**Supporting Statement – Part A**

**Submission of Information for the Hospital Outpatient Quality Reporting (OQR) Program:**
**CY 2022 OPPS/ASC Final Rule**

## A. Background

The Centers for Medicare and Medicaid Services' (CMS') quality reporting programs promote higher quality and more efficient healthcare for Medicare beneficiaries. CMS has implemented quality measure reporting programs for multiple settings, including for hospital outpatient care.

The Medicare Improvements and Extension Act of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109-432) Section 109(a) amended Section 1833(t) of the Social Security Act (the Act) by adding a new subsection (17) that affects the payment rate update applicable to Outpatient Prospective Payment System (OPPS) payments for services furnished by hospitals in outpatient settings on or after January 1, 2009.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under Section 1886(d)(1)(B) of the Act, states that hospitals that fail to report data required for quality measures selected by the Secretary in the form and manner required by the Secretary under Section 1833(t)(17)(B) of the Act will incur a reduction in their annual payment update (APU) factor to the hospital outpatient department fee schedule of 2.0 percentage points.

Sections 1833(t)(17)(C)(i) and (ii) of the Act require the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings. Such measures must reflect consensus among affected parties and, to the extent feasible and practicable, must be set forth by one or more national consensus building entities. The Secretary also has the authority to replace measures or indicators as appropriate. The Act also requires the Secretary to establish procedures for making the data submitted available to the public. Such procedures must provide the hospitals the opportunity to review such data prior to public release.

The CMS program established under Section 1833(t) of the Social Security Act is the Hospital Outpatient Quality Reporting (OQR) Program. The information collection requirements for the CY 2014 through CY 2023 payment determinations are currently approved under OMB Control Number 0938-1109. This information collection request covers the existing measure sets to be collected for the CY 2024 payment determination, and reflects policies to adopt three new measures, remove two existing measures, and require data collection for one previously adopted measure beginning with the CY 2024 reporting period and another beginning with the CY 2025 reporting period.

Section 3014 of the Patient Protection and Affordable Care Act of 2010 (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. The MAP is

convened by the National Quality Forum (NQF), a national consensus organization, with current organizational members including the American Association of Retired Persons (AARP), America's Health Insurance Plans, the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), the American Hospital Association, the American Medical Association, the American Nurses Association, the Federation of American Hospitals, and the Pacific Business Group on Health. Nationally-recognized subject matter experts are also voting members of the MAP. Prior to the ACA and the formation of the MAP, CMS utilized consensus processes consistent with the authorizing statute for selecting and adopting quality measures for the Hospital OQR Program.

In implementing this and other quality reporting programs, CMS' overarching goal is to support the National Quality Strategy (NQS).[1] The NQS is guided by three aims: better care, smarter spending, and healthier people. The NQS was released by the U.S. Department of Health and Human Services. The strategy was required under the ACA and is an effort to create national aims and priorities to guide local, state, and national efforts to improve the quality of healthcare in the United States.

The Hospital OQR Program strives to achieve the NQS goals by making collected information publicly available and fostering quality improvement. Taking into account the need to balance breadth with minimizing burden, program measures address, as fully as possible, the six domains of measurement that arise from the NQS: (1) making care safer; (2) strengthening person and family engagement; (3) promoting effective communication and coordination of care; (4) promoting effective prevention and treatment; (5) working with communities to promote best practices of healthy living; and (6) making care affordable.

The information collection requirements for the CY 2014 through CY 2023 payment determinations are currently approved under OMB Control Number 0938-1109.

## B. Hospital OQR Program Quality Measures and Forms

### 1. Introduction

Hospital OQR Program payment determinations are made based on Hospital OQR Program quality measure data reported and supporting forms submitted by hospitals, as specified through rulemaking. To reduce burden, a variety of different data collection mechanisms are employed, with every consideration taken 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.

This Medicare program has a responsibility to ensure that Medicare beneficiaries receive healthcare services of appropriately high quality, comparable to those provided under other payers. The Hospital OQR Program seeks to encourage care that is both efficient and of high quality in the hospital outpatient setting through collaboration with the hospital community to

[1] The 2011 Report to Congress: National Strategy for Quality Improvement in Health Care is available at https://www.ahrq.gov/workingforquality/reports/2011-annual-report.html.

develop and implement quality measures that are fully and specifically reflective of the quality of hospital outpatient services.

### 2. CY 2023 Payment Determination

Table 1 outlines the Hospital OQR Program measure set as finalized through prior rulemaking. We did not finalize any changes to the measure set in the CY 2021 OPPS/ASC final rule.

