ASC Quality Collaboration

September 11, 2023

VIA ELECTRONIC SUBMISSION

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1786-P
Baltimore, MD 21244-1850

Re CMS-1786-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; etc.

Dear Administrator Brooks-LaSure:

Please accept the following comments from the ASC Quality Collaboration (ASC QC) regarding CMS-1786-P (88 FR 49552, July 31, 2023) Section XV. Ambulatory Surgical Center Quality Reporting (ASCQR) Program Requirements, Proposals, and Requests for Comment. The ASC QC is a non-profit organization dedicated to advancing high quality, patient-centered care in ambulatory surgery centers (ASCs) through a collaborative membership 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 2,000 ASCs.

The ASC QC appreciates this opportunity to comment on proposals and other matters affecting the ASCQR Program.

I. Proposed Modification of ASC-20: COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

The COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure is a measure developed by the CDC to track COVID-19 vaccination coverage among HCP in various settings. CMS adopted the measure in its quality reporting programs as part of its response to the SARS-CoV-2 pandemic and public health emergency.

The public health emergency in response to the global outbreak of SARS-CoV-2 ended on May 11, 2023. On June 5, 2023, CMS removed regulations that had previously required ASCs (as

well as other healthcare facilities and suppliers) to develop and implement policies and procedures to ensure all staff were fully vaccinated for COVID-19. By way of explanation for removing the requirements, CMS stated its belief that regulations regarding COVID-19 vaccination of health care staff were no longer necessary for a variety of reasons, including "an evaluation of the evolving clinical and epidemiological circumstances of the COVID-19 pandemic, increased vaccine uptake, declining infection and death rates, decreasing severity of disease, increased instances of infection-induced immunity, public comments submitted to CMS, and the addition of COVID-19 vaccination quality measures to quality improvement and reporting programs" (88 FR 36488).

Despite these appropriate changes in response to the evolving nature of COVID-19, CMS is not making commensurate changes in the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure. What has been proposed is limited to the measure specifications:

- A modification to utilize the term ''up to date'' in the HCP vaccination definition. The term ''up to date'' is to be defined as meeting the CDC's set of criteria on the first day of the applicable reporting quarter.
- An update to the numerator to specify the time frames within which an HCP is considered up to date with CDC recommended COVID-19 vaccines, including booster doses.

These changes would take effect beginning with the CY 2024 reporting period/CY 2026 payment determination. The proposals are reasonable to allow the measure to remain current, and we support them. However, additional, but much needed, changes in the reporting requirements for the measure have not been proposed.

Specifically, ASCs and other healthcare providers and suppliers are still expected to collect data on HCP vaccination rates for at least one week of every month and to submit that data to NHSN on a quarterly basis. CMS has already received many comments seeking relief from the excessive burden of this ongoing intensity of reporting. These comments included a recommendation to scale back the frequency of reporting from a nationally recognized association dedicated to infection prevention and epidemiology. In response, CMS indicated, "the model used for this measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431), which is reported annually, and it [the measure developer] intends to utilize a similar approach to the modified COVID-19 Vaccination Coverage among HCP measure if vaccination strategy becomes seasonal. While monitoring and surveillance are ongoing, we do not currently have data demonstrating seasonal trends in the circulation of SARS-CoV-2 and therefore at this time, reporting at least one self-selected week during each month of the reporting quarter remains appropriate". (88 FR 59142 August 28, 2023)

Review of the publicly available measure data shows HCP vaccination rates have been essentially flat across providers and suppliers, even prior to the end of the public health emergency. There have been no meaningful fluctuations from week to week, month to month, or quarter to quarter. Consequently, there is no benefit to requiring ongoing intensive data collection for the sake of continuing to document a static rate of vaccination among HCP. Absent

a major resurgence of COVID-19, vaccination rates are unlikely to shift significantly, regardless of whether the circulation of SARS-CoV-2 and current vaccination strategy is seasonal.

The agency should continue to relax the sweeping and frequently changing requirements put in place to address the pandemic phase of COVID-19. As noted above, CMS has already made other needed and very appropriate changes to adapt to the end of the public health emergency. It is very difficult to understand why CMS is so reticent to alleviate burden in its quality reporting programs when it has responded judiciously to the evolving situation in other COVID-19 related matters. Now that COVID-19 is endemic, data collection and reporting expectations for the COVID-19 Vaccination Coverage Among Healthcare Personnel measure should be eased for all reporters, including ASCs. For other endemic infections, such as influenza, annual reporting has been sufficient to support ongoing public reporting.

The agency should act immediately to remedy this situation, and not wait until the next rulemaking cycle to address this matter.

II. Proposed Adoption of the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM)

As a result of the recent addition of total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures to the ASC Covered Procedures List, CMS is proposing that a patient-reported outcome-based performance measure for these procedures be adopted. The Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) would report the improvement rate in patient-reported outcomes following elective primary THA/TKA for Medicare beneficiaries aged 65 years and older. This measure has recently been implemented in the Hospital Inpatient Quality Reporting (IQR) Program (participation is currently voluntary) and is also being proposed for inclusion in the Hospital Outpatient Quality Reporting (HOQR) Program.

We believe patient-reported outcomes (PRO) data is important, yet we cannot support adoption of this measure as proposed.

A. Measure Overview

The measure is built around two standardized instruments used to collect patient-reported data about joint pain and function. The six-item Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) would be used to collect PRO data for THA patients. The seven-item Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) would be used to collect PRO data for TKA patients.

The numerator is the risk-adjusted proportion of patients undergoing an elective primary THA/TKA who report a certain level of improvement in hip or knee pain and/or function between preoperative and postoperative assessments. In order to calculate the change in a

patient's score on these assessments, data must be collected both preoperatively (90 to 0 days before the surgery) and postoperatively (300 to 425 days after the surgery).

The measure denominator includes Medicare Fee for Service patients 65 years of age and older undergoing elective primary THA/TKA procedures in the ASC setting. The cohort does not include patients with revision THAs/TKAs, partial hip or knee arthroplasties, THA/TKAs with concurrent resurfacing procedures or with simultaneous removal of implanted devices/protheses, or patients with fractures, neoplasms, or a mechanical complication of a prior THA/TKA. CMS would identify the total number of eligible primary elective THA/TKAs performed by ASCs using Medicare administrative claims data. These claims would also be used to identify and exclude THA/TKAs for patients with staged procedures (multiple elective primary THA or TKA procedures performed on the same patient during distinct encounters during the reporting period), and discontinued procedures (procedures that were started but not completed).

The risk adjustment methodology requires additional patient-level information beyond the HOOS, JR or KOOS, JR. Table 1 below summarizes the data elements ASCs would be required to collect and submit.

