**Supporting Statement – Part A**

**Submission of Information for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program: CY 2024 OPPS/ASC Proposed Rule**

# **Background**

The Centers for Medicare and Medicaid Services’ (CMS’) quality reporting programs promote higher quality, more efficient health care for Medicare beneficiaries by collection and reporting on quality-of-care metrics. This information is made available to consumers, both to inform Medicare beneficiaries’ decision-making, as well as to incentivize healthcare facilities to make quality improvements.

Specifically, CMS has implemented quality measure reporting programs for multiple settings, including for ambulatory surgical centers (ASCs), to achieve its overarching priorities and initiatives, including the National Quality Strategy and the Meaningful Measures 2.0 Framework. In particular, Meaningful Measures 2.0 promotes innovation and modernization of all aspects of quality to better address health care priorities and gaps, emphasize digital quality measurement, and promote patient perspectives by supporting five interrelated goals: (1) empower consumers to make good health care choices through patient-directed quality measures and public transparency, (2) leverage quality measures to promote health equity and close gaps in care, (3) streamline quality measurement, (4) leverage measures to drive outcome improvement through public reporting and payment programs, and (5) improve quality measure efficiency by transitioning to digital measures and using advanced data analytics.

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program was established under section 1833(t) of the Social Security Act (the Act). CMS began data collection under this program in calendar year (CY) 2012. As required by authorizing statute, these data have been made publicly available after providing ASCs the opportunity to review the data. ASCQR Program payment determinations are made based on reported quality measure data and submission of supporting forms by ASCs, as specified through rulemaking. The information collection requirements for the CY 2014 through CY 2025 payment determinations are approved under OMB control number 0938-1270 (expiration date August 31, 2025). This information collection request covers data collection requirements for CYs 2026 through 2029 payment determinations and subsequent years.

**B. Justification**

**1. Need and Legal Basis**

A quality reporting program for ASCs was authorized by section 109(b) of the Medicare Improvements and Extension Act of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA)[[1]](#footnote-3) which amended section 1833(i) of the Act. Section 1833(i)(2)(D)(iv) of the Act states that the Secretary may provide that any Ambulatory Surgical Center (ASC) that does not submit quality measures to the Secretary in accordance with paragraph (7) may incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year.

Section 1833(i)(7)(B) of the Act provides that, ‘‘[e]xcept as the Secretary may otherwise provide,’’ the hospital outpatient quality data provisions of subparagraphs (B) through (E) of section 1833(t)(17) of the Act shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC, respectively. Section 1833(t)(17)(B) of the Act requires that hospitals submit quality data in a form, manner, and at a time that the Secretary specifies.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus-building entities (CBE). Section 1833(t)(17)(C)(ii) of the Act allows the Secretary to select measures that are the same as (or a subset of) the measures for which data are required to be submitted under the program developed for the Hospital Inpatient Quality Reporting Program.

Section 1833(t)(17)(D) of the Act gives the Secretary the authority to replace measures or indicators as appropriate, such as where all hospitals are effectively in compliance, or the measures or indicators have been subsequently shown not to represent the best clinical practice. Section 1833(t)(17)(E) of the Act requires the Secretary to establish procedures for making data submitted under the program developed for ASCs available to the public. Such procedures include providing facilities with the opportunity to review their data prior to public release.

Continued expansion and refinement of the quality measure set is consistent with the letter and spirit of the authorizing legislation, MIEA-TRCHA, to collect and make publicly available ASC-reported information on the quality of care delivered in the ASC setting.

**ASCQR Program Measures**

The ASCQR Program seeks to collect and publicly report data on quality-of-care measures for the ASC setting. Measure data are submitted via one of three modes: (1) web-based; (2) claims-based; and (3) survey-based, as seen in Table 1.

For measure data submitted as “web-based (CMS),” ASCs are required to submit non-patient level, aggregated data directly to CMS via a web-based tool located on a CMS website. One web-based measure is submitted differently; specifically, the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure is calculated using data submitted to the Centers for Disease Control and Prevention’s (CDC) National Healthcare Safety Network (NHSN) under OMB control number 0920-1317 (expiration date January 31, 2024). We note that the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (enacted on November 14, 1986) (NCVIA).[[2]](#footnote-4)

For measure data submitted as “claims,” information is derived through analysis of administrative Medicare Fee-for-Service (FFS) claims and beneficiary enrollment data and do not require additional effort or burden from ASCs.

For measures submitted as “survey-based,” information is derived through analysis of responses to the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey and do not require additional effort or burden from ASCs that is not captured under OMB control number 0938-1240 (expiration date November 30, 2024).