**Table 1. Previously-Finalized Hospital OQR Program Measures for the CY 2023 Payment Determination**

| Short Name | Measure Name | NQF No. |
|---|---|---|
| **Chart-Abstracted Measures** | | |
| OP-2 | Fibrinolytic Therapy Received Within 30 Minutes of emergency department Arrival | 0288 |
| OP-3 | Median Time to Transfer to Another Facility for Acute Coronary Intervention | 0290 |
| OP-18 | Median Time from ED Arrival to ED Departure for Discharged ED Patients | 0496 |
| OP-23 | Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 minutes of emergency department Arrival | 0661 |
| **Claims-Based Measures** | | |
| OP-8 | MRI Lumbar Spine for Low Back Pain | 0514 |
| OP-10 | Abdomen CT Use of Contrast Material | N/A |
| OP-13 | Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery | 0669 |
| OP-32 | Colonoscopy Measure: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy | 2539 |
| OP-35 | Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy | N/A |
| OP-36 | Risk-standardized Hospital Visits within 7 Days after Hospital Outpatient Surgery | 2687 |
| **Web-Based Measures** | | |
| OP-22 | Patient Left Without Being Seen | 0499 |
| OP-29 | Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients | 0658 |
| OP-31 | Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery | 1536 |
| **Survey-Based Measures** | | |

| Short Name | Measure Name | NQF No. |
|---|---|---|
| OP-37a-e | OAS CAHPS Survey<br>OP-37a: About Facilities and Staff*<br>OP-37b: Communication about Procedure*<br>OP-37c: Preparation for Discharge and Recovery*<br>OP-37d: Overall Rating of Facility*<br>OP-37e: Recommendation of Facility* | N/A |

* Measures delayed beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking.

Measures labeled as having an information collection mode of "chart-abstracted" have information derived through analysis of data abstracted from a patient's medical record. Chart-abstracted data involves manual data entry effort and requires additional effort or burden from hospitals.

Measures labeled as having an information collection mode of "web-based" require hospitals to submit aggregate chart-abstracted data directly to CMS via a web-based tool located on a CMS website.

Measures labeled as having an information collection mode of "claims-based" have information derived through analysis of administrative Medicare claims data and do not require additional effort or burden from hospitals.

Measures labeled as having an information collection mode of "survey-based" have information derived through analysis of data submitted via the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey and require hospitals to administer the survey and submit the survey data to CMS. These survey administration burdens are captured under a previously finalized PRA Package, OMB Control Number 0938-1240, which expires December 31, 2021. A revised PRA package has been submitted to OMB for approval under 0938-1240. In the CY 2018 OPPS/ASC final rule (82 FR 59433), CMS finalized the delayed implementation of the five OAS CAHPS survey-based measures until further action. In the CY 2022 OPPS/ASC final rule, we are finalizing to require this OAS CAHPS measure with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination and add related administration methods.

In the CY 2022 OPPS/ASC final rule, we are finalizing to adopt an electronic clinical quality measure (eCQM) for the first time (the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM); eCQMs use data routinely collected through the electronic health record (EHR) and are designed to be calculated by the hospitals' certified EHR technology (CEHRT) using patient-level data and submitted to CMS.

### 3. Forms Used in Hospital OQR Program Procedures

To administer the Hospital OQR Program, three forms are utilized: (1) Validation Review; (2) Extraordinary Circumstances Exception (ECE) Request; and (3) Reconsideration Request. 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 for providers associated with forms utilized in the Hospital OQR Program is nominal, if any.

(1) Validation Review Form

CMS performs a random and targeted selection of OPPS hospitals on an annual basis. The selection includes up to 500 hospitals including 450 randomly selected hospitals and up to 50 targeted hospitals. In the event that CMS determines that a hospital did not meet any of the Hospital OQR Program requirements due to a confidence interval validation score of less than 75 percent, the hospital may complete and submit the Validation Review form.

In the CY 2022 OPPS/ASC final rule, we are finalizing to enhance the targeting criteria used for hospital selection for validation by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years. This policy will not have any impact on burden because the total number of hospitals selected for targeted validation remains unchanged.

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(2) Extraordinary Circumstances Exception (ECE) Request Form

In the event of extraordinary circumstances not within the control of the hospital, such as a natural disaster, a hospital can request an exception from meeting program requirements. For the hospital to receive consideration for an exception, an Extraordinary Circumstances Exception Request must be submitted.[2] This form can be found online and can be submitted electronically, by mail, or by fax.

In the CY 2022 OPPS/ASC final rule, we are finalizing to expand our existing ECE policy to apply to eCQMs, to further align with the Hospital IQR Program. We note that the burden associated with completing and submitting this form is already accounted for under a separate PRA Package, OMB Control Number 0938-1022 and, therefore, is not accounted for in this PRA Package.