TABLE 1. THA/TKA PRO-PM Measure Data Elements Collected Pre- and Postoperatively

Data Element Type	Preoperative Data Elements	Postoperative Data Elements
Patient-Reported Outcome Measures (PROMs)	THA patients: 6 item HOOS, JR TKA patients: 7 item KOOS, JR	THA patients: 6 item HOOS, JR TKA patients: 7 item KOOS, JR
Risk Variables	Mental Health responses from either the PROMIS-Global 1.1 or 1.2 (4 items) or VR-12 (6 items)	N/A
	Health Literacy (SILS 2)	
	BMI or Height and Weight	
	Use of Chronic Narcotics	
	Total Painful Joint Count: Patient-reported pain in non-operative lower extremity joint	
	Patient-reported back pain, Oswestry Index Question	
Matching Variables	Medicare Provider Number	Medicare Provider Number
	Medicare Beneficiary Identifier	Medicare Beneficiary Identifier
	Patient Date of Birth	Patient Date of Birth
	Date of Procedure	Date of Procedure
	Procedure Type	Procedure Type
	Date of Admission	Date of Admission
PROM-related Variables	Date of PRO Data Collection	Date of PRO Data Collection
	Mode of Collection	Mode of Collection
	Person Completing the Survey	Person Completing the Survey
	Generic PROM Version (the Mental Health Survey used)	N/A

The amount of data ASCs would be required to collect and submit for this measure is substantial: a total of 44 to 47 data elements for each THA patient and a total of 46 to 49 data elements for each TKA patient when complete PRO data is provided by the patient.

Calculation of the measure score requires data from other sources in addition to the data elements above. Medicare claims data would be used to identify the eligible elective primary THA/TKA procedures performed by the ASC, patient demographics, and the patient's clinical comorbidities during the 12 months prior to surgery. The Medicare Enrollment Database would be used to identify Medicare Fee for Service enrollment and patient race. The Master Beneficiary Summary File would be used to determine dual eligibility status. Finally, the Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) index score would be used for non-response bias. Beyond the normal practice of submitting claims for THA/TKA procedures performed, ASCs would not be responsible for collecting and submitting this additional data.

CMS would calculate the measure result, providing a risk-standardized improvement rate, or RSIR, for each ASC. The RSIR is the risk-standardized proportion of eligible THA/TKA procedures that resulted in substantial clinical benefit. A patient's scores on the preoperative and postoperative assessments would be compared to determine whether the threshold for substantial clinical benefit was met. For hip patients, the threshold for showing substantial clinical benefit would be an improvement of 22 points on the postoperative HOOS, JR. For knee patients, the threshold would be a 20-point improvement in the postoperative score on the KOOS, JR. (Note that these thresholds are based on differences in the interval score, not the raw score.) Improvement scores would then risk-adjusted to account for differences in patient case-mix.

In addition, CMS would determine each ASC's response rate for PRO data, defined as the percentage of elective primary ASC THA/TKA procedures with complete and matched preoperative and postoperative PRO data submitted divided by the total number of eligible primary THA/TKAs performed.

B. Measure Specifications and Guidance

There are several issues with the measure specifications and/or guidance materials supporting the measure:

- Medicare patients undergoing THA or TKA would have to be enrolled in Parts A and B for at least 12 months prior to the procedure and on the day of the procedure in order to be included in the measure calculation. However, the supporting guidance for "Who Do I Collect Data On?" does not make this clear. ASCs might not realize data collected for "new" beneficiaries would not be used.

- The postoperative PRO collection timeframe does not align with that of the American Joint Replacement Registry (https://www.aaos.org/registries/registry-program/american-joint-replacement-registry/), which is 270 to 425 days.

- One of the measure exclusion criteria is "Patients who die within 300 days of their procedure". According to the measure developer, this exclusion was put in place to "remove patients who die prior to the postoperative window and are not "available" to provide PROs during [the] postop assessment". Given that patients can complete the

postoperative assessment for up to 425 days following their procedure, setting the number of days to 300 does not align with the postoperative data collection period. Patients who die during the 300 to 425-day postoperative survey period before completing the survey would not be "available to provide PROs". It is unclear how patient death would be ascertained and by whom.

- The Veterans Rand (VR)-12© questionnaire is not readily available from the link provided in the supporting materials for the measure. According to the website referenced, although the VR-12© is in the public domain, permission is required to use it. When we requested access, we were asked to submit 1) "A letter requesting to use the questionnaire on your letterhead that includes the Terms of Use and a statement that you agree to these terms", and 2) "An abstract of the proposed project". We submitted both items, yet never received a follow-up response after three separate attempts. If CMS includes this as an option for patient mental health data collection, it should provide the questionnaire.

- The "Use of Chronic Narcotics" is not sufficiently defined and is subject to wide variation in interpretation. The guidance materials state the "variable is defined as having any daily or regular intermittent dose of morphine (or hydromorphone equivalent) for at least 90 days". The guidance further states the data element is "somewhat subject to interpretation" and "[w]e leave it to individual surgeons or healthcare providers (that is, clinicians interacting with the patient/the patient's medical record) to determine whether the medication the patient is on is a narcotic and whether very short replacement narcotic use warrants coding as chronic narcotic use for the purposes of collecting this variable." Providers are also instructed to "collect data that reflects overall narcotic use (or any narcotic use), not just narcotic use specific to joint pain". Clearer guidance is needed, especially when asking clinicians to report "any narcotic drug use", which presumably means non-prescription narcotic use in addition to prescribed narcotics. The Drug Enforcement Agency maintains a list of controlled substances which includes almost 200 substances classified as narcotics, some of which are known by a variety of trade and other names. To "leave it to" providers "to determine whether the medication the patient is on is a narcotic" is unsatisfactory. A standardized definition or list of drugs considered narcotics for the purposes of this measure should be created.

- The data element labelled "Total Painful Joint Count" is not a total painful joint count but rather an assessment of whether the patient has pain in the non-operative hip or knee. This should be reworded to avoid confusion and to reflect the data to be collected.

C. Data Collection for the THA/TKA PRO-PM

CMS has highlighted the flexibility it proposes to allow for the data collection process, elaborating on all the "touchpoints" it says are available to ASCs: "[t]he possible patient touchpoints for preoperative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that can occur in an office or at the hospital. The modes of PRO data collection could include completion of the pre-operative surveys using

electronic devices (such as an iPad or tablet), pen and paper, mail, telephone, or through a patient portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection can occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for preoperative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection could include completion of the post-operative survey using email, mail, telephone, or through a patient portal."

Most of the "touchpoints" CMS indicates above are not available to ASCs. Per Federal regulation, ASCs may only act as the site for outpatient surgery and may only be involved with the care of the patient immediately before, during, and immediately after a surgical procedure. Unlike other outpatient surgical settings, such as clinician offices or hospital outpatient departments, ASCs may not provide preoperative services or postoperative follow-up care after patient discharge.

Because ASCs do not see patients prior to the day of surgery and do not see patients for follow-up visits, options for patient data collection are more limited than suggested by CMS. Based on the instructions provided regarding how and when to collect data for this measure, ASCs would need to collect preoperative data on the day of surgery (the patient would complete with the presurgical intake staff) and the postoperative data would have to be collected "using email, mail, telephone or through a patient portal" 10 to 14 months later.

