Outpatient Quality Program Systems and Stakeholder Support Team

Making the Case: ASCQR in the CY 2024 OPPS/ASC Proposed Rule
Presentation Transcript

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Karen VanBourgondien: Hello everyone. My name is Karen VanBourgondien and we appreciate you joining us. Today, CMS will be addressing the proposed rule and its impact on the ASC Quality Reporting Program.

Our guest speaker today is Dr. Anita Bhatia. Anita is the CMS Program Lead for the ASC Quality Reporting Program. She received her PhD from the University of Massachusetts Amherst and her Masters in Public Health from Johns Hopkins University. Dr. Bhatia plays a crucial role in

development of the OPPS/ASC proposed and final rulings. Her contributions to the rulings are essential to the continuing success of the program. We are fortunate to have her commitment.

Before we get started and I hand things over to Anita, let me just cover a few housekeeping items.

The objectives for today are here on the slide. We will cover proposals as they relate to the program, we'll locate the rule, and how to submit comments.

We will also have a quick program review to make sure everyone knows what to report and when.

If you need the slides, you can just click on that paper icon that is located on your screen. We also have the slides posted on our website QualityReportingCenter.com and we'll put that link in the chat box.

I'd like to make certain that the content covered on today's call should not be considered official guidance. This webinar is only intended to provide information regarding program requirements.

Please refer to the proposed rule, located in the *Federal Register* to clarify and provide a more complete understanding of the modifications and proposals for the program which Anita will be discussing. We have placed the direct link to this document here on this slide. We will also put it in the chat box.

So, without any further delay, let me hand things over to our Speaker, Dr. Anita Bhatia. Anita?

Anita Bhatia: Thank you, Karen. And thank you everyone for joining us today. I am going to discuss with you what CMS is proposing in the current rulemaking cycle for the Ambulatory Surgical Center Quality Reporting Program.

In the first section, we will cover proposals for measures that are currently part of the ASC Quality Reporting Program.

In this proposed rule, we are proposing to modify three previously adopted measures: the COVID-19 Vaccination Coverage Among Healthcare Personnel measure; the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure; and the Cataracts: Improvement in Patient's Visual Function within 90 days Following Cataract Surgery measure. We will begin with

discussing our proposed modifications to the COVID-19 Healthcare Personnel Vaccination measure.

We are proposing to modify the term "up to date" in the Healthcare Personnel Vaccination definition beginning with the calendar year 2024 reporting period which affects calendar year 2026 payment determinations for the ASC Quality Reporting Program. We are proposing to adopt the same modification to versions of the measure that we have adopted for other quality reporting programs.

Additionally, we are proposing that public reporting of the modified version of the COVID-19 Vaccination Coverage Among Healthcare Personnel for the ASC Quality Reporting Program would begin with the fall 2024 refresh, or as soon as technically feasible.

The term "up to date" is defined as meeting the Centers for Disease Control and Prevention's, or CDC's, set of criteria on the first day of the applicable reporting quarter. We are proposing to update the numerator to specify the time frames within which an individual Healthcare Personnel is considered up to date with CDC recommended COVID-19 vaccines, including booster doses.

Additional guidance on up to date is available on the NHSN, or National Healthcare Safety Network, website.

Next is our proposal to modify this colonoscopy measure to align with current guidelines beginning with the calendar year 2024 reporting period which affects calendar year 2026 payment determinations.

Based upon recent changes on clinical guidelines for colonoscopy screening, we are proposing to amend the measure's denominator language by replacing the phrase "aged 50 years" with the phrase "aged 45 years." This is to apply the recent changes which recommend colonoscopy screening should begin at age 45 instead of age 50 for average risk patients.

The measure denominator would then be modified to "all patients aged 45 to 75 years receiving screening colonoscopy without biopsy or polypectomy" from "all patients aged 50 years to 75 years receiving screening colonoscopy without biopsy or polypectomy." There are no changes proposed to the measure numerator, or other measure specifications, exclusions, or data collection for this measure. The reason that we are proposing this change in rulemaking, as we are required to do so, is because the change will modify the measure denominator.