**TABLE 1. ASCQR Program Measures for the CY 2024 Payment Determination and Subsequent Years**

| **CBE No.** | **Measure Name** | **Data Submission Mode** |
| --- | --- | --- |
| 0263 | Patient Burn | Web-based  (CMS) |
| 0266 | Patient Fall | Web-based  (CMS) |
| 0267 | Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant | Web-based  (CMS) |
| 0265 | Hospital Transfer/Admission | Web-based  (CMS) |
| 0658 | Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients | Web-based  (CMS) |
| 1536 | Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery | Web-based (CMS) |
| 2539 | Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy | Claims |
| N/A | Normothermia Outcome | Web-based  (CMS) |
| N/A | Unplanned Anterior Vitrectomy | Web-based  (CMS) |
| N/A | OAS CAHPS – About Facilities and Staff | Survey-based |
| N/A | OAS CAHPS – Communication About Procedure | Survey-based |
| N/A | OAS CAHPS – Preparation for Discharge and Recovery | Survey-based |
| N/A | OAS CAHPS – Overall Rating of Facility | Survey-based |
| N/A | OAS CAHPS – Recommendation of Facility | Survey-based |
| 3470 | Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures | Claims |
| 3366 | Hospital Visits after Urology Ambulatory Surgical Center Procedures | Claims |
| 3357 | Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers | Claims |
| N/A | COVID-19 Vaccination Coverage Among HCP Measure | Web-based (NHSN) |

In the CY 2024 OPPS/ASC proposed rule, we are proposing to modify three previously adopted measures: (1) COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) Cataracts: Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery measure, beginning with the voluntary CY 2024 reporting period; and (3) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination.

We are also proposing to re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure, beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. Lastly, we are proposing to adopt 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), beginning with voluntary reporting in the CYs 2025 and 2026 reporting periods, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

**ASCQR Program Forms**

The ASCQR Program uses three administrative forms: (1) Extraordinary Circumstances Exception Request form; (2) Reconsideration Request form; and (3) Withdrawal of Participation form. These forms are completed only on a need-to-use, exception basis and most ASCs will not need to complete either of these forms in a given year. Thus, the burden for providers associated with forms utilized in the ASCQR Program is nominal, if any.

1. Extraordinary Circumstances Exception (ECE) Request Form

In the event of extraordinary circumstances not within the control of an ASC, such as a natural disaster, an ASC can request an exception or extension for meeting program requirements by submitting an ECE Request form. CMS provides this form to ASCs online and facilities may submit the form electronically, by mail, or fax. We note that the burden associated with completing and submitting an ECE request is accounted for in a separate PRA package, OMB control number 0938-1022 (expiration date January 31, 2026).[[3]](#footnote-5) Therefore, the burden associated with completing and submitting an ECE Request is not addressed here.

1. Reconsideration Request form

When an ASC is determined by CMS to not have met program requirements and has had a 2.0 percentage point reduction in their annual payment update (APU), the ASC may submit a Reconsideration Request form to CMS no later than the first day on or after March 17 that is not a non-work day[[4]](#footnote-6) of the affected payment year. CMS provides this form online and ASCs may submit the form by email or by fax. While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations exclude collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions. Therefore, the burden associated with submitting a Reconsideration Request form is not accounted for in this PRA package.

1. Withdrawal of Participation form

An ASC is considered an ASCQR Program participant if the ASC submits quality measure data (e.g., using the web-based data collection tool), and the submission is accepted. The ASC will continue to be considered a participant, regardless of whether the ASC continues to submit quality measure data, until formally withdrawing from the program. To withdraw from the program after submitting quality measure data, an ASC must complete and submit an online withdrawal form by August 31st for the applicable CY. While there is burden associated with filing a Withdrawal of Participation Form, regulations under the Paperwork Reduction Act of 1995, 5 C.F.R. § 1320.4, exclude collection activities during the conduct of administrative actions. Therefore, the burden associated with submitting a Withdrawal of Participation Form is not accounted for in this PRA package.

**2.** **Information Users**

The ASCQR Program as a pay-for-reporting program strives to have a streamlined measure set that provides meaningful measurement that also serves to differentiate facilities by quality of care while limiting burden to the fullest extent possible. This information is also available to Medicare beneficiaries, as well as to the general public, to provide information to assist them in making decisions about their health care. ASCQR Program data are published on the data.cms.gov website in a form that allows consumers to review both facility-level and national performance on quality measures selected for use in the ASCQR Program.

This information gathered by the program can be utilized by ASCs as metrics for required quality assessment and performance improvement (QAPI) programs under ASC conditions for coverage (CfC). As described in 42 CFR 416.43, these programs must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes and improves patient safety by using quality indicators or performance measures associated with improved health outcome and by the identification and reduction of medical errors.