When we have pointed out the challenges associated with delayed postoperative patient data collection in the past, CMS often suggests ASCs just get this information from the offices of the physicians performing the procedure. However, this is unlikely to work. As CMS is aware, Federal regulations intentionally isolate the operations of ASCs from those of clinicians. This makes the acquisition of data that is not generated in the process of providing care during the patient's time-limited stay in the ASC difficult. It would require significant additional resources to get patient data from other providers and/or their contractors, assuming the data has been collected by them in the first place.

In fact, it is entirely possible physicians would not have collected the patient data required by the measure. This is for two reasons. First, the measures physicians currently report for THA and TKA procedures are not aligned with the proposed ASC THA/TKA PRO-PM. The THA measure currently included in the physician Quality Payment Program is Quality ID #376: Functional Status Assessment for Total Hip Replacement. This measures the percentage of patients 19 years of age and older who received an elective primary THA and completed a functional status assessment within 90 days prior to the surgery and in the 270 to 365 days after the surgery. The proposed ASC measure requires additional data elements and the postoperative periods are not the same. For TKA patients, the most closely related measure is Quality ID #401: Functional Status After Primary Total Knee Replacement, which only evaluates postoperative functional status. Instruments used include both the KOOS, JR and the Oxford Knee Score. This measure includes additional CPT codes (27445 and 27446) in the denominator. No risk adjustment variables or patient-reported data are specified. Therefore, as a result of the

differences in currently reported physician measures, it would not be possible for ASCs to get all the needed data for the proposed THA/TKA measure from physician offices.

A CMS contractor has developed a Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure. It sounds like it would be aligned. However, as endorsed, this measure does not have the same postoperative timeframe, the specifications for the measure exclusions do not align, and it is unclear whether the CPT codes for elective primary THA/TKAs are the same. This measure is not currently an option for physician reporting.

The second reason physicians may not have collected the data ASCs need is that physicians may choose which quality measures they report. Data from the 2021 Quality Payment Program Experience Report presented on the data.cms.gov website shows very limited reporting of the related clinician THA/TKA measures discussed above. For the related hip measure (Quality ID #376) less than 2 percent of the 16,637 participating non-hospital-based orthopedic surgeons reported the measure. For the related knee measure (Quality ID #470) approximately 0.13 percent of 16,637 participating orthopedic surgeons reported the measure. Based on these levels of participation, we are not optimistic the newly developed Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure would be reported by large numbers of orthopedic surgeons if adopted in the future.

Based on the absence of an aligned measure in the clinician Quality Payment Program and the very low participation rates for measures with similar topics, it is highly unlikely ASCs would be able to get the information needed for the proposed THA/TKA PRO-PM from physician offices.

D. Proposed Data Completeness Requirement

The agency proposes ASCs be required to submit complete and matching preoperative and postoperative PRO data for at least 45 percent of their eligible elective primary THA/TKA procedures.[1] However, data completeness for this measure is not solely in the hands of the ASC. If a patient does not respond to all the items on each of the instruments requiring their input (the preoperative and postoperative HOOS, JR or KOOS, JR, the mental health items from the PROMIS-Global or VR-12, the Health Literacy SILS2, the "Total Painful Joint Count" and the Oswestry Index Question), the patient PRO data submission would be considered incomplete. As proposed, ASCs failing to meet the minimum 45 percent data completeness requirement once mandatory reporting begins would have their Annual Payment Update reduced in the CY 2030 payment determination. We do not believe facilities should be penalized for patient choices.

While the 45 percent threshold is slightly less than the 50 percent threshold set for the Hospital IQR Program and proposed for the HOQR Program, it is still much too high. Under the CMS Comprehensive Care for Joint Replacement Model, the agency anticipated "potential challenges that may result from collecting post-operative data on all patients for whom pre-operative data

[1] We see a statement that a 50 percent minimum is proposed for ASCs at 88 FR 49883 but have elected to reference the 45 percent minimum as stated elsewhere. Clarification would be welcome.

were collected", advised "hospitals should consider collecting data for more than the minimum requirement of procedures during the pre-operative data collection timeframe" and also encouraged hospitals "to account for potential challenges with response rates when setting internal pre-operative PRO survey response goals". For the Hospital IQR Program, CMS recommends hospitals collect and submit complete data on more than 50 percent of their eligible inpatient THA/TKA patients to maximize the potential for success in meeting the 50 percent data completeness requirement.

Because it is not possible to know in advance which patients would respond completely or would respond at all to the postoperative HOOS, JR or KOOS, JR assessment, providers would have to collect preoperative data on all their THA/TKA patients.

If this measure is adopted, a more reasonable data completeness standard would be needed, and its selection should be supported by current data regarding survey response rates. The results of the OAS CAHPS 2019 mode experiment showed the following response rates by modality: 35% mail-only; 19% phone-only; 29% web-only; 39% web with mail follow-up; and 35% web with telephone follow-up. These surveys were conducted no more than 2 to 3 months following the patient's episode of care. The proposed postoperative data collection period of 300 to 425 days after the patient's THA/TKA surgery is well beyond that of the OAS CAHPS and response rates are unlikely to be as high. In addition, ASCs would not have the benefit of collecting postoperative PRO data during a follow-up visit, which would be expected to negatively impact data completeness and overall response rates. Further, patient response rates to surveys have been declining in recent years, as documented by the HHS Office of the Assistant Secretary for Planning and Evaluation and many others.

We believe empirical testing of the measure in the ASC setting would be needed to determine a reasonable requirement for data completeness. The agency states it expects the measure to perform similarly to the clinician-group level and the hospital-level measures, but there is no evidence to support this assumption. Good measurement science requires testing.

Experience with the THA/TKA PRO-PM in both the Comprehensive Care for Joint Replacement Model and the IQR program has led hospitals to express concerns about the high level of administrative effort and resources needed to collect PRO data. Hospital participation in the Comprehensive Care for Joint Replacement Model was originally mandatory in 67 Metropolitan Statistical Areas (MSAs). In 2018, when hospital participation became voluntary for 33 of these MSAs, 73 percent of the hospitals in those 33 MSAs dropped out. Among the reasons for this exodus were hospital reports that patient follow-up was often very challenging, making it difficult to meet the agency's standards for data completeness. Compared to hospitals, ASCs have fewer administrative resources. We are therefore very concerned ASCs would find the measure even more difficult to implement.

Setting the response rate threshold based on complete PRO data puts ASCs at a disadvantage. Each patient is entitled to decide whether to respond to all the survey items. These individual choices must be respected yet should not adversely affect the ability of the ASC to meet program requirements. If the measure is adopted, CMS should redefine the response rate to include both

complete and incomplete responses because any level of patient response would reflect an attempt to meet requirements for the measure.

E. Proposal for Phased Implementation of the THA/TKA PRO-PM

CMS proposes to adopt the THA/TKA PRO–PM beginning with two voluntary reporting periods, followed by mandatory reporting. The first voluntary reporting period would begin in 2025 with THA/TKA procedures from January 1 to December 31, 2025. The second would begin in 2026 with THA/TKA procedures from January 1 to December 31, 2026. Mandatory reporting would begin in 2027 for THA/TKA procedures occurring between January 1 and December 31, 2027. Due to the long length of time between surgery and the postoperative data collection, CMS proposes a 3-year gap between the reporting period and the payment determination year, meaning data collected mandatorily for THA/TKA procedures during calendar year 2027 would impact the 2030 payment determination.