Last, is the modification related to the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery survey measure. This patient reported outcome measure is a voluntary measure that has a cadre of facilities that maintain reporting.

We considered comments we received for this measure previously, and we agree that survey instruments for the assessment of visual function pre- and post-cataract surgery should be standardized to improve measure reliability while minimizing data collection and reporting burden.

As a result, we are proposing a modification to the specific survey instruments to be used for the assessment of visual function pre- and post-cataract surgery beginning with the calendar year 2024 data collection period.

The proposed allowable survey instruments are listed here on the slide.

The first listed is the original survey instrument developed by the National Eye Institute with the remaining two being validated, streamlined versions of the original. While the patient's physician or optometrist can administer, collect, or report the survey results to the ASC, the survey instruments required for this measure can be administered by staff at the ASC itself via phone, can be completed by the patient via regular or electronic mail, or during clinician follow-up. Scientific literature supports that self-administered survey instruments produce statistically reliable results for this measure. The inclusion of these multiple options ensures that patients will be able to respond to the survey in their preferred format.

We can now discuss proposals for adding measures to the program.

We are proposing to re-adopt with modification the ASC Facility Volume Data on Selected Outpatient Surgical Procedures measure and adopt the Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty patient-reported outcome-based performance measure, also referred to as THA/TKA PRO-PM.

Hospital care has been gradually shifting from inpatient to outpatient settings. Research indicates that volume of services performed in ambulatory surgical centers will continue to grow. In light of these trends in facility volume, and more recent studies finding that volume can be an indicator of quality, it is now especially important to track volume within ASCs, as it could provide valuable insight into the quality of ASC services for CMS and patients.

The ASC Quality Reporting Program previously included a facility level surgical procedure volume data measure. Last year, in rulemaking, we requested comment on the addition of a volume-related measure. In response to our request for comment, while some commenters stated that they believed there is a lack of evidence showing a relationship between volume and quality, recent studies show that volume does serve as an indicator of quality of care, though the underlying reasons for this can be varied.

Regarding our hip/knee arthroplasty measure, hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults, and roughly 80 percent of patients with osteoarthritis have some limitation in mobility. Elective THA and TKA are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans. However, not all patients experience benefit from these procedures. Many patients note that their pre-operative expectations for functional improvement have not been met.

In the calendar year 2021 OPPS/ASC final rule, we announced that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list and added to the ASC covered procedures list (CPL). Though we acknowledge that currently the total number of ASCs performing these procedures, and the number of procedures being performed in ASCs, is relatively low and there is wide variation in number of procedures performed in those ASCs performing those procedures, the number of procedures performed in the ASC setting is steadily growing.

Based on the shift in performing these procedures in ASCs, we requested comment on the potential future adoption of the THA/TKA PRO-PM into the ASC Quality Reporting Program in previous rulemaking. With this background information inline, lets discuss the proposals for these two measures in more detail.

First, the ASC Facility Volume Data on Selected Outpatient Surgical Procedures measure.

We are proposing to readopt with modification the ASC Facility Volume Data on Selected Outpatient Surgical Procedures measure, with voluntary reporting in the calendar year 2025 reporting period followed by mandatory reporting beginning with the calendar year 2026 reporting period which would affect calendar year 2028 payment determinations.

As mentioned earlier, a volume measure was a part of the ASC Quality Reporting Program previously. At that time, ASCs would report all-patient

volume data with respect to six categories: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. This proposed re-adoption will have two modifications.

The first modification is that the ASC Outpatient Surgical Volume measure data collection will cover eight categories. The two categories added are Cardiovascular and Respiratory, making the eight categories to be: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.

The second modification to this measure is that instead of collecting and publicly displaying data in these eight broad categories, we would collect and publicly display data reported for the top five most frequently performed procedures among ASCs within each category.

