Hospital Inpatient Quality Reporting (IQR) Program

Inpatient Value, Incentives, and Quality Reporting (VIQR) Outreach and Education Support Contractor

Voluntary Reporting of the Hospital-Level THA/TKA PRO-Based Performance Measure

Question and Answer Summary Document

Speakers

Kristina Burkholder, MS, CAS
Measure Implementation and Stakeholder Communication Lead
Hospital Outcome Measure Development,
Reevaluation, and Implementation Contractor
Colleen Toby
Product Manager, Access and Submissions
Hospital Quality Reporting Application Development Organization

Moderator

Donna Bullock, MPH, BSN, RN
Program Lead, Hospital IQR Program
Inpatient VIQR Outreach and Education Support Contractor

August 3, 2023
2:00 p.m. Eastern Time

DISCLAIMER: This presentation question-and-answer summary document was current at the time of publication and/or upload onto the Quality Reporting Center and QualityNet websites. Medicare policy changes frequently. Any links to Medicare online source documents are for reference use only. In the case that Medicare policy, requirements, or guidance related to these questions and answers change following the date of posting, these questions and answers will not necessarily reflect those changes; given that they will remain as an archived copy, they will not be updated. The written responses to the questions asked during the presentation were prepared as a service to the public and are not intended to grant rights or impose obligations.

Any references or links to statutes, regulations, and/or other policy materials included are provided as summary information. No material contained therein is intended to take the place of either written laws or regulations. In the event of any conflict between the information provided by the question-and-answer session and any information included in any Medicare rules and/or regulations, the rules and regulations shall govern. The specific statutes, regulations, and other interpretive materials should be reviewed independently for a full and accurate statement of their contents.

Subject-matter experts researched and answered the following questions after the live webinar. The questions may have been edited for grammar.

Measure Overview

Question 1: **What is the benefit for collecting the Total Hip Arthroplasty/Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) information? What is the desired improvement scoring from preoperative to postoperative assessments?**

The goal of a hospital-level outcome measure is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patients' health and reducing the burden of their disease.

The THA/TKA PRO-PM uses a substantial clinical benefit (SCB) improvement threshold to define the patient-level outcome. The measure evaluates whether a patient had an SCB improvement of 22 points or more on the hip disability and osteoarthritis outcome scores (HOOS), joint replacement (JR) for hip patients, and 20 points or more on the knee disability and osteoarthritis outcome scores (KOOS), JR for knee patients between the preoperative and postoperative assessments. The SCB thresholds were identified in analyses of published literature, tested in measure development data, and evaluated with considerable stakeholder input. For more information on the SCB improvement thresholds, please see Section 2.4 of the THA/TKA PRO-PM Development Methodology Report on the CMS QualityNet website.

Question 2: **If a patient dies during the data collection period, would we still submit that data, or do we exclude the patient?**

The THA/TKA PRO-PM cohort excludes patients who died before having the opportunity to complete postoperative PRO data. Therefore, if a patient dies within 300 days of the procedure, they would be excluded from the measure cohort. If you are unsure if a patient should be excluded or not, submit their data and CMS will evaluate the measure cohort inclusion/exclusion criteria during measure calculation after PRO data are submitted by hospitals to determine eligibility.

Question 3: **Are patients able to refuse to participate in the surveys? What happens if a patient opts out after the preoperative files are submitted?**

Yes, patients can refuse to participate in the PRO data collection for the THA/TKA PRO measure.

CMS acknowledges that some patients may choose to not provide answers to some or all questions.

CMS encourages hospitals to ask patients to respond to the questions to the best of their ability and to work with their patients to help them understand the importance of PRO data collection, and how it will help to promote the improvement in care that is provided to them as the patient, as well as other patients with similar backgrounds. Hospitals can customize and share with their patients the THA/TKA PRO-PM Patient Brochure on QualityNet.

If a patient opts out of postoperative PRO data collection after the hospital submitted a preoperative PRO data file, the hospital could exclude the patient from postoperative PRO data collection. The patient will have missing postoperative PRO data, but the hospital could include them in the hospital's eligible patient population (provided the patient met all measure inclusion/exclusion criteria).

Please be aware that if a patient does not complete a required data element, they may be considered in the hospital's eligible patient population (provided the patient met all measure inclusion/exclusion criteria). To account for potential patient refusal, CMS only requires hospitals to collect and submit complete preoperative data with matching complete postoperative data for 50 percent of eligible inpatient THA/TKA procedures as a minimum amount of data for mandatory reporting in the Hospital Inpatient Quality Reporting (IQR) Program. CMS recommends hospitals collect and submit complete data on more than 50 percent of their eligible inpatient THA/TKA patients for hospitals to maximize the potential for success in meeting the Hospital IQR Program requirement. Hospitals that fail to meet the 50-percent Hospital IQR Program reporting requirement when mandatory reporting begins will receive a reduction in their annual payment update (APU).

While there is no data element for "patient refused" or "patient opts out," any eligible THA/TKA patient who does not respond to all required PRO data elements is counted in the statistical approach used for addressing potential non-response bias. Using inverse probability weighting (IPW), weights for responders, incomplete responders, and non-responders across all hospitals are calculated and applied to the hierarchical risk model for the calculation of hospital measure scores. This approach considers the patient characteristics of all eligible THA/TKA patients to address potential non-response bias. For more information on full measure specifications, including details on measure cohort, outcome, and risk adjustment, please see the THA/TKA PRO-PM Development Methodology Report on QualityNet.