The choice of 2025 to begin voluntary reporting does not take the beginning of mandatory reporting for OAS CAHPS into account. Given the extensive preparatory work needed for the THA/TKA PRO-PM, voluntary reporting in 2025 is not reasonable and should be delayed.

If the measure is adopted, the extended follow-up period for the postoperative PRO data collection would mean a longer voluntary reporting period would also be needed to allow sufficient time to put preliminary processes in place and amend those processes based on experience. Because this measure was never tested in the ASC setting, the voluntary reporting period would essentially become the pilot test that was never performed. The agency indicates it considered extending the length of voluntary reporting. We believe this would be necessary and would encourage CMS to do so if the measure is adopted.

F. Data Submission for the THA/TKA PRO-PM

CMS proposes ASCs would either submit the THA/TKA PRO-PM measure data themselves or contract with a vendor of their choice to submit the data on their behalf. The HQR System would be used.

The agency proposes that data for THA/TKAs performed in a single calendar year would have two different data submission periods – one submission for the preoperative data and another for the postoperative data. This would apply to both the voluntary and mandatory reporting periods. The proposed data submission deadlines are summarized in Table 2 below.

TABLE 2. Proposed Data Submission Deadlines for the THA/TKA PRO-PM Measure

Reporting Cycle	Dates of THA/TKA Cases	Preoperative Data Submission Deadline	Postoperative Data Submission Deadline
CY 2025 (Voluntary)	Jan 1 – Dec 31 2025	May 15 2026	May 15 2027
CY 2026 (Voluntary)	Jan 1 – Dec 31 2026	May 15 2027	May 15 2028
CY 2027 (Mandatory)	Jan 1 – Dec 31 2027	May 15 2028	May 15 2029

This proposal means that for any given May 15 deadline after 2026, ASCs would submit both preoperative data for THA/TKAs performed the prior year and postoperative data for THA/TKAs performed two years prior. We notice, for example, that ASCs would submit both preoperative data for 2028 THA/TKAs and postoperative data for 2027 THA/TKAs for the same May 15, 2029 submission deadline.

There is no compelling reason for two separate submission deadlines for a single year's THA/TKA procedures. Both preoperative and postoperative measure data for THA/TKAs performed in a single calendar year could be entered at the same time for the May 15 submission deadline two years hence. Again, it is not possible to know in advance which of the patients with complete preoperative PRO data would subsequently respond completely to the postoperative PRO survey. Having a single deadline would avoid the extra work needed to enter preoperative data for patients who did not choose to respond completely (or who did not elect to respond at all) to the postoperative PRO assessment. This is important because any patient with incomplete data is not included in the denominator population or the calculation of the RSIR or the response rate. Entering the data in a single session would also avoid the need to enter the six "Matching Variables" (see Table 1: THA/TKA PRO-PM Measure Data Elements Collected Pre- and Postoperatively) a second time. One submission deadline for each year's THA/TKA cases – the deadline currently proposed for the postoperative data submission - would be less complicated, more efficient and less burdensome.

G. Incomplete Patient PRO Data and Non-Response Bias Weighting

CMS may point to the inclusion of non-response bias weighting as justification for having ASCs submit incomplete patient PRO data. Although any patient with incomplete PRO data or no PRO data is not included in the measure denominator (cohort) or measure result/outcome, these patients are included in the measure methodology for non-response bias weighting.[2] This is a statistical approach used to account for potential non-response bias in the calculation of RSIRs.

Stabilized inverse probability weighting - stabilized IPW - is used for non-response bias weighting in the proposed THA/TKA PRO-PM measure. In addition to incomplete/absent PRO data, the calculations for non-response bias weighting also rely on additional data elements, including those derived from Medicare administrative claims data (race, dual eligibility) and from the Agency for Healthcare Research and Quality Socioeconomic Status (SES) Index score. The calculation assigns higher weight to patients who are less likely to respond and gives less weight to patients who are more likely to respond. However, comparison of the measure outcome with and without this statistical approach revealed little impact. Despite this, the developers retained it, stating they "expect that non-response bias will be a factor for the THA/TKA PRO-PM, due to associations with non-response including socioeconomic status and health status."

[2] See the Hospital IQR Program transcripts for Voluntary Reporting of the Hospital-Level THA/TKA PRO-Based Performance Measure Presentation dated September 14, 2022, and August 3, 2023.

This "expectation" has not been substantiated by the statistical modeling performed for the clinician/clinician-group level THA/TKA PRO-PM measure. The measure developer indicated "there is not an association between the residuals of the improvement outcome and the probability of response based on our models". In addition, the developer stated, "[t]he comparison of clinician-level and clinician group-level RSIRs for a risk-adjusted model of SCB improvement with stabilized IPW and without stabilized IPW suggests that the results are not sensitive" to the weighting.[3] Elsewhere, the measure developer stated, "[w]e assessed the non-response bias by the Pearson correlation between the Pearson residuals of the hierarchical outcome model with only clinical risk factors and the probability of response. This correlation among clinicians was - 0.00784 (p-value=0.27) and among clinician groups was -0.00709 (p-value=0.32). This indicates that there is not a significant association between the residuals and the probability of response. The correlation between RSIR unadjusted and inverse probability weighted RSIR is very high (0.9958 for clinicians and 0.9956 for clinician groups) suggesting that the results are not sensitive to our weighting adjustment".[4] It is important to note that the same lack of association was seen for the hospital-level measure.[5]

In other words, non-response bias weighting did not have a significant impact on the measure outcome. It is, therefore, non-essential. ASCs (and other providers) should not be asked to devote resources to submitting data for patients whose PRO responses are incomplete or non-existent when there is no evidence to indicate it makes a meaningful difference in the measure outcome. It creates additional burden where none is needed.

H. Proposal for Public Reporting During the Voluntary and Mandatory Reporting Periods

CMS proposes to publicly report which ASCs choose to participate in voluntary reporting. The agency would also report the percent of preoperative data submitted by participating ASCs for the first voluntary reporting period, and the percent of matched complete preoperative and postoperative PRO data submitted for subsequent voluntary reporting periods. The agency further proposes that ASCs participating in voluntary reporting submit matching preoperative and postoperative PRO data for at least 45 percent of their eligible elective primary THA/TKA procedures. CMS would provide confidential feedback reports during voluntary reporting that would include the RSIR as well as "other results to support understanding performance".

For the mandatory reporting cycles, CMS proposes to provide ASCs with confidential preview reports before publicly reporting each ASC's RSIR and response rate on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare*.

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[3] Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and Total Knee Arthroplasty (THA and TKA) Patient-Reported Outcome- Based Performance Measures (PRO-PMs) Measure Methodology Report.

[4] National Quality Forum, Measure Worksheet NQF #: 3639 Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA and TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM).

[5] Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure, Version 1.0 Methodology Report.