Also, under section 3014 of the ACA, CMS is required to evaluate the impact and efficiency of CMS measures in quality reporting programs and to post the report every three years. Following the compilation of data from the ASCQR Program and other CMS programs, CMS’ findings were formally written into the latest triennial National Impact Assessment Report, which was released in June 2021.[[5]](#footnote-7)

**3. Use of Information Technology**

To assist ASCs successfully abstracting and submitting data for chart-abstracted measures, CMS provides a secure data warehouse and use of the CMS Hospital Quality Reporting (HQR) system secure portal (previously known as the CMS QualityNet Secure Portal) for storage and transmittal of data prior to the release of data to the CMS website. ASCs also have the option of using vendors to transmit their data. CMS has engaged a national support contractor to provide technical assistance with the data collection tool, other program requirements, and to provide education.

This section is not applicable to claims-based measures as these measures are calculated from data included on claims submitted by ASCs to Medicare for reimbursement. Therefore, no additional information collection effort will be required for ASCs for these measures.

As reflected by the collection and reporting of claims-based quality measures and quality measures submitted via the CMS web-based tool, efforts are made to reduce burden by limiting the adoption of measures requiring the submission of patient-level information that must be acquired through chart-abstraction and to employ existing data and data collection systems.

The complete list of measures and data collection forms are organized by type of data collected and data collection mechanism in Table 1.

**4. Duplication of Efforts**

The information to be collected is not duplicative of similar information collected by CMS or other efforts to collect quality-of-care data for ASCs. As required by statute, CMS requires ASCs to submit quality measure data for services provided.

**5. Small Business**

Based on industry survey, ASCs have an average of twenty employees, and many are considered small businesses. All the program information collection requirements are designed to allow maximum flexibility possible for facilities to encourage participation in the program. The program is designed with the goal that the collection of quality-of-care data be the minimum necessary for the calculation of summary figures that are reliable estimates of individual ASC performance. We have also incorporated measures that use data collected from Medicare FFS claims to ease facility burden.

Based on an analysis of the CY 2023 payment determination data, we found that, of the 5,697 ambulatory surgical centers (ASCs) that met eligibility requirements for the ASCQR Program, 5,181 ASCs received the full APU because they complied with all applicable data reporting requirements for the ASCQR Program. In addition, 687 ASCs that were not required to participate in reporting did so, as well as 195 Hospitals Without Walls returned to active ASC billing, for a total of 6,063 participating facilities participating in the ASCQR Program. All 5,181 ASCs that met eligibility requirements for the ASCQR Program received the APU including all facilities which were required but exempted; 4,175 of these ASCs were required to participate without a COVID-19 public health emergency (PHE) exception (not applicable for current APU). On this basis, we estimate that 5,057 ASCs (4,175 + 687 + 195) will submit data for the ASCQR Program for the CY 2026 payment determination unless otherwise noted.

**6. Less Frequent Collection**

We have designed the collection of quality-of-care data to be the minimum necessary for calculation of summary figures to be reliable estimates of individual ASC performance. Under the ASCQR Program, ASCs are required to submit CMS web-, survey-, and claims-based measure data on an annual basis relevant to their performance period to make payment determinations. More specifically, claims-based measures are calculated from Medicare FFS claims data; hospitals submit claims for reimbursement or payment per claims processing timeliness requirements. In addition, the NHSN web-based measure collected by the CDC is submitted for at least one self-selected week during each month of the reporting quarter. To collect these measure data less frequently would compromise the timeliness of any calculated estimates.

**7. Special Circumstances**

All ASCs reimbursed under the ASC Payment System are required to meet ASCQR Program requirements to receive the full APU under the revised ASC payment system for a given CY. Failure to meet all requirements may result in a 2.0 percentage point reduction in the APU. Under program requirements, ASCs with fewer than 240 Medicare FFS claims in two calendar years prior are not required to participate.

**8. Federal Register Notice/Outside Consultation**

The 60-day Federal Register notice for this data collection was published on July 31, 2023 (88 FR 49552).

Measures adopted for the ASCQR Program are required by statute to undergo a recognized consensus process. Section 3014 of the ACA modified section 1890(b) of the Act to require CMS to develop quality and efficiency measures through a “consensus-based entity.” To fulfill this requirement, the Measure Applications Partnership (MAP) was formed to review measures consistent with this provision of the Act. Beginning in CY 2023, the MAP will continue under a new name - the Partnership for Quality Measurement (PQM) - and will provide input on the Measures under Consideration (MUC) list as part of the Pre-Rulemaking Measure Review (PRMR). We refer readers to <https://p4qm.org/PRMR-MSR> for more information on the PRMR process. Prior and in addition to the ACA and the formation of the MAP or its predecessor, CMS has utilized consensus processes consistent with the authorizing statute for selecting and adopting quality measures for the ASCQR Program.

CMS also regularly engages interested parties (e.g. the ASC Quality Collaboration; solicitation of comments).