Question 4: **Where can we find the Hip Dysfunction and Osteoarthritis Outcome**

The HOOS, JR and KOOS, JR surveys are found here: https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp

Additional resources related to the THA/TKA PRO-PM measure are on QualityNet under the THA/TKA PRO-PM Resource webpage.

Question 5: **Does Medicare Fee for Service (FFS) include patients that have Medicare Advantage? Does it include patients who have private insurance or who are less than 65 with traditional Medicare or Medicare Advantage?**

At this time, only patients who are 65 years or older and enrolled in Medicare FFS Parts A and B for the 12 months prior to the date of admission and Part A during the index admission are included in the THA/TKA PRO-PM measure. Patients who are billed solely through Medicare Advantage or private insurance are not included. In terms of age, the measure cohort does not include any patients younger than 65.

Question 6: **Does Medicare have to be the primary insurance? Do we include patients who have Medicare as a secondary insurance?**

Patients with Medicare FFS as primary insurance OR as secondary insurance (to commercial/private insurance or Medicaid, for example) are included in the cohort. Medicare FFS is not required to be the primary payer. Inclusion in the measure cohort is driven by the presence of a Medicare FFS claim for an eligible THA/TKA admission.

Question 7: **Where do we find the list of inclusions and exclusions to identify the patients to include?**

The full inclusion/exclusion criteria for the THA/TKA PRO-PM cohort can found in Section 2.3 of the THA/TKA PRO-PM Development Methodology Report on QualityNet.

International Classification of Diseases (ICD)-10 codes to define the THA/TKA PRO-PM cohort will be available on QualityNet at a later date. The elective, primary THA/TKA procedures for the THA/TKA PRO-PM align with the elective, primary THA/TKA procedures for the THA/TKA complication measure.

You can refer to the ICD-10 codes found in Tables 1 and 2 of the 2023 THA/TKA Complications Measure Code Specifications - Supplemental File on QualityNet.

Question 8: **Are all six elements listed in the "patient or provider reported risk variables" (i.e., mental health, health literacy, body mass index, narcotics, joint count, spinal pain) required preoperatively? Please clarify if the Mental Health Subscale items are required preoperatively and postoperatively.**

Yes, all six data elements listed as the patient- or provider-reported risk variables are required preoperatively (0–90 days prior to a THA/TKA procedure). The mental health subscale items are only required to be collected preoperatively.

CMS posted the list of preoperative and postoperative data elements required for the THA/TKA PRO-PM in the THA/TKA PRO-PM Data Elements Excel file and the What Data Should I Collect? fact sheet on QualityNet.

Question 9: **Where can I find a list of required elements for the Hospital Quality Reporting (HQR) system to ensure our electronic health record (EHR) can pull it into a report so we can upload it?**

Please refer to the THA/TKA PRO-PM Data Elements Excel file which defines the data elements, response options, and timing of collection.

Question 10: **Do the Health Literacy, Narcotic Use, and Other Joint Pain questionnaires need to be filled out?**

Yes, the *Health Literacy*, *Use of Chronic Narcotics*, and *Other Joint Pain* data elements are all required for preoperative data collection. CMS posted the list of preoperative and postoperative data elements required for the THA/TKA PRO-PM in the THA/TKA PRO-PM Data Elements Excel file and the What Data Should I Collect? fact sheet on QualityNet.

Question 11: **Are there required mental health and health equity surveys that we must use with this measure? Can the provider use a mental health and health equity survey of their own?**

Hospitals will need to collect and submit the mental health related questions included in the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global or Veterans Rand-12 (VR-12).

In addition, hospitals can use Version 1.0 or 1.2 of the PROMIS-Global survey. During data submission, hospitals will need to indicate which generic PROM (PROMIS-Global or VR-12) and which version of the PROMIS-Global was used (1.0 or 1.2) if it was used, so CMS can correctly score the questions. The questions/response options for the PROMIS-Global and VR-12 are in the THA/TKA PRO-PM Data Elements Excel file on QualityNet.

No health equity surveys are required for PRO data collection for the THA/TKA PRO-PM.

Question 12: **The PROMIS survey has 10 questions, but only questions 2, 4, 5, and 10 were included on the template sent out. Do we only need those four questions for submission?**

Yes. For the THA/TKA PRO-PM preoperative PRO data collection, during voluntary and mandatory reporting, only the four PROMIS-Global mental health-related questions are required for collection and submission (Questions 2, 4, 5, and 10). These four questions comprise the mental health subscale.

During development of the measure, the full PROMIS-Global survey was evaluated. For voluntary reporting and future mandatory reporting, the mental health-related questions will be utilized in the measure's risk model.

Question 13: **Is there a specific question or tool that we should use for Narcotic Use?**

To clarify, for the purposes of this measure, hospitals will need to collect and submit the *Use of Chronic Narcotics* data element. This variable is required for the preoperative PRO data collection (0–90 days before a THA/TKA) only and will be used as a risk variable in the risk model.

The *Use of Chronic (> 90 days) Narcotics* data element (with response options of Yes or No) is defined as having any daily or regular intermittent dose of morphine (or hydromorphone equivalent) for at least 90 days. These data can be collected within 90 days of the patient's elective primary THA/TKA procedure if the clinical care team expects the patient to remain on narcotics until surgery, at which time the patient will have been on narcotics for at least 90 days.

This definition intends to capture patients with severe pain requiring chronic narcotics prior to THA/TKA procedures and is somewhat subject to interpretation. We leave it to individual surgeons or healthcare providers (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. Lastly, providers should collect data that reflects overall narcotic use (or any narcotic use), not just narcotic use specific to joint pain.