(3) Reconsideration Request Form

When CMS determines that a hospital has not met program requirements and receives a 2.0 percentage point reduction in its annual percentage update, hospitals may submit a Reconsideration Request to CMS. The request must be submitted no later than the first business day on or after March 17 of the affected payment year. This form can be found on the QualityNet website; it can be submitted via Managed File Transfer using the Hospital Quality Reporting (HQR) system secure portal (previously referred to as the QualityNet secure portal) or via secure fax. While there is burden associated with filing a Reconsideration Request, regulations under the Paperwork Reduction Act of 1995, 5 C.F.R. § 1320.4, exclude collection activities during the conduct of administrative actions such as reconsiderations. Therefore, the

[2] We note that this process was previously referred to as an Extraordinary Circumstances "Extension/Exemption" Request. However, in the CY 2018 OPPS/ASC final rule with comment period, we noted our intent to begin referring to the process as the Extraordinary Circumstances Exception process.

burden associated with submitting a Reconsideration Request is not accounted for in this PRA package.

## C. Justification

### 1. Need and Legal Basis

Section 109(a) of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109-432) amended Section 1833(t) of the Social Security Act (the Act) by adding a new subsection (17) that affects the annual payment update applicable to OPPS payments for services furnished by hospitals in outpatient settings on or after January 1, 2009. Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under Section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for quality measures selected by the Secretary in the form and manner required by the Secretary under Section 1833(t)(17)(B) of the Act will incur a reduction in their annual payment update to the hospital outpatient department fee schedule of 2.0 percentage points. Sections 1833(t)(17)(C)(i) and (ii) of the Act require the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings.

Continued expansion of the quality measure set is consistent with the letter and spirit of the authorizing legislation, TRCHA, to collect and make publicly available hospital-reported information on the quality of care delivered in the hospital outpatient setting and to utilize a formal consensus process as defined under the ACA. 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 instead employ existing data and data collection systems.

The goal of the Hospital OQR Program is to collect quality reporting data from hospital outpatient departments and to publicly report that information to consumers for use in their decision-making when selecting a care provider and to hospitals for use in their quality improvement initiatives. To achieve the goal of quality data collection, the Hospital OQR Program makes extensive education and outreach efforts via webinars, listservs, targeted emails, and targeted phone calls; this outreach has contributed to high levels of hospital data submissions. For example, of the approximately 3,300 hospitals that met eligibility requirements for the CY 2021 payment determination, we determined that 68 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. To achieve the goal of publicly reporting data, the Hospital OQR Program publicly displays data on the *Care Compare* website as soon as feasible following submission of measure data to CMS.[3] Patient-level data that are chart-abstracted are updated on *Care Compare* on a quarterly basis, while data from claims-based measures and measures that are submitted using a web-based tool are updated annually.

While the statutory authority of the Hospital OQR Program is focused on the collection and public reporting of quality data, these data have many uses beyond simple reporting. We are

[3] The *Care Compare* website is available at https://www.medicare.gov/care-compare/.

aware that many hospitals and Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs) use Hospital OQR Program data in developing and refining their quality improvement initiatives. The data collected by the Hospital OQR Program helps these groups identify trends in performance and can provide justification for administrative support to update processes that improve the quality of services provided. Analysis of data collected under the Hospital OQR Program's statutory authority may also help hospitals and QIN-QIOs identify best practices, improve the cost effectiveness of care, and better focus on providing patient-centered care to all patients.[4]

### 2. Information Users

Under the Hospital OQR Program, hospital outpatient departments must meet the administrative, data collection and submission, validation, and publication requirements, or receive a 2.0 percentage point reduction in their annual payment update under OPPS. The measure information collected will be made available to hospitals for their use in internal quality improvement initiatives. CMS uses this information to direct its contractors, such as QIN-QIOs, to focus on particular areas of improvement and to develop quality improvement initiatives. Most importantly, this information is available to Medicare beneficiaries, as well as to the general public, by providing hospital information on the *Care Compare* website to assist them in making decisions about their healthcare.

QIN-QIOs use Hospital OQR Program data to improve quality of care through education, outreach, and sharing best practices. Specifically, QIN-QIOs work with their recruited hospitals participating in the Hospital OQR Program to demonstrate improvement on two quality measures in order to meet or exceed the national average. In addition, data collected for OP-2, OP-3, OP-18, and OP-22 are included in the Medicare Beneficiary Quality Improvement Project (MBQIP), a quality improvement activity under the Medicare Rural Hospital Flexibility (Flex) grant program of the Health Resources and Services Administration's (HRSA) Federal Office of Rural Health Policy (FORHP). The goal of MBQIP is to improve the quality of care provided in critical access hospitals (CAHs) by increasing quality data reporting by CAHs and then driving quality improvement activities based on the data. The MBQIP provides an opportunity for individual hospitals to look at their own data, measure their outcomes against other CAHs and partner with other hospitals in the state around quality improvement initiatives to improve outcomes and provide the highest quality care to each and every one of their patients.[5] In the CY 2022 OPPS/ASC final rule, we are finalizing to remove the Fibrinolytic Therapy Received Within 30 Minutes measure (OP-2) and the Median Time to Transfer to Another Facility for Acute Coronary Intervention measure (OP-3) effective with the CY 2023 reporting period/CY 2025 payment determination.