**9. Payment/Gift to Respondent**

ASCs are required to submit program measure data to receive the full APU provided under the revised ASC payment system for a given CY. No other payments or gifts will be given to respondents for participation.

**10. Confidentiality**

All information collected under the ASCQR Program will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for CMS data, including the Privacy Act of 1974 (5 U.S.C. 552a), the Health Insurance Portability and Accountability Act (HIPAA), and the Quality Improvement Organizations confidentiality requirements, which can be found at 42 CFR Part 480. CMS maintains this information in the CMS data warehouse, which contains all information collected under this and other quality data reporting programs. In addition, the tools used for transmission and storage of data are considered confidential forms of communication and are HIPAA-compliant.

**11. Sensitive Questions**

This program does not collect information on “sexual behavior and attitudes, religious beliefs, etc.,” but it does collect health information, which could be considered “matters that we commonly considered private.” This includes clinical data elements that will be collected and are necessary to calculate statistical measures. These statistical measures are the basis of subsequent improvement activities for ASC facilities and cannot be calculated without the case-specific data. Case-specific data will not be released to the public and is not releasable by requests under the Freedom of Information Act. Only ASC-specific data will be made publicly available as mandated by statute. In addition, the tools used for transmission of data are considered confidential forms of communication and are HIPAA-compliant.

**12. Burden Estimate (Total Hours & Wages)**

For the ASCQR Program, the burden associated with meeting program requirements includes the time and effort associated with completing administrative requirements and collecting and submitting data on the required measures.

As previously stated, we estimate that 5,057 ASCs will submit data for the ASCQR Program for the CY 2026 payment determination and future years unless otherwise noted.

All burden hour and cost estimates have been rounded to the nearest whole number.

1. Calculation of Wage Rate

We estimate that collecting and reporting data required under the ASCQR Program can be accomplished by staff with a median hourly wage of $52.12 per hour in accordance with the Bureau of Labor Statistics, based upon the median wage for Medical Records Specialists working in “general medical and surgical hospitals” which is $26.06 per hour before inclusion of overhead and fringe benefits.[[6]](#footnote-8) BLS describes Medical Records Specialists as those who ”compile, process, and maintain medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the healthcare system”; therefore, we believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for submission for the ASCQR Program. We estimate the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, as is currently done in other CMS quality reporting programs. This is necessarily a rough adjustment, because fringe benefits and overhead costs vary significantly from employer to employer. Nonetheless, we believe that doubling the hourly wage rate ($26.06 x 2 = $52.12) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will use an hourly labor cost estimate of $52.12 ($26.06 salary plus $26.06 fringe and overhead) for calculation of burden forthwith.

1. Estimated Burden for Claims-Based Measures Not Using Quality Data Codes

There are four previously adopted measures for the ASCQR Program that are claims-based: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, Hospital Visits after Urology Ambulatory Surgical Center Procedures, and Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers. Because data for these measures are collected via claims (ASCs are already submitting claims data for the purposes of payment) they do not require any additional data collection. Therefore, we estimate that any burden resulting from the data collection for these measures would be nominal, if any.

1. Estimated Burden for Data Submission of Web-Based Measures

Certain web-based measures for the ASCQR Program are also chart-abstracted while the remaining measures are not. Based on our data for the CY 2023 payment determination for the Patient Burn, Patient Fall, Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and All-Cause Hospital Transfer/Admission web-based measures experience approximately one case per month per ASC. These measures are chart-abstracted for claims purposes rather than solely for the purposes of quality reporting; therefore, our estimate is based on the chart-abstraction for these four measures being complete by the ASC at the time of web-based entry. Measure data for these measures would be submitted via the HQR system secure portal. Consistent with prior years (78 FR 75171 through 75172), we estimate that each participating ASC will spend 10 minutes per measure per year to collect and submit the data via a CMS web-based tool. As a result of this policy, we estimate a total annual burden estimate for all ASCs of 843 hours (0.1667 hours/measure x 5,057 ASCs) at a cost of $43,937 (843 hours x $52.12) per measure.

In the CY 2024 OPPS/ASC proposed rule, we are proposing to re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. This measure was previously finalized in the CY 2012 OPPS/ASC final rule with a burden estimate of 10 minutes per response (76 FR 74554). This measure was subsequently removed from the ASCQR Program in the CY 2017 OPPS/ASC final rule with the same estimate of 10 minutes per response (82 FR 59479). We continue to believe the burden per response to be 10 minutes per ASC per year. For the voluntary CY 2025 reporting period, we assume 20 percent of ASCs would report data, resulting in an annual burden of 168.5 hours (5,057 ASCs x 20 percent x 0.167 hours) at a cost of $8,782 (168.5 hours x $52.12) for voluntarily participating ASCs. For mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, we estimate an annual burden of 843 hours (5,057 ASCs × 0.167 hours) at a cost of $43,937 (843 hours × $52.12) for all ASCs.