We propose that ASCs would submit aggregate-level data through the CMS web-based tool located on the Hospital Quality Reporting, or HQR, system. ASCs would submit these data during the time period of January 1 through May 15, in the year prior to the effected payment determination year, just as you all have been submitting your other measures in the HQR system.

Data received through the HQR system would then be publicly displayed on the Care Compare website or another CMS website after a 30-day preview period.

As I stated earlier, we requested comment on the potential future adoption of the THA/TKA PRO-PM into the ASC Quality Reporting Program in previous rulemaking.

We are proposing to adopt the THA/TKA PRO-PM. The reporting and submission requirements for PRO-PMs as a new type of measure to the ASC Quality Reporting Program, and to begin with voluntary reporting beginning with the calendar year 2025 reporting period followed by mandatory reporting beginning with the calendar year 2027 reporting period to affect calendar year 2030 payment determinations is our current proposal.

The mandatory reporting will then use eligible elective outpatient procedures occurring January 1, 2027, through December 31, 2027, impacting the calendar year 2030 payment determination and subsequent years. Because this proposed measure requires collection of data during the three-month pre-operative period and the greater than one-year post-operative period, there is a delay between when the elective THA/TKA procedures occur, to when the results would be reported under the ASC

Quality Reporting Program, and when payment determinations occur. Therefore, we are proposing a three-year gap between the reporting period and the payment year affected.

Thus, this measure reports the facility-level risk-standardized improvement rate, or RSIR, in Patient Reported Outcomes (PRO) following elective primary THA or TKA.

It will include Medicare fee-for-service beneficiaries aged 65 years and older who were enrolled in Medicare fee-for-service Part A and B for the 12 months prior to the date of the procedure and in Medicare fee-for-service Part A and B during the procedure. The measure includes only elective primary outpatient THA/TKA procedures, patients with fractures and revisions are not included, performed at ASCs and does not include any inpatient procedures.

The measure excludes patients with staged procedures, such as multiple elective primary THA or TKA procedures performed on the same patient during distinct encounters, that occur during the measurement period and excludes discontinued procedures.

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: Patient Reported Outcome data; Medicare claims data; Medicare enrollment and beneficiary data; and U.S. Census Bureau survey data.

This patient-reported data are collected by facilities pre-operatively and post-operatively, and limited patient-level risk factor data are collected with patient reported outcome data and identified in claims.

For risk-adjustment by pre-operative mental health score, ASCs would submit one of two additional Patient Reported Outcome instrument data, all the items in either the Patient Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health subscale; or the Veterans RAND 12-Item Health Survey, known as the VR–12, Mental Health subscale.

The goal of the ASC-level THA/TKA PRO-PM is to capture the patient's self-assessment of their pain and function and measure their improvement following their THA/TKA procedure or procedures. This will use patient voice in the measure outcome and directly captures the results of the patient's THA/TKA procedure or procedures.

There is additional information and additional specifications for this measure located on the CMS.gov website.

For this measure, clinical improvement is measured by a pre-defined score on one of two joint-specific Patient Reported Outcome instruments—the HOOS, JR for completion by THA recipients and the KOOS, JR for completion by TKA recipients.

Improvement is measured from the pre-operative assessment and data will be collected 90 to 0 days before surgery to the post-operative assessment when data will be collected 300 to 425 days following surgery.

Improvement scores are risk-adjusted to account for differences in patient case-mix. The measure, as proposed, accounts for potential non-response bias in measure scores through inverse probability weighting based on likelihood of response. ASCs should submit these assessments for at least 45 percent of eligible procedures.

While we do not propose to publicly report the data we receive during the voluntary reporting periods for the THA/TKA PRO-PM, we are proposing to publicly report which ASCs choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating ASCs for the first voluntary reporting period, and their percent of pre-operative and post-operative matched patient reported outcome data submitted for subsequent voluntary reporting periods.