Question 14: **If the data are collected on different dates by different people, do we enter only one name and one date?**

Only one submission is needed per eligible procedure.

Question 15: **Is it feasible to just keep submitting the preoperative and postoperative data and CMS will do the matching?**

To clarify, CMS will match preoperative PRO data to claims data after hospitals submit their preoperative data. Additionally, CMS will match preoperative PRO data to postoperative PRO data after hospitals submit their postoperative PRO data. In terms of frequency of data submission, there are specific timeframes for preoperative and postoperative PRO data submission. We include a summary of the timeframes and preoperative and postoperative data submission periods below.

Reporting Period	Eligible Elective Procedure Period	Pre-Op Data Collection	Pre-Op Data Submission	Post-Op Data Collection	Post-Op Data Sub
2025 Voluntary Reporting	January 1, 2023–June 30, 2023	October 3, 2022–June 30, 2023	October 2, 2023	October 28, 2023–August 28, 2024	Sept 30, 2024
2026 Voluntary Reporting	July 1, 2023–June 30, 2024	April 2, 2023–June 30, 2024	Sept 30, 2024	April 26, 2024–August 29, 2025	Sept 30, 2025
2027 Mandatory Reporting	July 1, 2024–June 30, 2025	April 2, 2024–June 30, 2025	Sept 30, 2025	April 27, 2025–August 29, 2026	Sept 30, 2026

Question 16: **One of the risk variables include "patient reported back pain." How is the back pain related to THA/TKA?**

The THA/TKA PRO-PM includes key clinical risk variables identified by clinical experts and supported by orthopedic professional societies, including back pain. Inclusion of back pain in the risk model ensures accurate assessment of the index THA/TKA procedure and accounts for concomitant comorbidities.

Question 17: **Is there a list of procedure, diagnosis, or Diagnosis-Related Group (DRG) codes available to identify the initial population? Additionally, are there any electronic clinical quality measure (eCQM) code sets/value sets associated with the measure?**

ICD-10 codes to define the THA/TKA PRO-PM cohort will become available on QualityNet. The elective, primary THA/TKA procedures for the THA/TKA PRO-PM align with the elective, primary THA/TKA procedures for the THA/TKA complication measure.

You can refer to the ICD-10 codes found in Tables 1 and 2 of the 2023 THA/TKA Complications Measure Code Specifications - Supplemental File on QualityNet. The DRGs are not utilized to define the measure cohort. Additionally, this measure is not an eCQM; therefore, no value sets are associated with the measure.

Question 18: **Do we submit preoperative assessments after coding is complete and then submit postoperative assessments one year later? Do we submit both at the end of the year?**

To clarify, preoperative PRO data are submitted separately from postoperative PRO data. In addition, there are specific timeframes for preoperative and postoperative PRO data submission. Refer to Question 15 for a summary of the Voluntary 1 and Voluntary 2 timeframes and preoperative and postoperative data submission periods.

Question 19: **How do we complete the postoperative data when we don't see the patient after their surgical procedure?**

The THA/TKA PRO-PM was developed for the hospital setting. Its goal is to promote collaboration and shared decision-making between patients and providers across the full spectrum of care.

Given that the procedure is taking place at the hospital, it is important for the hospital to collect and track trends in patient-reported outcomes. CMS seeks to advance patient-centered measurement with as little burden as possible to both providers and patients.

CMS acknowledges that hospitals will need to determine the mode of data collection that works for their clinical workflows and patient population. CMS encourages hospitals to use PRO data collection processes best suited to them. Patients typically meet with providers, clinicians, and other health care workers approximately one year following their THA/TKA procedure. In cases where patients are not seen after their procedures or do not attend their follow up appointment, hospitals can request patients complete PRO data using the following modes of collection: email, phone, mail, or electronic method (such as a patient portal).

While PRO-PMs require providers to integrate data collection into clinical workflows, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision making and benefit patients by engaging them in discussions about potential outcomes.

Question 20: **Postoperative surgery dates were 270 to 425 days. Why are they now 300 to 425 days?**

The 300–425-day postoperative PRO data collection timeframe for the THA/TKA PRO-PM was selected to align with clinical workflow and typical one-year follow-up scheduling. CMS will continue to monitor potential areas for alignment, as appropriate.

Question 21: **Is the measure required for critical access hospitals (CAHs)? If not, when will it become mandatory?**

CAHs are not part of, or eligible for, the Hospital IQR Program. As such, they are not required to submit the measure to CMS. However, CAHs may voluntarily report this measure under the Hospital IQR Program. As with all other Hospital IQR Program measures, CMS strongly encourages that CAHs use the measures and voluntarily submit data for quality improvement.

Measure Implementation Timeline

Question 22: **How will CMS know if we enter 50 percent of our procedures? Do we enter our total number of procedures?**

For hospitals that choose to participate in the first or second voluntary reporting period, hospitals are encouraged to collect and submit as much preoperative and postoperative data as they can for each patient. Hospitals will receive confidential feedback reports with response rate information during voluntary reporting.

Question 23: **Is there a minimum number of procedures or threshold number of procedures that the hospital must perform to submit these data? Since the minimum submission requirement is 50 percent of the cases, do we randomize the selection of cases?**

Hospitals participating in the Hospital IQR Program with at least one eligible THA/TKA procedure would be eligible for mandatory reporting of the THA/TKA PRO-PM. The THA/TKA PRO-PM does not have an exclusion based on the volume of procedures for the eligible procedure time period.