The remaining web-based measures will incur a burden associated with both chart-abstraction and submission of measure data to the web-based tool. For web-based submission, we estimate that each participating ASC would spend 10 minutes per measure to submit the data. There are currently three mandatory measures: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (Colonoscopy Follow-Up Interval), Normothermia Outcome, and Unplanned Anterior Vitrectomy. We estimate the reporting burden for each measure to be 0.1667 hours (10 minutes/60 minutes) at a cost of $8.69 (0.1667 hours x $52.12/hour). We further estimate a total burden of 843 hours (5,057 ASCs x 0.1667 hours) and $43,937 (843 hours x $52.12/hour) for each of these three measures.

In the CY 2024 OPPS/ASC proposed rule, we are proposing to amend the Colonoscopy Follow-Up Interval measure denominator language by removing the removing the phrase “aged 50 years” and adding in its place the phrase “aged 45 years.” Because this modification neither changes the amount of data required nor frequency of submission, we do not believe this modification would result in a change in burden for submission of measure data.

In the CY 2024 OPPS/ASC proposed rule, we are also proposing to modify the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure by limiting the visual function surveys that can be used to administer this measure to three survey instruments: NEI VFQ-25, VF-14, and VF-8R, beginning with the voluntary CY 2024 reporting period. Because the three survey instruments being proposed are currently in use by clinicians for administering this measure, we do not believe limiting clinicians to using these three surveys would result in a change in burden for submission of measure data.

1. Estimated Burden for Chart-Abstraction for Web-Based Measures

ASCs will incur a financial burden associated with the Colonoscopy Follow-Up Interval, Normothermia Outcome, and Unplanned Anterior Vitrectomy measures for their chart-abstraction in addition to submitting the measure data to the web-based tool. For the chart-abstracted aspect of the measures, we estimate that each participating ASC would spend 2.92 minutes (0.049 hours) per case to collect and submit the data for the minimum required yearly sample size of 63 as designated in the ASCQR Program Specifications Manual. We, therefore, estimate the reporting burden for an ASC with 63 cases would be approximately 3.1 hours (0.049 hours x 63 cases) at a cost of $159 (3.1 hours x $52.12/hour). We further estimate a total burden of 15,399 hours (5,057 ASCs x 3.1 hours) and $802,573 (5,057 ASCs x 3.1 hours x $52.12/hour) for each measure.

1. Estimated Burden for PRO-PM Measures

In the CY 2024 OPPS/ASC proposed rule, we are proposing to adopt the THA/TKA PRO-PM, beginning with voluntary reporting in the CYs 2025 and 2026 reporting periods, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 7.25 minutes (0.120833 hours) per patient to complete both the pre-operative and post-operative surveys and 10 minutes (0.167 hours) per hospital per response to collect and submit the measure data via the HQR system (87 FR 49386 through 49387). We believe the estimated burden for both patient surveys and data submission would be the same for the ASCQR Program.

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) patient-reported outcome (PRO) data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms such as Medicare enrollment forms, CMS-1500 form, and U.S. Census Informational Questionnaires. Many ASCs have already incorporated PRO data collection into their workflows. While we are not proposing to require how ASCs collect PRO data for this measure, ASCs new to collecting PRO data would have multiple options for when and how they would collect these PRO data so they could best determine the mode and timing of collection that works best for their patient population.

The possible patient touchpoints for pre-operative PRO data collection include the doctor’s office, pre-surgical steps such as education classes, or medical evaluations that could occur in an office or at the ASC. The modes of PRO data collection could include completion of the pre-operative surveys using electronic devices, 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 could occur before the follow-up appointment, at the doctor’s office, or after the follow-up appointment. If the patient does not or cannot attend a follow-up appointment, the modes of data collection would be completion of the post-operative survey using email, mail, telephone, or through a patient portal. Similar to other surveys like the OAS CAHPS, we believe the use of multiple data collection modes would maximize response rates as it allows for different patient preferences.

For the THA/TKA PRO–PM data, ASCs would be able to submit data during two voluntary periods. The first voluntary reporting period would begin in CY 2025 for eligible procedures occurring between January 1, 2025, through December 31, 2025, and the second voluntary reporting period would begin with CY 2026 for eligible procedures occurring between January 1, 2026, through December 31, 2026. Voluntary reporting would be followed by mandatory reporting for eligible elective procedures beginning with the CY 2027 reporting period (occurring between January 1, 2027, through December 31, 2027), impacting the CY 2030 payment determination.