I. CMS Has Significantly Underestimated the ASC Cost of the THA/TKA PRO-PM Measure

When estimating the burden of information collection for patients completing surveys for this proposed measure, CMS assumed most ASCs would perform the PRO data collection "through a screening tool incorporated into their electronic health record or other patient intake process." Environmental scans have shown the use of electronic health records (EHRs) in the ASC industry is more limited than in other healthcare settings. This reflects the history of Federal incentives for the adoption of EHRs. The Health Information Technology for Economic and Clinical Health Act of 2009 authorized financial incentives for hospitals and clinicians to adopt EHR technology. However, ASCs were not included in the Act and were ineligible for the financial incentives under the CMS Promoting Interoperability Program. As a result, most ASCs do not have an EHR and would have to collect the THA/TKA preoperative PRO data manually. Similarly, and because the patient would not be seen in the ASC for any postoperative visits, the postoperative PRO data collection would also involve manual processes for many ASCs. Finally, the data submission process is likely to require manual input of data for each patient.

CMS has estimated an ASC would spend 20 minutes annually - 10 minutes apiece for each of the two PRO surveys - to collect and submit all the data for the THA/TKA PRO-PM measure. (FR 88 49883) This is a serious underestimate of the amount of time that would be involved. As noted above, this measure would require ASCs to collect and submit a total of between 44 and 49 data elements per patient. It would take more than 20 minutes of effort to collect and submit the data for each patient. An estimate of 20 minutes per year per ASC for the entire process of preoperative and postoperative PRO data collection and submission is a sizable understatement of the burden that would be imposed by this measure.

CMS acknowledges there would be some non-recurring costs associated with data collection for the measure. The agency assumes most ASCs would report data for this measure directly to CMS via the HQR System. CMS estimates a cost of $5,212 for any ASCs choosing to submit measure data via a third-party vendor. Based on industry experience with OAS CAHPS third-party vendors, this estimate is also well below the actual cost.

J. Requirement for Establishing Consensus Among Affected Parties

This measure was not tested in the ASC setting, nor has this measure been endorsed for the ASC setting by a consensus-based entity. CMS points to two endorsed versions of this measure, one at the clinician/clinician-group level and one at the hospital level, but endorsement for these health care providers cannot serve as proxy for ASCs, which are entirely distinct entities.

When endorsement is lacking, it is possible to meet the requirement that measures reflect consensus among affected parties in other ways, such as through the measure development process, through broad acceptance, use of the measure, and through public comment. CMS is proposing this measure without endorsement "based upon strong MAP [Measure Applications Partnership] and public support combined with the importance of the measure for Medicare beneficiaries".

We do not believe MAP support for this measure meets the requirement for consensus among affected parties. For over seven years, neither the Hospital Workgroup nor the Coordinating Committee of the MAP have had any ASC representation. This lack of representation is something we have made the agency aware of in our yearly comment letters. Without any input from an ASC representative, CMS cannot claim the MAP committees provide legitimate representation of, or consensus among, ASCs.

Further, the claim for strong public support is overstated, appearing to be based on the input of sixty-six patients, who "expressed a desire to see measure results that reflect physician-level performance but agreed that a hospital-level measure is a good way to encourage communication across providers to improve coordination of care" (please see the submission for the Measures Under Consideration List MUC2022-026 Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the HOPD or ASC Setting). The patients were asked about hospitals, not ASCs, so there has not been a statement of patient support for an ASC measure through this process.

The measure cannot be said to meet the requirement for consensus through "broad acceptance" by ASCs, or by "use of the measure" by ASCs. There is none in evidence. ASCs were not involved in the development of either the hospital or clinician measures, so there was no opportunity to establish consensus through the measure development process.

We note CMS intends to use the ASC community by collecting ASC data during voluntary reporting to support the measure, only then submitting it for endorsement. This approach is completely unacceptable to us. If any entity other than a CMS contractor were to develop a measure without any testing in the affected setting and without any input from affected parties, there would no doubt be objections regarding its suitability for adoption into a CMS quality reporting program, and rightly so. CMS is allowing its contractors exemption from processes put in place to assure measures adopted into its quality reporting programs have been properly tested and vetted. These exceptions would not be available to other independent measure developers. The agency should have the same expectations for its contractors as are required of other developers.

K. An Alternative Approach to THA/TKA PRO Measurement

CMS has said it "seeks to advance patient-centered measurement with as little burden as possible to both providers and patients". The agency should rethink its approach to the measurement of PROs in order to achieve this goal.

CMS has frequently been asked why this measure is being proposed for and/or adopted into CMS quality reporting programs for hospitals and outpatient surgery settings when the functional assessments are done before and after surgery in physician offices. We believe an alternative measurement approach should be adopted in order to leverage PRO data collection where it would typically occur during the preoperative and postoperative care of the patient.

To minimize burden across multiple quality reporting programs, CMS should use a single data collection and submission to develop THA/TKA PRO data for all involved providers. We

recommend the measure developer add a data element to the clinician/clinician group measure to collect the facility provider number for the site of surgery. This approach is used in the American Joint Replacement Registry. This single data element makes it possible to then match the clinician THA/TKA PRO data with the hospital, HOPD or ASC where the surgery was performed. The site of service could subsequently be verified using administrative claims data and facility preview reports. If adopted as a mandatory clinician measure, the results for all involved facilities could be reported. This approach would be an effective, efficient one for capturing THA/TKA PRO data at the clinician and facility levels. It would also negate the need for both clinicians and facilities to attempt to capture the same patient PRO data or to coordinate data collection efforts across settings, which under the current method will undoubtedly lead to duplicative requests to patients. Further, it is more easily incorporated into typical clinical workflow, assuring patients that the data collection is legitimate.

If CMS chooses not to consider this alternative, there are several matters needing attention prior to considering adoption of the THA/TKA PRO-PM measure for the ASCQR Program. The most important of these is testing the measure in the ASC setting. Modifications to the measure specifications and measure methodology as well as revised performance expectations and data submission requirements would also be needed as discussed above.

III. Proposed Re-Adoption of a Modified Version of the ASC Facility Volume Data on Selected ASC Surgical Procedures Measure

CMS has proposed to reintroduce a modified version of ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures. This is a "structural measure of facility capacity" (88 FR 49810) which originally collected procedure volume data on a varying number of procedure categories during the time the measure was previously included in the ASCQR Program. This measure was removed from the ASCQR Program beginning with the 2017 data collection period based on the availability of other measures more strongly associated with desired patient outcomes (82 FR 59449-59450). A facility volume measure is also being proposed for the HOQR Program.

If re-adopted, reporting of the measure would be voluntary for the CY 2025 reporting period, then mandatory beginning with the CY 2026 reporting period for the CY 2028 payment determination.

We do not support the readoption of this measure for the reasons discussed in more detail below.

A. Lack of Evidence to Support Volume as a Measure of Quality in Low-Risk Procedures

The literature CMS has quoted in supporting its claim that measuring volume is important in ASCs is focused on high-risk surgical procedures. The studies the agency presented to support its position evaluated procedures such as distal gastrectomy for gastric cancer, emergency general surgery in high-risk patients, coronary artery bypass grafting, cardiac valve surgery (including cases with concomitant coronary artery bypass grafting), transcatheter aortic valve replacement

and percutaneous coronary interventions in patients experiencing acute myocardial infarction. These high-risk surgeries are not performed in ASCs.