CMS selected the 50-percent reporting threshold after considering numerous factors and the experience of the Center for Medicare and Medicaid Innovation Comprehensive Care for Joint Replacement (CJR) Model participants. CMS will evaluate the reporting threshold during voluntary reporting and consider adjustments based on feedback prior to mandatory reporting, but any changes would require future rulemaking.

Cases do not need to be randomized. In terms of reporting requirements, during mandatory reporting in 2027, hospitals must collect and submit 50 percent of eligible, complete, preoperative PRO data with matching complete postoperative data as a minimum amount of data for mandatory reporting in the Hospital IQR Program.

Question 24: **What does "applicable percentage increase in their APU" mean in "Hospitals that fail to meet the 50 percent reporting requirement during mandatory reporting are subject to a one-fourth reduction of the applicable percentage increase in their APU for the applicable fiscal year." What is the specific impact and what would be the specific loss of Medicare dollars?**

Per Section 1886(b)(3)(B) of the Social Security Act, failure to meet requirements of the Hospital IQR Program will result in a reduction to a hospital's APU by one-fourth of such applicable percentage increase. The impact and loss of Medicare dollars is specific to each individual hospital.

Question 25: **What is the rationale for waiting to upload data until the end of the submission deadline versus submitting it daily, weekly, or monthly?**

Currently, data can only be submitted during the data submission period. CMS will take your suggestion into consideration for the future.

Question 26: **What are the due dates for the voluntary reporting? When does mandatory reporting begin?**

Please refer to Question 15 for the eligible elective procedure period, preoperative and postoperative data collection, and preoperative and postoperative data submission. Beginning with the 2027 Public Reporting, for fiscal year (FY) 2028 payment determination, reporting of the measure will impact hospital payments under the Hospital IQR Program and measure results will be publicly reported.

Question 27: **During the voluntary reporting period, if you don't have data to submit, how do you inform or report that to CMS?**

CMS is taking this under review and consideration. Currently, there is not an avenue for a hospital to indicate if they have no eligible cases for voluntarily reporting.

Question 28: **Is it too late to participate in the calendar year (CY) 2026 voluntary reporting if we do not have preoperative data for the entire span of time? We would just now start with the preoperative data collection.**

No, it is not too late to start participating. We strongly encourage hospitals to participate in voluntary reporting, even if you have not started yet. The eligible procedure period for 2026 Voluntary Reporting is July 1, 2023–June 30, 2024, and the preoperative Patient Reported Outcome (PRO) data collection period is April 2, 2023–June 30, 2024. You're still in the preoperative PRO data collection timeframe for 2026 Voluntary Reporting, and this will give your hospital the opportunity to get experience with both data collection within your facility and data submission prior to mandatory reporting. There is no penalty for how much data that you submit for voluntary reporting. Hospitals will be able to submit their preoperative PRO data for 2026 voluntary reporting in the summer of 2024 and will submit postoperative PRO data in the summer of 2025.

Question 29: **Since the specifications were released just a couple of weeks ago, will CMS consider extending the mandatory deadline?**

To clarify, the data submission period for the first voluntary reporting period preoperative PRO data collection is open through October 2, 2023. Mandatory reporting of the THA/TKA PRO-PM in the Hospital IQR

Program begins in 2027, impacting FY 2028 payment determination. Hospitals have the opportunity to participate in two voluntary reporting periods to prepare for mandatory reporting.

Measure Data Submission

Question 30: **Are we able to use a third party, like Cerner, to submit the data? How do we know which vendors and registries are approved by CMS to submit these data on behalf of the hospital?**

Hospitals, as with other Hospital IQR Program measures, can either submit the data themselves or contract with a vendor (or a registry) of their choice to submit the data on their behalf. If using a vendor or registry, the hospital will follow an authorization process within the *HQR Secure Portal* for that vendor/registry to submit data on its behalf. As there is no contractual agreement between CMS and vendors, there is no list of vendors or registries identified as available to submit data to CMS.

Question 31: **What methods are available to submit data to the HQR system?**

There are three methods available for submitting the data to HQR:

1.) Extensive Markup Language (XML) file

2.) Comma-Separated Value (CSV) file

3.) Manual data form

Question 32: **Is there a template for the CSV and XML files? Must we adhere to it?**

Yes. The templates/file layouts for both CSV and XML files are on the THA/TKA PRO-PM Resources page of QualityNet.

Question 33: **Will CMS accept Quality Reporting Data Architecture (QRDA) Category I files?**

At this time, QRDA files will not be accepted. Files must follow the defined format for either CSV or XML files. They are on the THA/TKA PRO-PM Resources page of QualityNet.

Question 34: **Will we be able to use the CMS Abstraction Reporting Tool (CART) to enter and submit this data?**

No, CART will not support the THA/TKA PRO-PM measure.

Question 35: **On the CSV question column T *Pain in Other Joint* where is that found in the HOOS and KOOS or VR-12?**

You can find a complete list of required data elements in the data dictionary. The data dictionary lists the data elements, response options, and data collection timeframe on QualityNet.

The question and response options for the *Pain in Other Joint* data elements are: "What amount of pain have you experienced in the last week in your other knee/hip?"

0 = None

1 = Mild

2 = Moderate

3 = Severe

4 = Extreme

Question 36: **As the CMS CSV template includes only four questions from the Global PROMIS Survey, do we not report on the other questions from the Global PROMIS Survey?**

Correct. Hospitals will only need to collect and submit the mental health questions for the PROMIS-Global. During data submission, hospitals will need to indicate which version of the PROMIS-Global 10 was utilized.