Whether participating in the voluntary reporting period or during subsequent mandatory reporting, ASCs would need to submit data twice (pre-operative data and post-operative data). For the purposes of calculating burden, we applied similar assumptions used for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386 through 49387). Specifically, we estimate that, during the voluntary periods, 50 percent of ASCs that perform at least one THA/TKA procedure would submit data and would do so for 50 percent of THA/TKA patients. For purposes of calculating burden for the mandatory period, we estimate that ASCs would submit for 100 percent of patients. While we propose to require ASCs to submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case ASCs exceed this threshold.

To estimate the cost burden for patients completing the surveys for this proposed measure, we believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hour. We base this estimate on the “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,”[[7]](#footnote-9) which identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate an hourly pre-tax wage rate of $24.95/hour. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hour. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

To estimate the burden of information collection for patients completing surveys for this proposed measure, we assume that most ASCs would likely undertake PRO data collection through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. We estimate that approximately 42,706 THA/TKA procedures occur in an ASC each year, and that many patients could complete both the pre-operative and post-operative questionnaires. However, from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire would complete the post-operative questionnaire. For the voluntary CYs 2025 and 2026 voluntary reporting periods, we assume 50 percent of patients from 50 percent of the ASCs, or 10,677 patients, would complete the survey (42,706 patients × 0.50 × 0.50 of ASCs) for a total of 1,290 hours annually (10,677 respondents × 0.120833 hours) at a cost of $26,716 (1,290 hours × $20.71). Beginning with mandatory reporting in the CY 2027 reporting period/CY 2030 payment determination, we estimate a total of 5,160 hours (42,706 patients × 0.120833 hours) at a cost of $106,864 (5,160 hours × $20.71) across all ASCs.

Regarding ASCs’ burden related to submitting data for this proposed measure, which would be reported via the HQR System, we estimate a burden of 10 minutes per response. ASCs would submit data associated with pre-operative surveys by March 31 of the CY following the CY in which the eligible procedures took place and would submit data associated with post-operative surveys by March 31 of the CY following the CY in which pre-operative data were submitted. Therefore, for the first voluntary reporting period for eligible procedures occurring in CY 2025, pre-operative survey data submission would occur in the first quarter of the CY 2026 reporting period and post-operative survey data submission would occur in the first quarter of the CY 2027 reporting period. For each of the two voluntary reporting periods, we estimate that each ASC would spend 20 minutes (0.33 hours) annually (10 minutes × 2 surveys) to collect and submit the data. For the voluntary CY 2026 reporting period, we estimate a burden for 50 percent of participating ASCs of 422 hours (0.167 hours × 2,529 ASCs) at a cost of $21,995 (422 hours × $52.12). For the voluntary CY 2027 reporting period, we estimate a burden for 50 percent of participating ASCs of 843 hours (0.33 hours × 2,529 ASCs) at a cost of $43,937 (843 hours × $52.12). For the mandatory CY 2028 reporting period, we estimate a burden for all participating ASCs of 1,264 hours [(0.167 hours × 2,529 ASCs) + (0.167 hours x 5,057 ASCs)] at a cost of $65,880 (1,264 hours × $52.12). For the CY 2029 reporting period and subsequent years, we estimate a total of 1,686 hours (0.33 hours × 5,057 ASCs) at a cost of $87,874 (1,686 hours × $52.12).

1. Estimated Burden for Survey-Based Measures

The information collection requirements associated with measures ASC-15a–e are currently approved under OMB control number 0938-1240 which expires November 30, 2024; for this reason, we are not providing an independent estimate of the burden associated with the OAS CAHPS Survey administration for the ASCQR Program.

1. Estimated Burden for Administration of Program

Administrative burden involves the time and effort associated with completing program and system requirements and managing facility operations, and includes duties such as ensuring staffing, identifying and maintaining an active HQR system Security Administrator/Official, and filling out forms and other paperwork.

As previously noted, the ASCQR Program utilizes three forms in its administrative activities: (1) Extraordinary Circumstances Exception (ECE) Request; (2) Reconsideration Request; and (3) Withdrawal from Participation Form. None of these forms are completed on an annual basis; all are on a need-to-use, exception basis and most hospitals will not need to complete any of these forms in any given year. Thus, the burden associated with forms utilized in the ASCQR Program is nominal, if any.

The burden associated with submitting an ECE Request is accounted for in OMB control number 0938-1022 (expiration date January 31, 2026) and is therefore excluded from this burden estimate. Moreover, consistent with regulations under the Paperwork Reduction Act of 1995, 5 C.F.R. § 1320.4, the burden associated with filing a Reconsideration Request or a Withdrawal from Participation form is excluded from this package because this collection occurs during the conduct of an administrative action.

In the CY 2024 OPPS/ASC proposed rule, we are not proposing any changes to the administrative burden for the CY 2025 payment determination. Thus, our estimates for administrative burden remain the same as those previously approved for the CY 2024 payment determination under this OMB control number.

