 29 percent for web-only, 39 percent for web with mail follow-up and 35 percent for web with telephone follow-up. Higher response rates allow providers to achieve the minimum number of surveys required with less time and resources.

CMS states it has not proposed the web-only option because it “would create response bias since not all patients have the ability to respond by web.” We think the agency is taking an unnecessarily dim view of access to the web in the United States. Data from other government agencies continues to demonstrate that information technology resources used to access the web are prevalent among all Americans regardless of age, sex, educational attainment, household income and employment status. We encourage review of the most recent data from the US Census Bureau regarding Internet use, which is included in its dataset titled Computer and Internet Use in the United States: 2018, released in April 2021. Note particularly that the number of individuals aged 65 years and older living in a house with a computer continues to increase over time, standing at 80.1 percent in 2018. In households with less than \$25,000 of income, 76.9 percent had a computer in the home at that time. The National Telecommunications & Information Administration of the US Department of Commerce dataset of June 2020 at Digital Nation Data Explorer also points to continuing growth in the use of digital technology over time in all demographic groups. Further, alternate locations, such as local libraries, community centers and other such facilities are places where people who do not pay for internet access at home, as well as itinerant and homeless persons, *can and do* access the web for email, social media and internet use.

As CMS knows, not everyone has a mailing address and not everyone has a telephone. Yet, if it were necessary for all patients to have access to mail and telephone prior to their being used as survey modalities, those modes would also be precluded from use.

In summary, including a web-only mode would significantly minimize cost burden and is acceptable considering the high rates of access to the web seen in the United States population.

C. Number of Surveys Required

CMS plans to require a minimum of 300 completed surveys annually. If facility volume is too small to yield 300 completed surveys per year, a census is to be surveyed. We would like to see the agency adopt a lower minimum, particularly during the proposed voluntary reporting phase.

CMS has allowed lower minimums in other programs. A minimum of 200 completed surveys has been established for the In-Center Hemodialysis CAHPS Survey. The 300-survey threshold is also three times higher than that required during the initial years of survey implementation in other CMS programs. For example, CMS initially set a threshold of 100 completed surveys for hospital participation in its HCAPHS Star Ratings initiative under the Hospital Inpatient Quality

Reporting Program. The same standard was used in the Hospital Value-Based Purchasing Program.

D. Options to Limit Financial Burden

The ASC QC would like to see the highest possible levels of ASC use of the OAS CAHPS survey. Participating ASCs must pay for its administration and therefore CMS should take all possible steps to limit the financial burden. Options to reduce burden include:

- allowing a web-only survey administration mode as discussed above,
- allowing email and text (SMS) survey invitations for use with modes that include web administration, and
- shortening the survey, as suggested in previous comments to CMS, by focusing sharply on critical, actionable aspects of patient experience and only the demographic data essential to either patient-mix adjustment or compliance with the law.

In short, several obstacles remain to maximizing the use of the OAS CAHPS survey. For some ASCs, the costs of implementing the OAS CAHPS survey will prove to be in excess of the 2% payment update penalty for failing to meet ASCQR Program requirements. We encourage the agency to take the additional steps outlined above to encourage maximal participation.

E. OAS CAHPS Public Reporting Should Be by NPI

CMS has determined that ASCs and HOSDs sharing the same CCN must combine data for the OAS CAHPS Survey. These results would then be publicly reported by CCN, making it impossible to distinguish the performance of individual facilities. The agency intends to note instances where the OAS CAHPS measures combine results from two or more facilities.

The primary aim of public reporting of quality data is to ensure that consumers can distinguish performance at the individual facility level. Combining results is a significant barrier to full transparency. Therefore, we continue to advocate for the most meaningful and user-centric approach. In our opinion, an NPI-based reporting method is superior because it would allow the public to directly correlate quality measure data with an individual facility.

V. ASCQR Program: Measures and Topics for Future Consideration

CMS routinely invites public comment on potential future measures that address quality of care in ASCs. We appreciate this opportunity to share our thoughts and ideas.

A. 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 already mentioned above,

and the Ambulatory Breast Procedure Surgical Site Infection Outcome Measure. Both measures would be appropriate for inclusion in the Hospital OQR Program as well.

The Ambulatory Breast Procedure Surgical Site Infection Outcome measure was developed by the CDC. This measure assesses the risk-adjusted Standardized Infection Ratio (SIR) 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. It was also conditionally supported by the MAP pending NQF endorsement, which was subsequently obtained.

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.

B. Future Measures to Address Newly Eligible ASC Procedures

CMS has invited public comment on potential future measures that address care quality when procedures transition from inpatient settings to outpatient settings of care. With the recent addition of elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures to the ASC Covered Procedures List, the agency is seeking input on the potential future adoption of a (yet to be) re-specified version of a patient-reported outcome-based performance measure (PRO-PM) for these procedures. The measure in question is NQF #3559: Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). This measure reports the risk-standardized improvement rate in patient-reported outcomes following elective primary THA/TKA for Medicare beneficiaries aged 65 years and older. Improvement is measured through scores on one of two validated joint-specific patient surveys measuring hip or knee pain and functioning. Improvement is determined by comparing the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk adjusted to account for differences in patient case mix.