Question 37: **Are we able to submit PROMIS-Global 10, HOOS, and KOOS on separate lines for the same patient/procedure/time point, if they have the same essential four data elements? If a new row comes in, will the system overwrite existing incomplete data?**

No. If there is a new row with the PROMIS-Global 10, but it does not contain the HOOS/KOOS, the new row would overwrite the previous one. The latest submission with those four data elements is the one that is counted towards meeting submission.

You are able to submit via multiple methods, but the system will overwrite it if you don't include everything from your previous submission in your last submission.

Question 38: **For the XML collection format, does this mean the required data elements are documented in the EHR, then the XML files are run from the EHR?**

If submitting an XML file, the way that the file is created is left up to the individual hospitals or vendors.

Question 39: **In the CSV form, can we have data for all the patients together?**

Yes, multiple patients can be submitted within the CSV file. Each row in a CSV file represents one patient procedure survey.

Question 40: **Are we required to submit knees and hips together, or are we able to submit them separately? Are we required to submit a separate file for each procedure type?**

Knees and hips should be submitted separately. If submitting via an XML file, then a separate file is needed for each procedure type. If submitting via a CSV file, then a separate row would be used for each procedure type.

Question 41: **If bilateral joints are included in one entry, how do your account for laterality in data entry? Currently the CJR Model requires left versus right to be indicated.**

Hospitals will enter the procedure type using the variable P_TYPE. For a bilateral procedure, hospitals can enter either left or right for the hip or knee replacement and CMS will identify the procedure is bilateral using claims data.

Question 42: **Are we required to enter HOOS/KOOS data manually into the form?**

No, you are not required to enter HOOS/KOOS data manually into the data form. The HOOS/KOOS data can be submitted via a CSV or XML file with the rest of the data.

Question 43: **If the outpatient measure is finalized, will we be able to submit inpatient and outpatient procedures via a single submission?**

Should an outpatient THA/TKA PRO-PM be finalized, guidance on how data will be submitted will be provided later.

Question 44: **In addition to inpatient episodes of care, does this also include outpatient Medicare patients? If the patient is scheduled as an outpatient, but he becomes an inpatient, will that case be included? Many times, we don't know our patient is going to be an inpatient status. How do we manage this as a process without giving everyone the survey?**

Currently, the THA/TKA PRO-PM included in the Hospital IQR Program only includes inpatient Medicare FFS patients. It will not include outpatient Medicare FFS patients at this time.

It is possible for a patient who is scheduled as an outpatient and becomes an inpatient to be included in the THA/TKA PRO-PM cohort. Since hospitals will need to collect PRO data before coding or determining claim types for an eligible elective, primary THA/TKA, we recommend identifying eligible patients for PRO data collection using the clinical criteria included in the Who do I collect PRO data on? fact sheet on QualityNet.

Although the collection of PRO data for outpatient procedures is not required at this time, we acknowledge it may be easier for hospitals to collect PRO data on both inpatient and outpatient procedures given the following reasons:

1) It may be difficult to identify inpatient and outpatient procedures in advance.

2) It may be advantageous to collect PRO data on the outpatient population in the event CMS adopts the measure for the outpatient settings.

Any future adoption of the measure to other settings would be announced during future rulemaking. Of note, CMS proposed the adoption of the THA/TKA PRO-PM for the Hospital OQR Program and ASCQR Program in the CY 2024 Outpatient Prospective Payment System proposed rule.

You can find summaries of these proposals for the Hospital OQR Program on pages 579–590 and 621–626 and the ASCQR Program on pages 665–677 and 685–690.

Question 45: **If we do not have any patients that qualify for the measure, because all of our patients have TKA and THA procedures as outpatients and only have an observation stay, will we meet the requirement?**

If a patient underwent their procedure as an outpatient observation status, they would not be eligible for the hospital-level THA/TKA PRO-PM implemented in the Hospital IQR Program.

Question 46: **Can we still include and submit outpatient only cases?**

Yes. Although the THA/TKA procedures completed as an outpatient are not eligible for the THA/TKA PRO-PM cohort, if you are unsure whether a case would be considered inpatient or outpatient, you should submit your PRO data and CMS will determine eligibility.

Question 47: **Does this measure include bilateral TKAs?**

Yes, the measure does include bilateral procedures (performed on both hips or both knees on the same day) in the measure cohort. Hospitals should submit their hip or knee PRO data for both procedures. You only need to submit one. For example, if you have a right and left hip, for procedure type you can choose either right or left hip, and CMS will match the data. If you are uncertain what to enter, you can just enter both the left hip and right hip.

Question 48: **If you submit most of the elements, e.g., PROs, VR, HOO, KOOS, but miss one (e.g., the Oswestry single back pain question), do you still receive credit for submitting?**

During voluntary reporting, hospitals are encouraged to submit as much data as possible and are encouraged to submit their data even if they don't have every element completed.

Question 49: **What exactly does "include in the non-response bias" mean?**

If a patient does not complete a required data element or does not respond to the questions preoperatively or postoperatively, they may be considered in the hospital's eligible patient population (provided the patient met all measure inclusion/exclusion criteria). Any eligible THA/TKA patient who does not respond to all required PRO data elements is accounted for in the statistical approach used for addressing potential non-response bias.

This approach considers the characteristics of all eligible THA/TKA patients to address potential non-response bias. Using IPW, weights for responders, incomplete responders, and non-responders across all hospitals are calculated and applied to the hierarchical risk model for the calculation of hospital measure scores.

Details of this statistical approach can be found in Section 2.7.1 of the THA/TKA PRO-PM Development Methodology Report on QualityNet.