1. Summary

The following tables (Table 2 and Table 3) summarize the burden estimates for the CY 2026 through CY 2029 payment determinations and subsequent years.

**Table 2. Total Burden Hours for the CY 2026 through CY 2029 Payment Determinations**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Information Collection** | **CY2026** | **Difference from Currently Approved** | **CY2027** | **Difference from Currently Approved** | **CY2028** | **Difference from Currently Approved** | **CY2029** | **Difference from Currently Approved** |
| Patient Burn | 843 | +68.5 | 843 | +68.5 | 843 | +68.5 | 843 | +68.5 |
| Patient Fall | 843 | +68.5 | 843 | +68.5 | 843 | +68.5 | 843 | +68.5 |
| Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant | 843 | +68.5 | 843 | +68.5 | 843 | +68.5 | 843 | +68.5 |
| All-Cause Hospital Transfer/Admission | 843 | +68.5 | 843 | +68.5 | 843 | +68.5 | 843 | +68.5 |
| ASC Facility Volume Data on Selected ASC Surgical Procedures | 0 | 0 | 168.5 | +168.5 | 843 | +843 | 843 | +843 |
| Colonoscopy Follow-Up Interval | 16,242 | +1,223 | 16,242 | +1,223 | 16,242 | +1,223 | 16,242 | +1,223 |
| Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery | 3,246.5 | +243.5 | 3,246.5 | +243.5 | 3,246.5 | +243.5 | 3,246.5 | +243.5 |
| Normothermia Outcome | 16,242 | +1,223 | 16,242 | +1,223 | 16,242 | +1,223 | 16,242 | +1,223 |
| Unplanned Anterior Vitrectomy | 16,242 | +1,223 | 16,242 | +1,223 | 16,242 | +1,223 | 16,242 | +1,223 |
| THA/TKA PRO-PM | 0 | 0 | 1,290 | +1,290 | 1,712 | +1,712 | 6,003 | +6,003 |
| **TOTAL** | **55,345** | **+4,187** | **56,803** | **+5,645** | **57,900** | **+6,742** | **62,191** | **+11,033** |

**Table 3. Total Burden Dollars for the CY 2026 through CY 2029 Payment Determinations\***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Information Collection** | **CY2026** | **Difference from Currently Approved** | **CY2027** | **Difference from Currently Approved** | **CY2028** | **Difference from Currently Approved** | **CY2029** | **Difference from Currently Approved** |
| Patient Burn | $43,937 | +$7,954 | $43,937 | +$7,954 | $43,937 | +$7,954 | $43,937 | +$7,954 |
| Patient Fall | $43,937 | +$7,954 | $43,937 | +$7,954 | $43,937 | +$7,954 | $43,937 | +$7,954 |
| Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant | $43,937 | +$7,954 | $43,937 | +$7,954 | $43,937 | +$7,954 | $43,937 | +$7,954 |
| All-Cause Hospital Transfer/Admission | $43,937 | +$7,954 | $43,937 | +$7,954 | $43,937 | +$7,954 | $43,937 | +$7,954 |
| ASC Facility Volume on Selected ASC Surgical Procedures | $0 | $0 | $8,782 | +$8,782 | $43,937 | +$43,937 | $43,937 | +$43,937 |
| Colonoscopy Follow-Up Interval | $846,510 | +$148,728 | $846,510 | +$148,728 | $846,510 | +$148,728 | $846,510 | +$148,728 |
| Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery | $169,233 | +$29,706 | $169,233 | +$29,706 | $169,233 | +$29,706 | $169,233 | +$29,706 |
| Normothermia Outcome | $846,510 | +$148,728 | $846,510 | +$148,728 | $846,510 | +$148,728 | $846,510 | +$148,728 |
| Unplanned Anterior Vitrectomy | $846,510 | +$148,728 | $846,510 | +$148,728 | $846,510 | +$148,728 | $846,510 | +$148,728 |
| THA/TKA PRO-PM | $0 | $0 | $26,716 | +$26,716 | $48,711 | +$48,711 | $150,801 | +$150,811 |
| **TOTAL** | **$2,884,511** | **+$507,705** | **$2,920,009** | **+$543,204** | **$2,977,159** | **+$600,354** | **$3,079,249** | **+$702,454** |

\*Dollar amounts may vary slightly due to rounding

**13. Capital Costs (Maintenance of Capital Costs)**

There are no capital costs being placed on the ASCs. Successful submission will result in an ASC receiving the full APU, while having to expend no capital costs for participation. CMS is providing a data collection tool and method for submission of data to the participants. There are no additional data submission requirements placing additional cost burdens on ASCs.