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 Hospital OQR Program and other CMS programs, CMS'

[4] For example, the Texas QIO created a quality improvement and reporting network that shared best practices among critical access hospitals (CAHs) and used this information to drive improvement. For more information, please visit: www.ahqa.org/quality-improvement-organizations/qios-action/texas/texas-qio-assists-critical-access-hospitals.
[5] For additional details about the MBQIP project, please visit: www.ruralcenter.org/tasc/mbqip.

findings were formally written into the latest triennial National Impact Assessment Report, which was released in February 2018.[6]

### 3. Use of Information Technology

To assist hospitals in this initiative, CMS employs the use of an established, free data collection tool, the CMS Abstraction and Reporting Tool (CART). CMS also provides a secure data warehouse via the HQR system for storage and transmittal of data as well as data validation and aggregation services prior to the release of data to the CMS website. Hospitals have the option of using vendors to transmit the data. CMS has engaged a national support contractor to provide technical assistance with the data collection tool, other program requirements, and to provide education. CMS continues to improve data collection tools in order to make data submission easier for hospitals (e.g., the automated collection of electronic patient data in electronic health records (EHRs) for eCQMs and the collection of data from federal registries like the NHSN), as well as to increase the utility of the data provided by the hospitals.

This section is not applicable to claims-based measures since they are calculated from administrative claims data that result from claims submitted by hospitals to Medicare for reimbursement. Therefore, no additional information technology will be required for hospitals for these measures.

### 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 outpatient hospital care. As required by statute, CMS requires hospitals to submit quality measure data for services provided in the outpatient setting.

Hospitals are required to complete and submit a written form on which they agree to participate in the Hospital OQR Program. This declaration remains in effect, even as the measure set changes, until such time as a hospital specifically elects to withdraw.

### 5. Small Business

Information collection requirements are designed to allow maximum flexibility, specifically to small hospitals wishing to participate in hospital reporting. This effort will assist small hospitals in gathering information for their own quality improvement efforts.

### 6. Less Frequent Collection

CMS has designed the collection of quality of care data to be the minimum necessary for data validation and calculation of summary figures to be reliable estimates of hospital performance. Under the Hospital OQR Program, hospitals are required to submit chart-abstracted measures to

[6] The latest 2018 Impact Assessment Report, as well as earlier reports from 2012 and 2015, may be found at: 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.html.

CMS on a quarterly basis, and are required to submit eCQMs and web-based measures to CMS on an annual basis. In addition, for submission of claims-based measures, hospitals are required to submit paid Medicare FFS claims data for services from a 12-month period from July three years before the payment determination through June of the following year. CMS collects the data submitted by hospitals from the chart-abstracted measures, web-based measures, eCQMs, and claims-based measures to determine the annual payment updates to hospitals, which are decided on a yearly basis. To collect the information less frequently would compromise the timeliness of any calculated estimates.

### 7. Special Circumstances

All subsection (d) hospitals reimbursed under the OPPS must meet Hospital OQR Program requirements, including administrative, data submission, and validation requirements to receive the full OPPS payment update for the given calendar year. Failure to meet all requirements may result in a 2.0 percentage point reduction in the annual payment update.

### 8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice for this data collection was published on August 3, 2021 (86 FR 42246)). We did not receive comments regarding the burden estimates included in this PRA package in the CY 2022 OPPS/ASC final rule (RIN 0938-AU43, CMS-1753-F), which published on November 16, 2021 (86 FR 63458).

CMS is supported in this program's efforts by The Joint Commission, National Quality Forum (NQF), Measure Applications Partnership (MAP), and the Centers for Disease Control and Prevention (CDC). These organizations collaborate with CMS on an ongoing basis, providing technical assistance in developing and identifying quality measures, and assisting in making collected information accessible, understandable, and relevant to the public.

### 9. Payment/Gift to Respondent

Hospitals are required to submit these data in order to receive the full OPPS annual payment update. No other payments or gifts will be given to hospitals for participation.

### 10. Confidentiality

All information collected under the Hospital OQR 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 C.F.R. Part 480. Data related to the Hospital OQR Program is housed in the Hospital Quality Reporting (HQR) application group. HQR is a General Support System (GSS) housing protected health information (PHI). Users who access the HQR system are identity-managed to permit access to the system and have role-based restrictions (including log-in and password) to the data they can see. The System of Records

Notice (SORN) in use for the quality programs including the Hospital OQR Program is MBD 09-70-0536.

### 11. Sensitive Questions

Case-specific clinical data elements will be collected and are necessary to calculate statistical measures. These statistical measures are the basis of subsequent improvement activities and cannot be calculated without the case specific data. Case-specific data will not be released to the public and are not releasable by requests under the Freedom of Information Act. Only hospital-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)

#### (a) Background

In the CY 2022 OPPS/ASC final rule, we are finalizing to: (1) adopt the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period; (2) adopt the Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period; (3) adopt the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM, beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period;(4) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP-31), beginning with the CY 2025 reporting period/CY 2027 payment determination; (5) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (OP-37 a-e), with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (5) remove the Fibrinolytic Therapy Received Within 30 Minutes measure (OP-2), effective with the CY 2023 reporting period/CY 2025 payment determination; and (6) remove the Median Time to Transfer to Another Facility for Acute Coronary Intervention measure (OP-3), effective with the CY 2023 reporting period/CY 2025 payment determination.