The evidence CMS presented also relies on an opinion article - not a research study - quoted no less than five times. This opinion piece was prompted by the "Take the Volume Pledge" initiated by three health systems to restrict certain surgeries to hospitals that met procedure-specific hospital and surgeon minimum annual volume thresholds. Among these surgeries were resections for cancer of the esophagus, pancreas, rectum and lung – none of which are performed in ASCs. A subsequent study of outcomes for lung cancer resection compared results for hospitals and surgeons that did and did not meet the "Volume Pledge" criteria.[6] This study found '[t]he Volume Pledge was not associated with better outcomes except for a marginally shorter length of stay." The clinical data was also evaluated for potential alternative volume thresholds associated with better outcomes. This "yielded mixed results that did not reveal a practical alternative for volume-based quality improvement efforts."

In fact, CMS has not presented any evidence that measuring volume is a valid and reliable indicator of quality for low-risk procedures and surgeries, which are the types of services performed in ASCs. Nor has it presented any evidence supporting the notion that more volume results in better outcomes for low-risk procedures and surgeries.

Further, the measure appears to have been re-specified in a manner that selects the highest volume procedures in each procedure category for data collection and reporting. These are the principal services performed by ASCs, and those with which the center is most experienced. By focusing on low-risk, high-volume services, the measure evaluates the procedures presenting the least concern.

B. Measuring Volume Does Not Lead to Actionable Data

While volume can be an indirect indicator of experience, the measure is not specified in a manner that would allow comparisons of experience levels to be made. The measure is more closely associated with facility capacity than experience levels. Take the example of two ASCs equally experienced in performing one of the high-volume procedures identified by the measure specifications. If one ASC had two-room capacity and the other four-room capacity their results on the volume measure would differ. We could reasonably expect the four-room ASC to have roughly double the volume of the two-room ASC, but could not reasonably assume the higher-capacity (and therefore higher-volume) location provides superior care.

When scheduling cases, ASCs already use their available rooms, equipment and personnel as efficiently as is prudent. If we are to believe "more is better" and that increasing volume would improve the quality of patient care, then the center would need to schedule more patients using their fixed capacity. We find it hard to believe that picking up the pace is going to improve patient care. Setting a work pace appropriate to the capacity and other characteristics of each center is conducive to safe patient care. Trying to schedule more cases could in fact cause

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6 Farjah, F et al, Volume Pledge is Not Associated with Better Short-Term Outcomes After Lung Cancer Resection. J Clin Oncol. 2020 Oct 20;38(30):3518-3527. https://doi.org/10.1200/JCO.20.00329.

deterioration in the quality of care if staff previously working at a comfortable pace now rush to do more cases. In fact, an appropriate work pace is conducive to safety, so much so that the topic is included in the Surveys on Patient Safety Culture™ (SOPS®) developed by the Agency for Healthcare Research and Quality (AHRQ).

Capacity is not readily altered. Therefore, even if one believed capacity were tied to quality, an ASC cannot use the results of this measure to "improve" patient care. Most states have certificate of need (CON) laws requiring approval of the expansion of an existing facility or creation of a new healthcare facility. Even in the absence of CON laws, increasing capacity requires a clear indication of unmet need for surgical or procedural services in the community, available staffing, and significant capital investment.

C. Measure Modifications Are Unclear

CMS indicates the first modification to the measure would be to expand the data collection to eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. This is confusing because, in the past, ASCs were required to collect and submit data for up to nine categories of procedures – including the Cardiovascular and Respiratory categories identified as "new" by CMS.

We reviewed the Measure Information Form for this proposed measure (available at https://qualitynet.cms.gov/asc/ascqr/proposedmeasures), in which Table 1 presents "2022 ASC Claims with Surgical CPT Codes: Top Five CPT Code [sic] per Procedure Category". We found ten procedure categories listed in this table, rather than the eight described in this proposed rule. Seeking further clarification, we looked at other sources of data for the measure. CMS directed readers to the Center for Medicare and Medicaid Services Inventory Tool (CMIT). The CMIT file for the measure indicates six categories of procedures in the numerator statement, while the description for the measure in the same file lists eight categories of procedures. Elsewhere, the numerator statement for the Measures Under Consideration submission form for the measure references "six categories of procedures".

The second modification to this measure CMS proposed is that instead of collecting and publicly displaying data surrounding these eight (?) broad categories, CMS would more granularly collect and publicly display data reported for the top five most frequently performed procedures among ASCs within each category.

This statement of the proposed second modification again differs from what is presented in the CMIT file for the measure. The file indicates the measure would collect all-patient, all-payer surgical procedure volume data on selected categories, without mention of the top five procedures. The Measures Under Consideration submission form, used to obtain the MAP's recommendation, states the measure would collect the aggregate count of surgical procedures performed per category, with no mention of the top five most frequently performed procedures. The Measure Information Form is the only reference we see with five procedure codes per category included. However, although there are five codes listed for each of ten categories, the Measure Information Form indicates that the measure would determine the "aggregate count of

selected surgical procedures per category". Aggregate counts per category would not lead to more granular information for public reporting.

This is very confusing, and we would appreciate clarification. We are not convinced the measure that was reviewed and conditionally supported by the MAP is the same one CMS is now proposing. The prospect of submitting data for six or eight or even ten categories of aggregate procedure category data is very different from the prospect of having to submit 30 or 40 or even 50 "top five" procedure totals. The difference in burden between the two is significant, and something we would have liked to discuss in a more considered, specific manner with the agency in these comments. We were unable to obtain clarification despite our requests.

D. Measure Specifications Are Not Aligned Across the ASCQR and HOQR Programs

In discussing this measure, CMS indicates one of the key goals of the Hospital OQR and ASCQR Programs is to facilitate comparisons across ASCs and hospital outpatient departments. This is a goal we support when comparisons of measure data are based on identical measure specifications.

CMS states, "the MAP highlighted that the specifications of the volume measure proposed for the Hospital OQR Program are aligned with the volume measure we propose for the ASCQR Program and, therefore, would facilitate comparisons of equivalent procedure volumes across ASCs and hospital outpatient departments (HOPDs)". (88 FR 49813). Perhaps the measures were aligned when the MAP reviewed them. However, review of the Measure Information Forms for the proposed HOQR and ASCQR volume measures reveals the specifications for these measures are not aligned, possibly reflecting a later decision to select the top five procedures in each category for HOPDs and ASCs.

Because the scope of surgical services offered in the HOPD setting is more extensive than that allowed for ASCs, there are differences in the services with the highest volume across the two settings. Specifying the measure according to the highest volume procedures in each setting has created misaligned procedures and procedure categories. In fact, there is only one aligned category – Nervous System – in which all five selected codes are the same for HOPDs and ASCs. For the Gastrointestinal (also called Digestive System) procedure category four of five codes are the same; for the Eye and Ocular Adnexa and Urinary System procedure categories three of five codes are the same; for the Urinary (MGS) and Urinary (FGS) procedure categories two of five codes are the same; for the Musculoskeletal System and Cardiovascular System procedure categories one of five codes are the same; and for the Integumentary System (also called Skin) and Respiratory System procedure categories none of the five codes are the same. In all, only 21 of the 50 codes specified for each program – less than 50% - are the same across the measures. It is difficult to see how this would facilitate comparisons of "equivalent procedure volumes" across ASCs and HOPDs. Only "Nervous System" procedures could be compared.