We intend to provide ASCs with their results in calendar year 2030 before publicly reporting results on the Care Compare site. We would provide confidential feedback reports during the voluntary period which would include the RSIR as well as other results that support understanding of facility performance prior to public reporting.

The purpose of Voluntary Reporting is to allow ASCs to become familiar with the measure in advance of Public Reporting and any payment determinations made utilizing this measure. The Voluntary Reporting periods will provide ASCs with an opportunity to ask questions and test patient reported outcome data submission to CMS before Mandatory Reporting; receive confidential feedback reports that include their patient reported outcome data response rates and measure results; review the data; get information on how to interpret their measure results; and to provide feedback on the measure.

Finally, we have one administrative proposal, and that is to replace “QualityNet” with “CMS-designated information system” or “CMS website.”

This proposed change is to accommodate recent and future systems requirements and mitigate confusion for program participants. We are obligated to put forth this change through rulemaking.

That completes my review of our proposals. Please comment. We very much want to hear from you all as you all are the persons in the field and we want to receive your feedback. To discuss how to comment, let me turn things back over to Karen.

Karen VanBourgondien: Thank you, Anita. As Anita stated, commenting is crucial. It is your opportunity to influence CMS' decisions regarding the proposals for the ASC Quality Reporting Program.

To be assured consideration, comments must be submitted no later than September 11th.

CMS cannot accept comments by fax transmission and does encourage submission of comment by electronic means. However, you can submit comment via regular mail, or by express or overnight mail, those types of things. Be aware, though, that there are separate addresses for those types of mails. So, you can access the rule for those specific addresses.

Please allow sufficient time for any mailed comments to be received before the close of the comment period.

The proposed rule can be found in the *Federal Register*, and you can use the direct link we have here. If you prefer a PDF copy, we also have a link for the PDF version.

The ASC Quality Reporting Program specifically begins on page 253 of the PDF version.

So, when you first access the *Federal Register* link, you will be directed to the exact location of the rule in the *Federal Register*.

To begin the commenting process, you are just going select the green Submit a Formal Comment box, right there next to the arrow.

This will direct you to where you will actually be entering your comment. Here you see the top part of that page, you can enter your comment in the Comment field and add a file, if you wish to do so. You will scroll down that page.

And you'll enter your information in the designated fields. Fill in the necessary information and make sure you click on the "I read and

understand the statement above" box. The Submit Comment box will not turn green unless that box is selected. Once complete, you will simply click the Summit Comment button and that's it. That is all there is to submitting your comment.

Again, please do comment. CMS does look forward to hearing from you about the proposals that Anita went over with us today.

Okay, let's review program requirements and talk about what that means in relation to the proposals for this program that we just discussed.

Just a quick reminder here. In order to submit data in each of the data submission systems, each facility must have a Security Official in the HQR system, the Hospital Quality Reporting System, and a Facility Administrator in the National Healthcare Safety Network system, or NHSN.

So, for HQR, you need at least one SO, but we highly recommend having more than one. You know, for backup and what have you.

For NHSN, that system only allows one Facility Administrator. But, you can have multiple added users. So, the two systems vary a little bit. The point being, have more than one person that has access to these systems, so you that you don't have any delays in submitting your data.

Submission deadlines.

So, let's start with the web-based measures which are entered into HQR.

Here you can see all the measures, the reporting period and the submission period and this is for the 2025 payment determination. These data are due no later than May 15th, 2024. Remember that next year, you will be submitting data for ASC-1 through ASC-4 in the HQR system. We will bring you more details on this submission process in two upcoming webinars. The first one will be either very late in October or early November. So, make sure to join us for that webinar for details specifically for ASC 1 through 4, but we are going to cover a lot of other information, too.

Also, if the proposal for ASC-9 Anita discussed earlier is finalized, that change will take place one year after the time frame which we are seeing here on the slide.

The vaccination measure, ASC-20.

That data are entered into the NHSN system and they are entered quarterly. This slide is showing you the reporting periods and the submission deadlines again for the 2025 payment determination.