Currently the CDC does not estimate burden for COVID-19 vaccination reporting under the CDC PRA (OMB control number 0920-1317) because the agency has been granted a waiver under Section 321 of the National Childhood Vaccine Injury Act (NCVIA). As such, the burden associated with the COVID-19 Vaccination Coverage Among HCP measure is not accounted for under the CDC PRA 0920-1317 or 0920-0666 due to the NCVIA waiver. When the waiver expires, we will work with CDC to ensure that the burden is accounted for in an updated PRA under OMB control number 0920-1317.

#### (b) Burden for the CY 2024 Payment Determination

For the Hospital OQR Program, the burden associated with meeting program requirements includes the time and effort associated with: (1) completing administrative requirements;

(2) collecting and reporting data on the required measures under the Hospital OQR Program; and (3) submitting documentation for validation purposes.

Our burden estimates are calculated based on an estimated total of 3,300 hospitals participating in the Hospital OQR Program, unless otherwise specified.[7]

We estimate that collecting and reporting data required under the Hospital OQR Program can be accomplished by staff with a median hourly wage of $42.40 per hour in accordance with the Bureau of Labor Statistics, based upon the median wage for Medical Records and Health Information Technicians which is $21.20 per hour before inclusion of overhead and fringe benefits.[8] BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for submission for the Hospital OQR 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 ($21.20 x 2 = $42.40) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will use an hourly labor cost estimate of $42.40 ($21.20 salary plus $21.20 fringe and overhead) for calculation of burden forthwith.

**(1) Administrative Burden**

Administrative burden involves the time and effort associated with completing program and system requirements and managing facility operations (78 FR 75171), 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 in Section B(3), the Hospital OQR Program utilizes three forms in its administrative activities: (1) Validation Review; (2) Extraordinary Circumstances Exception (ECE) Request; and (3) Reconsideration Request. 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 Hospital OQR Program is nominal, if any.

The burden associated with submitting an Extraordinary Circumstances Exception (ECE) Request is accounted for in OMB Control Number 0938-1022, 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 is

[7] Consistent with prior OPPS/ASC final rules with comment period (79 FR 67013, 80 FR 70582, 82 FR 59478, 83 FR 58825), we continue to estimate a total of 3,300 participating hospitals in the Hospital OQR Program.

[8] In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86266), we finalized an hourly wage estimate of $19.40 per hour, plus 100 percent overhead and fringe benefits. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $21.20 per hour for a Medical Records and Health Information Technician professional. Occupational Employment and Wages. Available at: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm (accessed April 13, 2021)

excluded from this package because this collection occurs during the conduct of an administrative action.

In the CY 2022 OPPS/ASC final rule, we are not finalizing any changes to the administrative burden for the CY 2024 payment determination. Thus, our estimates for administrative burden remain the same as those previously approved for the CY 2023 payment determination under this OMB Control Number. Specifically, we previously estimated, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), that the burden associated with completing administrative requirements is 42 hours per hospital. Therefore, for all participating hospitals, we continue to estimate a total annual administrative burden of 138,600 hours (42 hours per hospital x 3,300 hospitals) and a total financial burden of $5,876,640 (138,600 hours x $42.40 per hour).

**(2) Chart-Abstraction Burden**

For the CY 2024 payment determination, the chart-abstracted measure set for the Hospital OQR Program is comprised of the following four measures: (1) OP-2; (2) OP-3; (3) OP-18; and (4) OP-23. In the CY 2022 OPPS/ASC final rule, we are finalizing to remove the Fibrinolytic Therapy Received Within 30 Minutes (OP-2) and the Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3) measures effective with the CY 2023 reporting period/CY 2025 payment determination.

For chart-abstracted measures where patient-level data are submitted directly to CMS, we previously estimated it would take 2.9 minutes, or 0.049 hours per case per measure to collect and submit the data for each submitted case (80 FR 70582). Additionally, based on the most recent data from CY 2019 reporting, we estimate that an average of 289 cases[9] are reported per hospital for chart-abstracted measures. We therefore estimate that it will take approximately 14.2 hours (0.049 hours x 289 cases) at a cost of approximately $600 per hospital (14.2 hours x $42.40/hour) to collect and report data for each chart-abstracted measure. Therefore, for all participating hospitals, we estimate an annual chart-abstraction burden of 46,860 hours (14.2 hours per hospital x 3,300 hospitals) at a cost of $1,986,864 per measure (46,860 hours x $42.40/hour). For the CY 2024 payment determination, the total burden to submit all four measures is estimated to be 187,440 hours (46,860 hours/measure x 4 measures) at a cost of $7,947,456 (187,440 hours x $42.40/hour). For the CY 2025 payment determination and subsequent years, the total annual burden for all hospitals to submit the remaining two measures (OP-18 and OP-23) is estimated to be 93,720 hours (46,860 hours/measure x 2 measures) at a cost $3,973,728 (93,720 hours x $42.40/hour).