E. Facility Volume Data on Selected ASC Surgical Procedures Is Not Useful to Consumers

CMS states patients and their caregivers may benefit from public reporting of facility-level volume measure data because volume data show which procedures are performed across ASCs and can serve as an indicator of which facilities are experienced with certain outpatient procedures.

However, as proposed, the measure does not provide helpful information to consumers. As in the past, the measure specifies aggregated procedure categories that are too large and diverse to provide meaningful consumer information. Revising each of the categories to reflect the five procedures ASCs perform most frequently does not alleviate this problem because the five would apparently be aggregated. Even if the five were not aggregated, the procedures in the top five lists for each category are not very diverse. The layperson would face many challenges using the publicly reported data; even the names of the procedure categories are potentially confusing.

Consider the following from the consumer perspective: If a patient needed a hernia repair, how would they use the information in the aggregated "Gastrointestinal" category data to distinguish a facility that performs a high volume of gastrointestinal endoscopies from a facility that performs a high volume of general surgery? For ASCs, if the top five procedures were to be used, only endoscopies would have been counted. If a patient needed a corneal transplant, how would they identify a facility performing a high volume of these by looking at the "Eye and Ocular Adnexa" category? If a patient needed carpal tunnel surgery, how would they know which facility did carpal tunnel surgery as compared to pain management injections by looking at the "Nervous System" category? If a patient needed a bunionectomy, how would they know if a facility did a lot of these by looking at the volume data for the "Musculoskeletal" category? If a patient needed breast surgery, how would they determine which facility performed these regularly by looking at the "Skin" category? As these few examples show, it would be very difficult for an individual patient or caregiver to use aggregated volume for a procedure category to inform a decision about a particular procedure. Aggregated volume data from very broad procedure categories is just not helpful in this regard, and the patient would have to rely on other sources of information to determine the volume of the pertinent service. Further, the proposed volume data would not provide any additional context for a consumer attempting to interpret it.

F. Potential Alternative Approaches

Given the unlikelihood of an impact on quality improvement efforts, we do not believe ASCs should be asked to collect and submit the data for this measure if it is readopted. If CMS wants to pursue an ASC volume measure, the agency should prepare and report the volume data based on Medicare claims using its own resources and not task ASCs with doing this. Though relying on Medicare claims would limit the measure results to Medicare patients only, this is preferable to burdening ASCs with data collection and submission when the results are not actionable and not helpful to consumers.

Alternatively, and given that CMS's justification for the volume measure is based on the movement of procedures from the inpatient to the outpatient setting, the volume measure should be specified to show the volume trends in those services. We recommend CMS develop a

volume measure focusing on procedures transitioning from the inpatient to the outpatient setting to replace this measure.

If CMS is not willing to use Medicare claims to calculate the measure or to pursue a different volume measure focusing on those procedures migrating from one setting to another, then we urge the agency to readopt this measure as a strictly voluntary one in 2025 and all subsequent years.

IV. Proposed Modification of the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (ASC-9)

In 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on Colorectal Cancer (CRC) Screening. Based on new evidence, the USPSTF recommended that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previously recommended age of 50. This is in alignment with the recommendations of multiple organizations, including the American Cancer Society, American Society of Colon and Rectal Surgeons, and the U.S. Multi-Society Task Force on Colorectal Cancer (which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy). Based on this change in clinical guidelines, CMS is proposing to modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure to align with these updated clinical guidelines.

Currently, this measure assesses the "percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report." CMS is proposing to change the measure's denominator by replacing the phrase "aged 50 years" with the phrase "aged 45 years." The measure denominator statement would be modified to "all patients aged *45 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy." No changes to the measure numerator, other measure specifications, exclusions, or data collection for this measure are proposed.

The ASC QC supports the modification of this measure to align with current clinical guidelines. The agency has proposed the changes be implemented beginning with the CY 2024 reporting period / CY 2026 payment determination. Given the short interval between the issuance of the Final Rule and the beginning of the CY 2024 reporting period, CMS should use all available avenues of communication to inform ASCs of the new measure specifications.

V. Proposed Modification of ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

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 this patient-reported outcome measure are based on patients' completion of surveys of both

preoperative and postoperative visual function. Currently, the measure has a voluntary reporting status.

A. Proposed Modification of Survey Instrument Use for ASC-11

In this proposed rule, CMS proposes to designate specific survey instruments to be used for the preoperative and postoperative assessments of visual function in both the ASCQR Program and Hospital OQR Program to ensure alignment of this measure's specifications. To that end, CMS is proposing to limit the allowable survey instruments used for the purposes of this measure to the following:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25)
- The Visual Functioning Patient Questionnaire (VF-14)
- The Visual Functioning Index Patient Questionnaire (VF-8R)

If adopted, these surveys would be the only ones approved for data collection beginning with the CY 2024 voluntary reporting period. We do not object to limiting the surveys used for purposes of this measure to these instruments.

However, we continue to have strong reservations regarding the feasibility of implementing this measure in ASCs for the reasons described below and urge the agency to continue voluntary reporting for this measure for as long as it is retained in the ASCQR Program.

B. Considerations for Data Collection Modes for ASC-11

As CMS has acknowledged in the past, it "can be operationally difficult for ASCs to collect and report this measure" because the results of the surveys might not be shared, "making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery" (79 FR 66984). In this proposed rule, CMS has reiterated "while we recommend the patient's physician or optometrist administer, collect, and report the survey results to the ASC, the survey instruments required for this measure can be administered by the ASC itself via phone, by the patient via regular or electronic mail, or during clinician follow-up." (88 FR 49810)

We have repeatedly highlighted the difficulties of obtaining the survey data from the patient's physician or optometrist. The physician measure corresponding to ASC-11 is Quality ID #303: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. Under the current Quality Payment Program, clinicians may select measures to report, so there is no requirement that ophthalmologists or optometrists report on the measure. The most current report of clinician data is included in the 2021 Quality Payment Program Experience dataset, available at data.cms.gov. The data indicates that of the 15,751 ophthalmologists with QPP data, only 50 (approximately 0.32%) reported data for this measure. Of the 10,418 optometrists with QPP data, only 25 (approximately 0.24%) reported data. These low rates of clinician data submission likely reflect the requirement that the measure be administered by a registry or third-party intermediary, which is expensive.

Given that very few clinicians are collecting the survey data ASCs would need, CMS's recommendation that ASCs obtain the data necessary for ASC-11 from clinicians is not workable. CMS is now emphasizing ASCs can administer the surveys "via phone, mail, email, or during clinician follow-up". However, ASCs do not see patients prior to the day of surgery, nor do ASCs see patients "during clinician follow-up" after discharge. As you know, CMS regulations at 42 CFR §416.2 prohibit ASCs from offering anything beyond limited surgical services or separate, but integral ancillary services immediately before, during or immediately after a surgical procedure.