If the proposal related to ASC-20 is finalized, that would take effect immediately, but you really are already using NHSN guidance for up to date when you're entering data. We do have a link here to the NHSN website, to the guidance document, should you need it - the guidance document for up to date.

Here are the claims-based measures and for those of you that are new or may have forgotten, data for these are collected via Medicare claims. So, there is no manual abstraction and reporting on the part of the ASC. The reporting period or the time period where these claims are pulled are here on this slide. There were no proposals related to any of these measures that Anita discussed today.

OAS CAHPS measures.

So, there are no changes proposed for these measures, as well. Remember, these measures were previously finalized to be part of the program with voluntary reporting beginning with the calendar year 2024 reporting period and mandatory reporting will begin the year after, which is what you're looking at here on the slide.

Mandatory reporting will begin with the calendar year 2025 reporting period and that would be for the 2027 payment determination.

To review what Anita spoke about earlier, if the proposal for the ASC Facility Volume measure is finalized, the voluntary reporting period will begin with the calendar year 2025 reporting period and mandatory reporting will begin the year after with the 2026 reporting period and that would be for the 2028 payment determination.

The THA/TKA measure, this measure is proposed to begin with two voluntary periods. The first period would be for calendar year 2025 reporting and the next would be for the calendar year 2026 reporting period and mandatory reporting would begin the following year, and that would be for the 2027 reporting period and that's for the 2030 payment determination. So, just to clarify, it is proposed that way because that measure requires collection of data during the three-month pre-operative period and the greater than one-year post-operative period. So, there is a delay between the elective procedure, when that actually occurs, and when the results of that procedure would be reported. So, that's the reason why

there is the three-year gap between the reporting period and the payment determination year.

Of course, when the final rule comes out, sometime in November, we will have another webinar to discuss the finalized proposals and the impacts to the program. So, stay tuned.

So, Anita I think we have some time for questions and this first question, we get this a lot. We get it on the phone, we get it in the Q&A tool, on webinars. The question is, the Public Health Emergency ended in May. Why are we still reporting data for ASC-20?

Anita Bhatia: Great question, Karen! As many of us know, the Public Health Emergency formally ended on May 11, 2023; however, the public health response to COVID–19 remains a public health priority and this includes vaccination efforts. Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID-19. We continue to believe it is important to incentivize and track healthcare personnel vaccination through quality measurement across care settings, including the ASC setting, to protect healthcare workers, patients, and caregivers, as well as to help sustain the ability of healthcare personnel in each of these care settings to continue serving their communities.

Karen VanBourgondien: Thank you, Anita. I know a lot of people really wanted to know why that was continuing to be reported so we appreciate your feedback on that. The next question is about ASC-11. What question is "What is CMS' view regarding the ASC-11 measure and the belief that this measure reflects surgical performance?" They go on to say "It's understood the impact of complications and infections, but other than the wrong lens being implanted, I don't really understand how reporting of this measure reflects quality of the ASC." Can you respond to that? That's kind of a long, long question, but a good one.

Anita Bhatia: Yes, Karen. It is an important question and it touches on some important points. The Functional Survey following Cataracts Surgery is a patient reported outcome measure that assesses improvement in functionality, not visual acuity. While visual acuity is an important measurable clinical outcome for cataract surgery, this alone does not measure the full benefit of cataract surgery. The ability to perform daily tasks is also very important outcome for patients; thus, surveys have been developed to assess ability to perform daily activities in relation to visual difficulties. Among patients with cataracts and no other eye disease, subjective visual function is improved after surgery.

So, regarding how this reflects on the quality of the ASC, there is this concept of ecological fallacy, so regarding the level of responsibility, ecological fallacy occurs from attributing responsibility from a larger entity to a smaller one. For example, an ASC to an individual clinician assuming that there is more than one clinician, not the other way around. Further, the surgery is being done at the facility and the performance of this includes many staff and processes; surgical outcomes depend on more than just the individual surgeon.