Question 50: **Are Employee Health Owned Plan cases excluded?**

Yes, at this time only Medicare FFS patients aged 65 and up are included.

Measure Data Submission in HQR

Question 51: **How do you add a user to the HQR platform? It states to search by Health Care Quality Information Systems Access Roles and Profiles Identification.**

Guidance on how to access HQR for the first time can be found on QualityNet under the Getting Started with QualityNet page. Once you are able to log into HQR, you can find guidance for adjusting permissions, tutorials, and additional resources on the HQR Support page.

Question 52: **Where will vendors be able to upload the files?**

Vendors who have been authorized by the provider and have the appropriate role will upload files into the HQR system in the same way as a provider.

Question 53: **If our data were accepted, but we receive an error message, can we correct the error? Is correcting the error required since the data were accepted?**

Yes, you can correct the error, but it is not required. We recommend that you correct the error and resubmit the data. If you want that specific data element/data to be sent to CMS, it should be corrected.

Question 54: **If the submitted file contains incomplete data, can we correct that data by going to the manual data form, or do we need to resubmit an updated file?**

If the file was "Accepted," you can correct the data by going to the manual data form. If the file was not accepted, you will need to submit an updated file. The data will not appear on the data form until the file is accepted.

Question 55: **If we add information via the data form, will it keep the old data and update the submission, or will we have to resubmit?**

Old or previously submitted data will remain in the form unless you remove or change it. Any data that are visible in the data form when you click Submit becomes your latest submission for that patient procedure survey.

Question 56: **For the manual data entry, are we required to enter individual patient-level survey responses?**

Yes, when entering data manually into the data form, a data form will need to be completed for each individual patient survey response.

Question 57: **If there are incomplete rows in the CSV file, will the entire file be rejected and not included in the analysis, or will only the incomplete rows be rejected?**

Only the incomplete rows will be rejected.

Question 58: **On "Partially Accepted" files, does CMS tell you which files are rejected? How are those files flagged?**

The errors report for a zip file that has a "Partially Accepted' status will list the individual files and their respective Accepted or Rejected status. The errors report can be viewed by clicking the Download hyperlink next to the file.

Question 59: **How long do we have to update an individual survey? When does the submission deadline close?**

Data submission for preoperative data for voluntary reporting 1 (eligible elective procedures performed January 1, 2023 through June 30, 2023) ends October 2, 2023.

Question 60: **Can CMS verify that a zip file that contains XML files will be allowed for submission?**

Yes, you will be able to submit zip files that contain XML files.

Question 61: **Is the manual data form, in HQR, individually done for each patient even though we can have separate rows in the CSV format?**

In HQR, the manual data form represents the procedure survey for just one patient. The CSV format would have one row for each patient survey. In the CSV file you could include multiple patients in which you would have multiple rows in that one CSV file.

Question 62: **When I open the PRO-PM data form, I cannot see the HOOS, JR or the KOOS, JR data field. The others are there except for those two.**

The HOOS/KOOS questions will appear on the data form once a procedure type is selected in the form. If a procedure type of 1 or 2 is selected, then the HOOS, JR questions will appear. If a procedure type of 3 or 4 is selected, then the KOOS, JR questions will appear.

Question 63: **What data elements are used for succession management for data submissions and HQR?**

The four elements include the CMS Certification Number (CCN), Medicare Beneficiary Identification (MBI), survey type, and procedure type.

Question 64: **If we decide to submit the data manually, via the HQR data form, how many times can it be submitted to QualityNet?**

You can submit and resubmit as many times as you need during the open submission period as long as you keep the four data elements (CCN, MBI, survey type, and procedure type) the same. Please remember that each time you upload your data, the system will overwrite it with that latest data that were submitted.

Question 65: **Can we submit some data via CSV and other data manually, or do we need to submit all data in the same format?**

Yes, if you have the four required data elements in your submission. It is important to remember that the latest submission replaces earlier submissions. As such, any information from a previous submission left out of the last submission will be overwritten.

Question 66: **Can you edit the data form even if you submit by CSV?**

If the CSV file was 'Accepted,' you should be able to find the surveys from your CSV in your data form. Then, you can edit them by clicking on that blue hyperlink for MBI.

Question 67: **Can I view and/or modify data uploaded by my authorized vendor?**

A provider can view and/or modify data uploaded by their vendor as long as you have the correct permission.

Question 68: **Where in HQR can I view my file feedback?**

You can review your file feedback on the File Upload page under the download link that appears next to your file in the error column.

Question 69: **What type of outcome reports will hospitals receive? How many areas of HQR reporting will display the successful submissions?**

During voluntary reporting, CMS will share confidential feedback reports to participating hospitals. If feasible, CMS will include the hospital's risk-standardized improvement rate and other results that support an understanding of their performance.

Registries and The Joint Commission

Question 70: **Is it possible that data collected for CMS will be coordinated with the information already being collected by the Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI)?**

The data collection process for the THA/TKA PRO-PM and the MARCQI is similar. There is alignment between the surveys collected, including the HOOS, KOOS, and PROMIS-Global. Please note that the THA/TKA PRO-PM uses the same preoperative PRO data collection window (0–90 days prior to a procedure) and that the postoperative PRO data collection window (300–425 days after a procedure) overlaps with the MARCQI recommendation. CMS will continue to monitor potential areas for alignment, as appropriate. Also, hospitals can utilize registries as an acceptable form of data collection and data submission for the measure. If a hospital elects to use a third party, like a registry, to submit measure data for the Hospital IQR Program, the registry will need a Vendor ID and the necessary HQR user role permissions and access to view, upload, and edit the data. The hospital will need to complete a process to authorize the third party to submit on its behalf.