**(3) Web-Based Measures Burden**

There are currently three web-based measures in the Hospital OQR Program for the CY 2023 payment determination and subsequent years: OP-22, OP-29, and OP-31. In the CY 2022 OPPS/ASC final rule, we are finalizing to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP-31), beginning with the CY 2025 reporting period/CY 2027 payment determination. We previously finalized voluntary

[9] We note that our estimated number of cases decreased from the 947 cases estimated for these measures in previous PRA Packages for the CY 2021 OPPS/ASC final rule.

reporting of this measure in the CY 2015 OPPS/ASC final rule (79 FR 66947 through 66948) and estimated that 20 percent of hospitals would elect to report it annually (79 FR 67014).

- We previously estimated, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), that hospitals spend approximately 10 minutes, or 0.167 hours, per measure to report web-based measures.

  For the CY 2024 through CY 2026 payment determinations in which OP-31 is still voluntary and assumed to be reported by 20% of hospitals, we estimate a web-based burden of 1,210 hours [(0.1667 hours/hospital x 3,300 hospitals x 2 measures) + (0.1667 hours/hospital x 3,300 hospitals x 20% x 1 measure)] at a cost of $51,304 (1,210 hours x $42.40/hour) for all three measures. For the CY 2027 payment determination and subsequent years, we estimate an annual web-based burden of 1,650 hours (0.1667 hours/hospital x 3,300 hospitals x 3 measures) at a cost of $69,960 (1,650 hours x $42.40/hour) for all three measures.

- There are two web-based measures in the Hospital OQR Program measure set that also require some chart-abstraction: OP-29 and OP-31.

  We previously estimated that chart abstraction for a web-based measure requires 25 minutes, or 0.417 hours, per case per measure (78 FR 75171),[10] and that hospitals would abstract an average of 242 cases[11] per year for this measure.

  For the CY 2024 through CY 2026 payment determinations in which OP-31 is still voluntary and assumed to be reported by 20% of hospitals, we estimate a chart-abstraction burden of 399,960 hours [(0.417 hours/hospital x 242 cases/measure x 3,300 hospitals x 1 measure) + (0.417 hours/hospital x 242 cases/measure x 3,300 hospitals x 20% x 1 measure)] at a cost of $16,958,304 (399,960 hours x $42.40/hour) for both measures. For the CY 2027 payment determination and subsequent years, we estimate an annual chart-abstraction burden of 666,600 hours (0.417 hours/case x 242 cases/hospital x 3,300 hospitals x 2 measures) at a cost of $28,263,840 (666,600 hours x $42.40/hour) for both measures.

Therefore, for all participating hospitals, we estimate a burden of 401,170 hours (1,210 hours for web-based burden and 399,960 hours for chart-abstraction) at a cost of $17,009,608 (401,170 hours x $42.40/hour) for the CY 2024 through CY 2026 payment determination years. For the CY 2027 payment determination and subsequent years, we estimate a total annual burden of 668,250 hours (1,650 hours for web-based burden and 666,600 for chart-abstraction) at a cost of $28,333,800 (668,250 hours x $42.40/hour).

### (4) Claims-Based Measures Burden

[10] In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated the time to chart-abstract a single case as 25 minutes, or 0.417 hours per case, based on chart-abstraction time less the time to submit web-based measures in the aggregate (0.583 hours – 0.166 hours = 0.417 hours per measure).

[11] We note that our estimated number of cases decreased from the 384 cases estimated for these measures in previous PRA Packages for the CY 2021 OPPS/ASC final rule.

In the CY 2022 OPPS/ASC final rule, we are finalizing to adopt the Breast Screening Recall Rates measure, beginning with the CY 2023 payment determination using a data collection period of July 1, 2020 to June 30, 2021, and then data collection periods from July 1 through June 30 of the following year starting three years before the applicable payment calendar year for subsequent years. Claims-based measures are derived through analysis of administrative claims data and do not require additional effort or burden on hospitals. As a result, the Hospital OQR Program's claims-based measures (OP-8, OP-10, OP-13, OP-32, OP-35, and OP-36) do not influence our burden calculations.

**(5) Survey Measures Burden**

In the CY 2018 OPPS/ASC final rule (82 FR 59433), CMS finalized the delayed implementation of the five OAS CAHPS survey-based measures (OPs-37a-e) until further action. In the CY 2022 OPPS/ASC final rule, we are finalizing to restart the five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey-based measures with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination and for subsequent years and add related administration methods. The information collection requirements associated with the five OAS CAHPS survey-based measures (OP-37a, OP-37b, OP-37c, OP-37d, and OP-37e) are currently approved under OMB control number 0938-1240, which expires December 31, 2021. A revised PRA package has been submitted to OMB for approval under 0938-1240. As a result, the policy to require data collection for these measures does not influence our burden calculations.