ASC-11 was developed as a clinician measure, and never intended to be applied in the ASC setting. Most ASCs would find it challenging to conduct phone, mail or emails surveys of cataract surgery patients both preoperatively and 90 days postoperatively. Our members report that hiring a third-party vendor to perform these tasks would be expensive. While a small number of ASCs have voluntarily reported the measure, we think it is unlikely that a significant number of additional ASCs would be able to do so. Therefore, we urge CMS to continue voluntary reporting of this measure until such time as an alternative measure of ophthalmic surgery outcomes can be put in place.

C. Recommendation of an Alternative Measure for Ophthalmic Surgery

Instead of continuing to make ongoing investments in the Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure, CMS should remove the measure from its facility-level quality programs and propose a different measure to address ophthalmic surgery outcomes. The ASC QC continues to recommend the Toxic Anterior Segment Syndrome (TASS) measure, which assesses the number of patients diagnosed with TASS within two days of undergoing anterior segment surgery. This measure to assesses outcomes related to frequently performed ophthalmic surgeries, including cataract surgery, in ASCs.

Millions of anterior segment surgeries are performed in ASCs every year, with the total number expected to increase due to an aging population. Studies in the literature have reported TASS complication rates of 1.8 to 2.1%, indicating a clear opportunity for improvement.

Prevention of TASS is important. The American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Registered Nurses have published recommended practices for cleaning and sterilizing intraocular surgical instruments aimed at the prevention of TASS. In addition, ASCRS, the American Academy of Ophthalmology, and the Outpatient Ophthalmic Surgery Society have released recommendations regarding the use of enzyme detergent for cleaning intraocular surgical instruments. The ASCRS also has a TASS registry, highlighting the importance of identifying and reporting occurrences.

Some have asserted data for TASS is difficult to collect and that ASCs would not be notified if TASS were diagnosed. The experience of our members refutes this. 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.

The measure was reviewed by the MAP and received conditional support. The TASS measure has been fully tested in the ASC setting and is currently in use among our members. Aggregate data is published in our quarterly public report of ASC quality data at www.ascquality.org/qualityreport.

We recommend the agency propose adoption into the ASCQR Program in the next rulemaking cycle. CMS should also propose adoption of this measure for the Hospital OQR Program.

VI. Revision of the ASCQR Program Claims Threshold is Needed

Presently, ASCs with fewer than 240 Medicare claims (primary plus secondary payer) per year during a reporting period are not required to participate in the ASCQR Program for the subsequent reporting period. As a result, an ASC with fewer than 240 Medicare claims in 2023 would not be required to submit 2024 data for the calendar year 2026 payment determination.

With mandatory reporting of the OAS CAHPS survey imminent, and the potential for significant additional data collection and reporting burdens if the measures CMS has proposed are adopted, the ASCQR Program is approaching an inflection point. Some centers will find the cost of participation in the ASCQR Program exceeds the two percent payment update sacrificed by not meeting program requirements. Consequently, CMS should propose to raise the claims threshold in the next rulemaking cycle so low volume centers are not penalized for lacking sufficient resources to comply with increasingly expensive Program requirements.

VII. Expanding Consumer Quality Measures Across Surgical Sites of Service

CMS should adopt additional quality measures across surgical sites of service. There are eight existing ASC measures that could be applied to other settings in order to advance the ability of consumers to compare clinically meaningful facility-level outcomes. These measures are:

- ASC-1: Patient Burn measure
- ASC-2: Patient Fall measure
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant measure
- ASC-4: Hospital Transfer/Admission measure
- ASC-13: Normothermia Outcome measure
- ASC-14: Unplanned Anterior Vitrectomy measure
- Toxic Anterior Segment Syndrome (TASS) measure
- Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure

The data from these measures would be helpful to prospective patients. We encourage CMS to make proposals in the next rulemaking cycle to adopt existing ASC measures into the HOQR Program, and to adopt the TASS and SSI measures into both programs.

VIII. Public Reporting of ASCQR Program Data

Over the years the ASC QC has offered many comments on ways to improve the public reporting of ASCQR Program data. We are pleased to see the Facility Compare Dashboard has been improved by adding information on claims-based measures. This is a helpful feature, and we appreciate the work done to enhance the dashboard.

This data should also be displayed on the CMS Care Compare website. Though providers are certainly interested in the quality measure data generated by the ASCQR and HOQR Programs, we believe healthcare consumers should be a primary focus of efforts to share this information. Consumers are most likely to look for this information on Care Compare.

Unfortunately, while the Care Compare landing page includes multiple buttons for various healthcare providers it does not include a link for ASCs. (We understand ASCs are a supplier type under the Medicare program, but it is unlikely the typical person looking for quality data would be aware of this.) Only after clicking on the "Hospitals" button and reading through the page does the question, "Or want to learn more about ambulatory surgical centers (ASC)?" appear with a link to ASC data on the data.CMS.gov website. This link is obscure and difficult to find. We are disappointed that ASC quality data are still not available on the CMS Care Compare site despite years of requests for action on this matter.

Until such time as CMS adds ASC data to the Care Compare website, the agency should make it easier for consumers to locate the link to ASC data on the data.cms.gov website. As a temporary solution, the current "Hospitals" button on the landing page could be renamed "Hospitals including Ambulatory Surgery Centers". Although we do not think data for ASCs belongs under a hospital heading, it would help consumers find the "Visit the ASC data on CMS.gov" link to ASC data more easily until a permanent solution is created.

While ASC quality measure data is available on the data.cms.gov site, unless a consumer is lucky enough to find the direct link from the "Visit the ASC data on CMS.gov" on the Care Compare website, it is challenging to find. This site is not user friendly for consumers looking for quality data, and the search box on the CMS.gov home page is not helpful. In fact, using an independent search engine is the most effective way to locate provider quality data. If one chances to find the Provider Data home page, there is no button for ASCs. Although it is unlikely consumers would intuitively search for ASC information under the Hospitals heading, ASC data is buried within the information shared under the "Hospitals" link.

For those who do manage to find the links to the ASCQR Program data, the display of the data is not helpful. Measure scores are listed under column titles such as "ASC-9 Rate", making it difficult to understand what data being presented and what it means. Clicking on the column title does not provide any additional information. It is also hard to find data for a specific facility without downloading the entire dataset and there is no easy way to compare measure data across various centers.

The current method of displaying ASCQR Program data for consumers needs improvement. ASCs are the most common site of outpatient surgery in the United States, and consequently it is essential for CMS to be effective in sharing ASC quality measure data with the public.

Significant effort from ASCs is needed to collect and submit quality data to the agency. The data resulting from this work deserves to be shared in a manner that is easily accessible and helpful. CMS should work promptly to include the data from the Facility Compare Dashboard on the CMS Care Compare site and to develop clear paths to ASC quality data on the data.cms.gov site.

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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,

Kathy Wilson

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ASC Quality Collaboration