Karen VanBourgondien: Thank you, Anita. We have another question about ASC-11. What is CMS' goal of continuity of care when reporting for the ASC-11 measure and are there any tips on how this will impact outcomes?

Anita Bhatia: Thank you, Karen. This measure is a patient reported outcome measure that assesses improvement following surgical procedures, as we have just discussed. Patient reported outcome measures are a current priority area for our quality reporting programs. As such, this measure can provide feedback to surgeons as well as to the facilities where the procedure is being performed; and this has the potential to impact outcomes for other patients.

Karen VanBourgondien: Thank you, Anita. So, here is a different kind of question. For the ASC Quality Reporting Program, will there be changes in reporting to focus on equity to include race, ethnicity, sexual orientation, gender identity, things of that nature? Anita, can you respond to that?

Anita Bhatia: Yes I can, Karen. Another very important question. Equity is a priority area of the current administration and program alignment regarding equity is a CMS priority for its quality reporting programs. In the recently released fiscal year 2024 In-Patient Prospective Payment System/Long-Term Care Hospital final rule, the importance of equity is fully discussed.

Karen VanBourgondien: Thank you, Anita. And we will put that link to that rule in the chat box for any of those of you that are interested in that. Next question. Why is CMS readopting the volume measure if it was previously removed from the program?

Anita Bhatia: Another great question, Karen. First, the ASC volume measure, as the question asked, was previously removed from the program. Since the removal of that measure, scientific literature has concluded that volume metrics can serve as an indicator of which facilities are experienced with certain outpatient procedures and this information can assist consumers in making informed decisions about where they receive care. Second, the recent shift of more surgical procedures being performed in outpatient settings has placed greater importance on tracking the volume of

outpatient procedures in different settings, including Ambulatory Surgical Centers. We believe that patients and their caregivers can benefit from the public reporting of facility-level volume measure data because the volume data illuminate which procedures are performed across ASCs, provide the ability to track volume changes by facility and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures.

Karen VanBourgondien: Thank you, Anita. We have several people asking the following question and they want to know why is CMS proposing the TKA/THA measure to begin reporting with two voluntary reporting periods and then mandatory reporting?

Anita Bhatia: So, again Karen, yet another important question. We proposed a phased implementation approach for adoption of this measure, with voluntary reporting periods in calendar years 2025 and 2026 followed by mandatory reporting beginning with the calendar year 2027 reporting period which would affect calendar year 2030 payment determinations in the ASC Quality Reporting Program. Similar to what we have done with the adoption of other new measures in our quality reporting programs. Given the numbers of ASCs, the varied number of procedures being performed, and the extended follow-up periods, we considered extending the length of voluntary reporting. However, settled on what we have proposed. We believe that by having voluntary reporting prior to mandatory reporting would allow time for facilities to become familiar with the measure, with the data collection methodologies, and to incorporate data collection into their clinical workflows.

Karen VanBourgondien: Thank you, Anita. I think we have time for one more question and this is a good question to end with. When will CMS let us know when these proposals are finalized?

Anita Bhatia: Well, Karen, after considering public comments that are received, CMS will develop and publish a final rule. For the calendar year OPPS/ASC payment rule, there is actually a statutory requirement to complete that rule under a specific timeline. So, for this program, the time frame is that the rule will be placed on display on or around November 1st of this year, 2023.

Karen VanBourgondien: Okay. So, perfect. I think I alluded to this earlier. We will do a final rule webinar. Anita will be kind enough to share the finalized proposals with us at that time. We look forward to all of you joining us for that.

Anita, I appreciate you joining us and walking us through the proposed rule. That is all the time we have. You can see some resources here on the

slide. Our number is right there at the top. Don't ever hesitate to reach out for any questions that you might have. We also have a link to the QualityNet Question and Answer Tool. So, again, reach out to us anytime.

Anita, thanks again for joining us and we hope that this helped everyone and we will see you next time. Thanks for joining everyone. Have a great day.