**(6) eCQM Measures Burden**

In the CY 2022 OPPS/ASC final rule, we are finalizing to adopt the STEMI eCQM, with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination. For the CY 2023 voluntary reporting period, hospitals will be able to voluntarily report the measure for one or more quarters during the year. In subsequent years, we are finalizing to gradually increase the number of quarters of data hospitals would be required to report on the measure starting with one self-selected quarter for the CY 2024 reporting period/CY 2026 payment determination, two self-selected quarters for the CY 2025 reporting period/CY 2027 payment determination, three self-selected quarters for the CY 2026 reporting period/CY 2028 payment determination, and four quarters for the CY 2027 reporting period/CY 2029 payment determination and for subsequent years.

For the voluntary reporting period in CY 2023, we estimate 20 percent of hospitals will report at least one quarter of data for the measure with 100 percent of hospitals reporting the measure as required in subsequent years. Based on experience with reporting of eCQMs on the Hospital IQR program, we are aligning our estimate of the time required for a Medical Records and Health Information Technician professional to submit the data required for the measure to be 10 minutes (.1667 hours) per quarter for each hospital. For the CY 2023 voluntary reporting period, we estimate an annual burden for all participating hospitals of 110 hours (3,300 hospitals x 20% x 0.1667 hours x 1 quarter) at a cost of $4,664 (110 hours x $42.40). For the CY 2024 reporting period/ CY 2026 payment determination, we estimate the annual burden for all hospitals to

be 550 hours (3,300 hospitals x 0.1667 hours x 1 quarters) at a cost of $23,320 (550 hours x $42.40). For the CY 2025 reporting period/CY 2027 payment determination, we estimate the annual burden for all hospitals to be 1,100 hours (3,300 hospitals x 0.1667 hours x 2 quarters) at a cost of $46,640 (1,100 hours x $42.40). For the CY 2026 reporting period/CY 2028 payment determination, we estimate the annual burden for all hospitals to be 1,650 hours (3,300 hospitals x 0.1667 hours x 3 quarters) at a cost of $69,960 (1,650 hours x $42.40). For the CY 2027 reporting period/CY 2029 payment determination and subsequent years, we estimate the annual burden for all hospitals to be 2,200 hours (3,300 hospitals x 0.1667 hours x 4 quarters) at a cost of $93,280 (2,200 hours x $42.40).

#### (7) Validation Burden

The burden associated with the validation procedures is the time and effort necessary to submit supporting medical record documentation for validation. We previously estimated that it would take each of the 500 selected hospitals approximately 12 hours to comply with these data submission requirements (76 FR 74553, 74577). To comply with the requirements, we also estimated that each hospital would submit up to 48 cases for the affected year for review (76 FR 74553).

Because all selected hospitals must comply with these requirements each year, we continue to estimate a total submission of up to 24,000 charts by the selected hospitals (500 hospitals $\times$ 48 cases per hospital) (76 FR 74553). Therefore, for the selected hospitals, we continue to estimate a total annual validation burden, for four quarters of data, of 6,000 hours (500 hospitals x 12 hours per hospital), and a total financial burden of approximately $254,400 (6,000 hours x $42.40 per hour).

As discussed above, in the CY 2022 OPPS/ASC final rule, we are finalizing to add two additional targeting criteria used for hospital selection for validation. This policy will not have any impact on burden because the total number of hospitals selected for targeted validation remains unchanged.

#### (8) Total Burden for the CY 2024 through CY 2027 Payment Determinations

Based on the preceding discussion, the table below summarizes our calculations of burden for the CY 2024 through CY 2027 payment determinations.

**Table 2. Total Burden for the CY 2024 through CY 2027 Payment Determinations**

| | CY 2024 Payment Determinations | | CY 2025 Payment Determination | |
|---|---|---|---|---|
| | **Total Hours** | **Total Cost*** | **Total Hours** | **Total Cost*** |
| Administrative Activities | 138,600 | $5,876,640 | 138,600 | $5,876,640 |
| Chart-Abstracted Measures | 187,440 | $7,947,456 | 187,440 | $7,947,456 |

| | | | | |
|---|---|---|---|---|
| Web-Based Measures | 401,170 | $17,009,608 | 401,170 | $17,009,608 |
| Claims-Based Measures | N/A | N/A | N/A | N/A |
| Survey-Based Measures | N/A | N/A | N/A | N/A |
| eCQM Measures | N/A | N/A | 110 | 4,664 |
| Validation | 6,000 | $254,400 | 6,000 | $254,400 |
| **Total** | **733,210** | **$31,088,104** | **733,320** | **$31,092,768** |