Question 71: **Are we able to merge the data that we are collecting for the American Joint Replacement Registry (AJRR)? If we are currently collecting the HOOS/KOOS PRO data through AJRR for The Joint Commission accreditation, will we continue to submit through them for CMS? Is AJRR a registry that will submit these data on behalf of a facility?**

The data collection between the THA/TKA PRO-PM and the AJRR is similar. There is alignment between the surveys recommended by AJRR, including the HOOS, JR; KOOS, JR; PROMIS-Global or VR-12; and the patient- or provider-reported risk variables (which were also collected in the CJR Model). CMS will continue to monitor potential areas for alignment, as appropriate.

Hospitals can utilize registries as an acceptable form of data collection and data submission for the measure. If a hospital elects to use a third party, like a registry, to submit measure data for the Hospital IQR Program, the registry will need a Vendor ID and the necessary HQR user role permissions and access to view, upload, and edit the data. The hospital will need to complete a process to authorize the third party to submit on its behalf.

Please note that hospitals participating in voluntary and future mandatory reporting of the THA/TKA PRO-PM will need to submit their data to CMS using the HQR system. The deadline for the preoperative PRO data submission for the first voluntary reporting period is October 2, 2023.

Question 72: **What are the submission requirements for the hospitals already submitting PROs for the CJR program? What is the difference between the CMS CJR and CMS PRO-PM submissions?**

A hospital can participate in both the CJR and THA/TKA PRO-PM voluntary efforts.

If a hospital chooses to participate in the voluntary reporting of the THA/TKA PRO-PM, the hospital will need to submit their data to HQR. Data submission templates and resources for the voluntary reporting of the THA/TKA PRO-PM can be found on QualityNet at Hospitals – Inpatient > Measures > THA/TKA PRO-PM > Resources. Both the data collection effort in CJR and the voluntary reporting of the THA/TKA PRO-PM are aligned, but they have slight differences. The THA/TKA PRO-PM uses data like the data required for CJR PRO data collection. The CJR model started in April 2016. The PRO and risk variable data collection for the voluntary reporting of the THA/TKA PRO-PM started in October 2022.

PRO and risk variable elements: The THA/TKA PRO-PM requires fewer data elements than the CJR PRO data collection. It only requires the mental health questions within the mental health subscale on the PROMIS-10 or VR-12 and only requires collection of these elements preoperatively. It does not allow submission of the HOOS/KOOS subscales. Instead, it includes the HOOS, JR and KOOS, JR surveys. It does not require race/ethnicity preoperatively.

Preoperative and postoperative PRO data collection timeframes: Both the voluntary PRO data collection in CJR and the THA/TKA PRO-PM have the same preoperative data collection timeframe: 0–90 days prior to an eligible elective primary THA/TKA. The voluntary PRO data collection in CJR postoperative PRO data collection timeframe is 270–425 days after an eligible elective primary THA/TKA procedure. The THA/TKA PRO-PM postoperative PRO data collection timeframe is 300–425 days after an eligible elective primary THA/TKA PRO-PM.

Eligible procedures and data submission timing:

Overlapping THA/TKA Procedures Between THA/TKA PRO-PM Voluntary Reporting 1, Voluntary Reporting 2, CJR Payment Year 7–8

THA/TKA Procedures Performed	Is this data used for CJR PRO Data Collection?	Are these data used for THA/TKA PRO-PM?
July 1, 2022 – June 30, 2023*	Yes – PY 7*	Only data for January 1, 2023 – June 30, 2023 THA/TKA procedures are used for Voluntary Reporting 1.
July 1, 2023 – June 30, 2024	Yes – PY 8	Yes – Voluntary Reporting 2

*Data submission deadlines between CJR and THA/TKA PRO-PM differs for PY 7/Voluntary Reporting 1 only.

Reporting requirement/submission requirement:

- Voluntary and mandatory reporting of the THA/TKA PRO-PM: Complete preoperative and complete matched postoperative PRO data for 50 percent eligible THA/TKA patients.

- CJR PY 7 and 8: postoperative data for eligible procedures July 1, 2021–June 30, 2022, ≥ 80 percent or ≥ 300 eligible procedures; preoperative data for eligible procedures July 1, 2022–June 30, 2023 ≥ 85 percent or ≥ 400 eligible procedures; postoperative data for eligible procedures July 1, 2022–June 30, 2023 ≥ 85 percent or ≥ 400 eligible procedures; and preoperative data for eligible procedures July 1, 2023–June 30, 2024≥ 90 percent or ≥ 500 eligible procedures.

- Data submission: CJR PRO data will need to be submitted via Managed File Transfer; THA/TKA PRO-PM data will need to be submitted via the HQR platform.

Question 73: **Can we use the old CJR data template to submit data, which was macro-enabled and easier to identify missing elements?**

No, you are unable to use the old CJR data template to submit data. Follow one of the file layouts defined on the QualityNet THA/TKA PRO-PM Resources page to submit THA/TKA PRO-PM files to HQR.

Question 74: **Is there any difference between the data collection and the American Academy of Orthopedic Surgeons (AAOS) orthopedic registry?**

The data collection between the THA/TKA PRO-PM and the AJRR is similar. There is alignment between the surveys recommended by AJRR, (including the HOOS, JR; KOOS, JR; PROMIS-Global, and VR-12) and the patient- or provider-reported risk variables (which were also collected in the CJR Model).

In terms of the data collection for the THA/TKA PRO-PM, please refer to the complete list of required data elements in the data dictionary. The data dictionary lists the data elements, response options, and data collection timeframe. You can also refer to the What Data Should I Collect? fact sheet on QualityNet.