According to the measure developer, the goal of having a hospital-level outcome measure is to capture the full spectrum of care in order to incentivize collaboration and shared responsibility for improving patients' health. This is reasonable in a hospital system that includes the full spectrum of preoperative, intraoperative and postoperative services involved in the care of THA/TKA patients under its ownership. However, we question how ASCs that are not owned or managed by a hospital system are to be held accountable for the full spectrum of patient care. As you know, federal regulations governing ASCs intentionally limit the scope of ASC services and the time frame ASCs are permitted to be involved in patient care - and also intentionally isolate the operations of ASCs from other providers.

We are also concerned about the patient survey instruments that provide the foundation for the measure. The appropriate survey is administered in advance of surgery and then again approximately a year after surgery - reflecting the normal time frames for clinical workflow for THA/TKA patients. This strikes us as an even more challenging version of the survey protocol for ASC-11 (please see discussion above) and one that we believe would be very difficult for ASCs to implement.

CMS also states that ASC-17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures provides valuable quality information for THA/TKA procedures. It is true that ASC-17, which includes THA and TKA procedures, provides some information on patient outcomes for Medicare beneficiaries following orthopedic surgery at ASCs. However, it does not focus strictly on THA/TKA, and, like the other claims-based measures of this type that CMS has developed, is not particularly useful to patients because the vast majority of ASCs perform “as expected”. Nor does the measure offer the opportunity to compare performance across settings that perform THA/TKA.

We believe a measure of surgical site infections following these procedures would be a very meaningful outcome to assess. We have had some positive exploratory conversations with CDC regarding a THA/TKA SSI measure. We encourage CMS to support this effort rather than investing resources in re-specifying the Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) measure.

C. Future Expansion of Disparities Reporting Using Social Risk Factors

To date, CMS has not expanded disparities reporting to the ASC setting. In this proposed rule, CMS is seeking comment on the potential for measuring disparities in care provided in ASCs. The agency has already tested some methods for measuring disparities for dually eligible individuals in the ASC setting. In initial analyses, few ASCs met the minimum sample size required to yield technically feasible, adequately representative, and statistically reliable disparity results. CMS states it is now considering several different approaches for quantifying the health impacts of adverse neighborhood level socioeconomic factors, one being the Agency for Healthcare Research and Quality (AHRQ) neighborhood Socioeconomic Status (SES) Index.

We agree this is a challenging issue, with conflicting information posing difficulties for measures seeking to incorporate these factors. For example, during the development of NQF #3559: Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (see above), the associations of dual eligibility, low socioeconomic status and race with the measure outcome were analyzed. The statistical testing did not provide evidence of significant differences in outcomes related to these factors and, as a result, CMS did not include dual eligibility, AHRQ SES index, or non-white race in the current risk model for the measure.

We encourage CMS to continue testing to determine if any such factors would be meaningfully applied to current or future ASCQR Program measures.

D. Future Measures to Address Pain Management Procedures

ASCs provide useful procedures for the initial treatment of pain and non-opioid treatments for chronic pain management. These procedures have long been among the most common provided to Medicare beneficiaries. CMS has invited public comment on the development and future inclusion of a measure to assess pain management procedures. We agree it would be helpful to have such a measure included in the ASCQR Program in the future.

However, we would like to see the development of alternatives to claim-based measures like ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures, or ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers. These measures are unlikely to drive improvement because the overwhelming majority of centers perform better than or as expected. There is also a significant delay between the time frame of the claims and the time the measure data is reported to the public, which can make the data less helpful.

Further, these measures do not allow comparisons across settings of care because they are based on Medicare claims data. Using Medicare claims has a significant impact on the accuracy of measure results in the HOPD setting which ultimately precludes valid comparisons between ASCs and HOPDs. The reasons for this include the following:

1. 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 subsequent "hospital visits" related to HOPD care.

CMS policy does not allow 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, measures based on HOPD claims 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 after the service. Such 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.

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

ASCs are not subject to the three-day payment window policy so identifying ASC Medicare claims is straightforward. ASC services can be *directly* identified using ASC claims. On the other hand, CMS identifies HOPD services during the three-day payment window *indirectly, using physician claims*. Place of service (POS) coding on these physician claims is used to establish the HOPD site of service.

However, 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 insignificant problem*. As a result, HOPD measure outcomes during the three-day payment window are systematically undercounted when POS coding is used.

The three-day payment window policy also applies to those physicians whose practice is wholly owned by a hospital. When the physician who performs an HOPD service is in a practice wholly owned by a 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 no means to identify the HOPD service. Many physicians are employed by hospitals and hospital systems, so the absence of a physician claim is not an infrequent occurrence.

3. 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.

The above factors impact the measure results and preclude valid comparisons across sites of service. Unfortunately, existing program measures ASC-12 and OP-32, Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy are affected by these issues. 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." CMS is obligated to present accurate information to consumers and 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 CMS revise the measure titles to make them distinct and add interpretive guidance clearly stating the measure results cannot be compared across the two settings.