For ASCs that are not currently collecting Facility-Level THA/TKA PRO-PM data, there would be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different facilities may utilize different modes of data collection (for example, paper-based, electronically patient-directed, clinician-facilitated, etc.). While we assume the majority of ASCs would report data for this measure via the HQR System, we assume some ASCs may elect to submit measure data via a third-party vendor, for which there are associated costs. Under OMB control number 0938-0981 for the HCAHPS Survey measure (expiration date September 30, 2024), an estimate of approximately $4,000 per hospital is used to account for these costs. This estimate originates from 2012, therefore, to account for inflation (assuming end of CY 2012 to April 2023), we adjust the price using the Bureau of Labor Statistics Consumer Price Index and estimate an updated cost of approximately $5,284 ($4,000 x 132.1 percent).[[8]](#footnote-10)

**14. Cost to Federal Government**

The cost to the Federal Government for maintaining program activities is for supporting data system architecture, data storage, maintenance and updating of information technology infrastructure on the HQR system secure portal, providing ongoing technical assistance to ASCs and data vendors, calculation of claims-based measures, measure development and maintenance, the provision of ASCs with feedback and preview reports as well as costs associated with public reporting. Estimated annual costs are $9,500,000 for data and infrastructure plus $3,000,000 for contracted support.

There is one FTE assigned full-time in a lead position to this program. Using a GS-14 step 5 salary, that provides a rough estimate of $150,016 plus benefits (30%) of $45,005 or $195,021 for the federal government labor cost for this program year and subsequent years.

Total estimated cost to the Federal Government for the ASCQR Program is $12,695,021.

**15. Program or Burden Changes**

The proposal to re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure increases burden by 843 hours at a cost of $43,937 through the CY 2029 payment determination. The proposal to adopt the THA/TKA PRO-PM increases burden by 6,846 hours at a cost of $150,811through the CY 2030 payment determination. In aggregate, we estimate a total net increase in burden of 7,689 hours at a cost of $194,748 associated with these proposals.

We are also updating the wage rate from $46.46/hour to $52.12/hour based on more recent BLS wage data, as previously discussed. This increase of $5.66/hour results in a total increase in burden of $313,253 for the estimated burden hours for the CY 2026 payment determination.

For the CY 2024 reporting period/CY 2026 payment determination, based on the proposals in the CY 2024 OPPS/ASC proposed rule, we estimate a total burden of 55,345 hours and $2,884,511: an increase of 4,187 hours and $507,705 from our currently approved burden estimates. This increase is entirely due to our updated estimate of the number of ASCs that will report measure data from 4,646 ASCs to 5,057 ASCs.

**16. Publication/Tabulation Dates**

The goal of the data collection is to tabulate and publish ASC-specific data. We will continue to display information on the quality of care provided in the ASC setting for public viewing as specified by authorizing statute. Data from this program are currently publicly displayed and are available for download on data.cms.gov.

**17. Expiration Date**

CMS will display the expiration date on the manual and data collection tool.

**18. Certification Statement**

There are no exceptions to the certification statement.

**19. Collections of Information Employing Statistical Methods**

To reduce burden, facilities may sample using their method of choice to reduce the number of cases for which to submit data for certain measures.

1. (Pub. L. 109-432) [↑](#footnote-ref-3)
2. Pub. L. 99-660. [↑](#footnote-ref-4)
3. This burden is captured under another package because the hospital and ASC quality reporting and value-based purchasing programs use a single request form to avoid the use of multiple forms. Accounting for this burden under a single package ensures that all programs are using the same form, process, and burden estimates and avoids the risk of inconsistency or misalignment in CMS policies on this issue, as well as reducing inefficiencies in form updates and request processing. [↑](#footnote-ref-5)
4. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order. 42 CFR § 416.310(f) [↑](#footnote-ref-6)
5. The latest 2021 Impact Assessment Report, as well as earlier reports from 2012, 2015, and 2018 may be found at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/National-Impact-Assessment-of-the-Centers-for-Medicare-and-Medicaid-Services-CMS-Quality-Measures-Reports>. [↑](#footnote-ref-7)
6. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250), we finalized an hourly wage estimate of $23.23 per hour, plus 100 percent overhead and fringe benefits. Since the CY 2023 OPPS/ASC final rule, BLS removed this labor category and added a new labor category titled “Medical Records Specialists.” Wage rate information is available at: <https://www.bls.gov/oes/current/oes292072.htm>. [↑](#footnote-ref-8)
7. This report is available at https://aspe.hhs.gov/sites/default/files/migrated\_legacy\_files//176806/VOT.pdf. [↑](#footnote-ref-9)
8. U.S. Bureau of Labor Statistics. Historical CPI-U data. Accessed on March 9, 2023. Available at: https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202304.pdf [↑](#footnote-ref-10)