Question 75: **Will CMS work with The Joint Commission to synchronize the postoperative data collection time frame? CMS requires one year post; The Joint Commission hip/knee certification requires three months post.**

Regarding alignment of the THA/TKA PRO-PM with The Joint Commission Advanced Hip and Knee certification requirements, we note that alignment exists in the PRO instruments, specifically the HOOS, JR and KOOS, JR (collected for the measure outcome for the THA/TKA PRO-PM), as well as the PROMIS-Global or VR-12 (collected for the risk model of the THA/TKA PRO-PM).

The 300–425-day postoperative PRO data collection time frame for the THA/TKA PRO-PM was selected to align with clinical workflow and typical one-year follow-up scheduling. CMS will continue to monitor potential areas for alignment, as appropriate.

Resources and PRO Questionnaires

Question 76: **What resources do you recommended for a hospital that does not currently collect these data? Are there CMS best practices for collecting PROS for these patients?**

CMS supports flexibility in collecting PRO data. Hospitals can collect PRO data using methods that align with their clinical workflow and patient preferences. We recommend you refer to the following resources:

- To learn more about the timing of PRO data collection and mode of collection options, please refer to the How and When can Patient-Reported Outcome (PRO) Data be Collected? fact sheet.
- To learn more about preoperative and postoperative data elements required, please refer to the What Data Should I Collect? fact sheet and the THA/TKA PRO–PM data dictionary. The data dictionary defines the data elements and response options.
- To access the data submission templates, please refer to the data submission resources on QualityNet.

In terms of data submission, hospitals have the flexibility to submit data through multiple approaches. Hospitals can:

- Send data to CMS for measure calculation directly.
- Utilize an external entity (vendor or registry).

Hospitals or vendors will utilize the HQR system to submit the data. CSV, XML, and manual data entry file formats can be used for data submission.

Question 77: **Are there CMS resources available to assist hospitals in small, rural, and medically underserved communities to collect data or make recommendations to assist with data collection? Most of these hospitals do not employ the surgeons, do not have electronic medical records that support the collection of data after discharge, and often do not have adequate cell service or internet bandwidth to connect patients to patient portals.**

While PRO-PMs require providers to integrate data collection into clinical workflows, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision-making and benefit patients by engaging them in discussions about potential outcomes.
To provide flexibility, CMS is not requiring hospitals to collect data in a specific way. CMS acknowledges hospitals may use a variety of data collection, storage, and submission approaches, and we encourage hospitals to use processes best suited to them and their patient populations.

CMS has shared resources regarding possible modes of data collection. Please refer to the How and When can Patient-Reported Outcome (PRO) Data be Collected? fact sheet available on QualityNet.

Question 78: **Is there a practice or test environment where we can view the data forms and data submitted without submitting actual data?**

Currently, there are no practice or test environments for the data forms. However, you can delete and modify any data submitted via the data form during the open submission period.

Question 79: **Will patient educational brochures be available in other languages?**

Other languages are not available at this time, but we are considering this for the future.

Question 80: **With respect to the preoperative questionnaires, is there a list of recommended sources? As an example, what questions should be asked in relation to chronic opioid use?**

You can find a complete list of required data elements in the data dictionary. The data dictionary lists the data elements, response options, and data collection timeframe. You can also refer to the What Data Should I Collect? fact sheet on QualityNet.

Question 81: **Are the HOOS, JR and KOOS, JR the only acceptable surveys?**

Yes, for the outcome, only the HOOS, JR and KOOS, JR are accepted.

Question 82: **Is it allowable to build the HOOS and KOOS into our computer system, or would we need a copyright to do that?**

The HOOS, JR and KOOS, JR instruments are nonproprietary and free to use. Please visit https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp for more information.

Question 83: **The PROMIS-Global questionnaire that we use has more/different questions than Version 1.1 and 1.2. Could you verify that these are the only versions for data collection that started on July 1, 2024?**

Hospitals will only need to collect and submit the mental health related questions on the PROMIS-Global. (Hospitals do not need to collect the full PROMIS-Global questionnaire.) Hospitals must submit these data during the preoperative data submission timeframe. In addition, hospitals can use Version 1.1 or 1.2 of the PROMIS Global survey. During data submission, hospitals will need to indicate the version of the PROMIS-Global they used.

The mental health questions and response options from PROMIS-10 are:

- In general, would you say your quality of life is:
- In general, how would you rate your mental health, including your mood and your ability to think?
- In general, how would you rate your satisfaction with your social activities and relationships?

Responses for each of these questions are:

5= Excellent

4=Very Good

3=Good

2= Fair

1=Poor

- How often have you been bothered by emotional problems, such as feeling anxious, depressed, or irritable in the past 7 days?

Version 1.1 responses for this question:

- 1 = Never
- 2 = Rarely
- 3 = Sometimes
- 4 = Often
- 5 = Always

Version 1.2 responses for this question:

- 1 = Always
- 2 = Often
- 3 = Sometimes
- 4 = Rarely
- 5 = Never

Question 84: **Are all PRO questionnaires free to use, or do they require a licensing fee to use from the questionnaire developers?**

All PRO questionnaires used in this measure are free to use, and stakeholders do not need a license to use the questionnaire instruments. You can find a complete list of required data elements in the data dictionary. The data dictionary lists the data elements, response options, and data collection timeframe). You can ale refer to the What Data Should I Collect? fact sheet on the THA/TKA PRO-PM Resources page on QualityNet.