In summary, we hope CMS will invest its resources in developing a pain management measure that would drive performance improvement and allow patients to compare care across surgical care settings. Potential topics include patient benefit from pain management procedures, appropriateness of those procedures, assessment of compassionate care and whether patients received a call from the center following their procedure.

E. Future Measures Should Allow Appropriate Comparisons Across Settings of Care

The ASC QC supports the adoption of additional measures for the ASCQR Program and Hospital OQR Program when services overlap and when the measures have been specified in a manner that would allow direct comparisons to be made. As discussed above, simple modifications would allow numerous measures such as 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 to be used by ASCs and hospitals. These measures are all based on clinical data routinely collected by health care facilities and would provide welcome comparative information for the healthcare consumer.

VI. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs

CMS has indicated it aims to move to fully digital quality measurement in the agency's quality reporting and value-based purchasing programs by 2025, just four years from now. In this proposed rulemaking, CMS has identified four potential future actions it believes would enable this transformation in the very short time frame stated. These actions include:

- Leveraging and advancing standards for digital data and obtaining all electronic health record (EHR) data required for quality measures via provider Fast Healthcare Interoperability Resources (FHIR®) based application programming interfaces (APIs).
- Redesigning quality measures by taking steps toward developing digital quality measurement software as end-to-end measure calculation solutions that would 1) retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; 2) calculate measure scores; and 3) produce reports.
- Building a pathway to data aggregation in support of quality measurement based on the thought that using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, the agency is considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators such as health information exchanges and clinical registries.

- Working toward the future alignment of measures across reporting programs, Federal and State agencies, and the private sector by using policy levers and involving stakeholders to solve the issue of interoperable data exchange. CMS is considering the future potential development and multi-staged implementation of a common portfolio of digital quality measures (dQMs) across its regulated programs, agencies, and private payers.

We agree moving toward digital quality measurement is desirable, but do not believe this is practical in the ASC setting over the very short implementation time frame CMS envisions. 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 EHRs, and past environmental scans have shown the use of EHRs in the ASC industry to be more limited than in other healthcare settings. Further, the ASCQR Program does not currently include any electronic clinical quality measures (eCQMs).

We believe it would be prudent for the agency to review the current information technology capabilities of the ASC industry through a detailed environmental scan prior to any additional action. Having a clear sense of current information technology resources, interfaces, software solutions and protocols would provide a solid foundation for developing a stepwise approach to the adoption of digital quality measurement in the ASC setting.

VII. Public Reporting of ASCQR Program Data

While the ASC QC was pleased to note the launch of the new CMS Care Compare site in September 2020, we remain disappointed that ASCs are still not among the providers included in the project despite comments last year urging the agency to make the addition of ASCs a priority.

In the past, ASC quality data was presented on the Hospital Compare website. When Hospital Compare was retired on December 1, 2020, no specific link to ASCQR Program data was created on the new CMS Care Compare website. The agency indicates on both its <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/asc-quality-reporting> and <https://qualitynet.cms.gov/asc/public-reporting> websites that ASC data is available at Care Compare and that the site is generally refreshed bi-annually for the ASCQR Program. However, we see no evidence of this. ASCs are not among the providers listed and using the search function does not lead to any ASC information. Further, there is no link provided to an alternate site for ASCs.

ASC quality measure data is available on the data.cms.gov site. Finding ASC information on this site is not easy or user friendly. On the Home page, there is no button for ASCs. On the Datasets page, there is no Ambulatory Surgical Center Topic listed. On the Topics page, there is no Ambulatory Surgical Center dataset link. ASC data is included in the datasets for “Hospitals” even though ASCs are not hospitals. It is hard to imagine that consumers would intuitively search for ASC information under the Hospital heading.

For those who do manage to find the links to the ASCQR Program data, 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. Measure scores are listed under column titles such as “ASC-9 Rate”. Clicking on the column title does not lead to any additional information, it only sorts the data. It is also hard to find a specific facility without downloading the entire dataset and there is no easy way to compare measure data from various centers.

The current method of displaying ASCQR Program data is unsatisfactory. As a group, ASCs are the most common providers of outpatient surgery in the United States. CMS needs to be more effective in sharing quality measure data for ASCs with the public. Among the many improvements needed to support consumers, including ASCs on the 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 those serving on the various committees and workgroups of the MAP. Unfortunately, there has not been a qualified ASC representative on the Hospital Workgroup of the MAP for six years. This is a serious gap in the expertise of the Workgroup, which is charged with developing recommendations regarding the ASCQR Program. Ongoing ASC organizational or subject matter expert presence on the MAP Hospital Workgroup is important to informed decision making. We continue to bring this issue to your attention because CMS is responsible for convening the MAP. CMS should work with the NQF to ensure this deficiency is corrected with the next cycle of appointments in 2022.

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,

Kathy Wilson

Kathy Wilson, RN, MHA
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
Proliance Surgeons
Regent Surgical Health
Surgery Partners
Surgical Care Affiliates
The Joint Commission
United Surgical Partners International
Value Health
Visionary Enterprises, Inc.