*Dollar amounts may vary slightly due to rounding

| | **CY 2026 Payment Determination** | | **CY 2027 Payment Determination** | |
|---|---|---|---|---|
| | **Total Hours** | **Total Cost*** | **Total Hours** | **Total Cost*** |
| Administrative Activities | 138,600 | $5,876,640 | 138,600 | $5,876,640 |
| Chart-Abstracted Measures | 187,440 | $7,947,456 | 93,720 | $3,973,728 |
| Web-Based Measures | 401,170 | $17,009,608 | 668,250 | $28,333,800 |
| Claims-Based Measures | N/A | N/A | N/A | N/A |
| Survey-Based Measures | N/A | N/A | N/A | N/A |
| eCQM Measures | 550 | $23,320 | 1,100 | $46,640 |
| Validation | 6,000 | $254,400 | 6,000 | $254,400 |
| **Total** | **733,760** | **$31,111,424** | **907,670** | **$38,485,208** |

*Dollar amounts may vary slightly due to rounding

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs being placed on the hospitals. In fact, successful submission will result in a hospital receiving the full annual payment update, 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 hospitals.

In the CY 2022 OPPS/ASC final rule, we are finalizing to adopt the STEMI eCQM. Similar to the FY 2019 IPPS/LTCH PPS final rule, we believe that costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining Program requirements, such as maintaining measure specifications in hospitals' EHR systems for all of the eCQMs available for use in the Hospital OQR Program (83 FR 41771).

Also in the CY 2022 OPPS/ASC final rule, we are finalizing certification requirements requiring the use of the 2015 Edition Cures Update for eCQMs beginning with the CY 2025 payment

determination. Although this policy will require some investment in systems updates, the Medicare Promoting Interoperability Program (previously known as the Medicare EHR Incentive Program) and the Hospital IQR Program previously finalized a requirement that hospitals use the 2015 Edition Cures Update for eCQMs (85 FR 84818 through 84825; 86 FR 45607. Because all hospitals participating in the Hospital OQR Program are subsection (d) hospitals that also participate in the Medicare Promoting Interoperability and Hospital IQR Programs, we do not anticipate any additional costs as a result of this policy.

14. Cost to Federal Government

The cost to the Federal Government includes costs associated with the collection and validation of the data. These costs are estimated at $10,050,000 annually for the validation and quality reporting contracts. Additionally, this program takes three CMS staff at a GS-13 Step 5 level to operate. GS-13 Step 5 approximate annual salary is $117,516 for an additional cost of $352,548.

For the claims-based measures, the cost to the Federal Government is minimal. CMS uses data from the CMS National Claims History system that is already being collected for provider reimbursement; therefore, no additional data will need to be submitted by hospitals for claims-based measures. CMS also calculates four additional claims-based imaging efficiency measures for hospital outpatient departments, and provides hospitals with feedback reports about all of the measures.

The total annual cost to the Federal Government is $10,402,548.

15. Program or Burden Changes

The changes in burden discussed below include updating the wage rate from $38.80/hour to $42.40/hour based on more recent BLS wage data, as previously discussed.

Combined with our updated assumption of the average number of cases required for chart abstracted measures from 947 to 289, the policy to remove the Fibrinolytic Therapy Received Within 30 Minutes (OP-2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3) measures effective with the CY 2023 reporting period result in a total decrease in annual burden of 513,480 hours at a cost of $21,771,552 (513,480 x $42.40/hour).

Combined with our updated assumption of the average number of cases required for web-based measures from 384 to 242, the policy to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP-31), beginning with the CY 2023 reporting period/CY 2025 payment determination will result in a total increase in burden of 32,931 hours at a cost of $1,396,274 (32,931 x $42.40/hour) due to the additional 80 percent of hospitals that will be required to report this measure.

The policy to adopt the STEMI eCQM, with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination will result in a total increase of 2,200 hours at a cost of $93,280 (2,200 hours x $42.40) for the CY 2029 payment determination. As shown in Table 2,

for the FY 2025 payment determination, we estimate an increase in burden of 110 hours at a cost of $4,664 (110 hours x $42.40/hour).

In aggregate, for the CY 2027 payment determination, we estimate the updated assumptions and policies finalized in the CY 2022 OPPS/ASC final rule will result in a total decrease of 479,449 hours (-513,480 + 32,931 + 1,100) at a cost of +$20,328,638 (479,449 x $42.40/hour) across 3,300 hospitals.

16. Publication

The goal of the data collection is to tabulate and publish hospital specific data. CMS will continue to display information on the quality of care provided in the hospital outpatient setting for public viewing as required by TRHCA. Data from this initiative is currently used to populate the *Care Compare* website. We anticipate updating these data on at least an annual basis.

17. Expiration Date

CMS will display the expiration date on the collection instruments.

18. Certification Statement

We certify that the Hospital OQR Program complies with 5 C.F.R. § 1320.9.