Supporting Statement – Part A

Submission of Information for the Hospital Outpatient Quality Reporting (OQR) Program:
CY 2018 OPPS/ASC Final Rule

A. Background

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

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 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 2020 payment determinations are currently approved under OMB Control Number 0938-1109. This information collection request covers the existing measure set to be collected for CY 2020 and CY 2021, and reflects finalized proposals to remove 6 measures beginning with CY 2021.

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. CMS consulted with the MAP and received its formal recommendations before identifying Hospital OQR Program measures to be included in the CY 2018 OPPS/ASC proposed rule. 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), available at http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.pdf. 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 health care 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: making care safer, strengthening person and family engagement, promoting effective communication and coordination of care, promoting effective prevention and treatment, working with communities to promote best practices of healthy living, and making care affordable.

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

Within the Hospital OQR program, there are four modes of data submission. (1) Chart-abstracted measures require the submission of patient-level information obtained through chart abstraction that is then submitted electronically to CMS. (2) Web-based measures require hospitals to chart-abstract and then submit non-patient level data directly to CMS via the CMS Web-based tool (QualityNet Website). (3) The National Healthcare Safety Network (NHSN) measure requires hospitals to submit data via the Centers for Disease Control (CDC) and Prevention Web-based tool located on the NHSN website. (4) Claims-based measures are derived through analysis of administrative claims data and do not require additional effort or burden on hospitals.

2. CY 2014 through CY 2020 Payment Determinations

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74472), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75096 through 78 FR 75104; 78 FR 75111 through 75112), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66944 through 79 FR 66956; 79 FR 66984 through 66985), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70507 through 80 FR 70511; 80 FR 70519 through 70520), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79753 through 79796), CMS finalized quality measures, administrative processes and data submission requirements for the CYs 2014 through 2020 payment determinations. The information collection requirements for the CY 2014 through CY 2020 payment determinations are currently approved under OMB Control Number 0938-1109.

In the CY 2018 OPPS/ASC final rule, for the CY 2020 payment determination and subsequent years, CMS finalized the removal of one chart-abstracted measure and one web-based measure. These measures are:

- OP-21: Median Time to Pain Management for Long Bone Fracture (Chart-abstracted)
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures (Web-based)

In the CY 2018 OPPS/ASC proposed rule, CMS proposed to remove three chart-abstracted measures and one web-based measure for the CY 2021 payment determination and subsequent years. In the CY 2018 OPPS/ASC final rule, CMS finalized these measures for removal for the CY 2020 payment determination and subsequent years, one year earlier than proposed. These measures are:

- OP-1: Median Time to Fibrinolysis (Chart-abstracted)
- OP-4: Fibrinolytic Therapy Received Within 30 Minutes of emergency department Arrival (Chart-abstracted)
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional (Chart-abstracted)
- OP-25: Safe Surgery Checklist Use (Web-based)

The estimated change in burden to hospitals is discussed in section C.12 below. The previously finalized measure set for the CY 2020 payment determination is outlined in the below table:

PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURES FOR THE CY 2020 PAYMENT DETERMINATION

Short Name	Measure Name	National Quality Forum Number	Data Collection Period
NHSN			
OP-27	Influenza Vaccination Coverage among Healthcare Personnel	0431	October 1, 2018 – March 31, 2019
Chart-Abstracted Patient-Level Measures			
OP-1	Median Time to Fibrinolysis[±*]	0287	April 1, 2018 – March 31, 2019
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of emergency department Arrival[±]	0288	April 1, 2018 – March 31, 2019
OP-3	Median Time to Transfer to Another Facility for Acute Coronary Intervention	0290	April 1, 2018 – March 31, 2019
OP-4	Aspirin at Arrival[±*]	0286	April 1, 2018 – March 31, 2019
OP-5	Median Time to ECG[±]	0289	April 1, 2018 – March 31, 2019
OP-18	Median Time from emergency department Arrival to emergency department Departure for Discharged emergency department Patients	0496	April 1, 2018 – March 31, 2019
OP-20	Door to Diagnostic Evaluation by a Qualified Medical Professional[±*]	N/A	April 1, 2018 – March 31, 2019
OP-21	Median Time to Pain Management for Long Bone Fracture*[±]	0662	April 1, 2018 – March 31, 2019

Short Name	Measure Name	National Quality Forum Number	Data Collection Period
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	April 1, 2018 – March 31, 2019
Claims-Based Measures			
OP-8	MRI Lumbar Spine for Low Back Pain	0514	July 1, 2018 – June 30, 2019
OP-9	Mammography Follow-up Rates	N/A	July 1, 2018 – June 30, 2019
OP-10	Abdomen CT Use of Contrast Material	N/A	July 1, 2018 – June 30, 2019
OP-11	Thorax CT Use of Contrast Material	0513	July 1, 2018 – June 30, 2019
OP-13	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	0669	July 1, 2018 – June 30, 2019
OP-14	Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT	N/A	July 1, 2018 – June 30, 2019
OP-32	Colonoscopy Measure: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	2539	January 1, 2018 – December 31, 2018
OP-35	Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy	N/A	January 1, 2018 – December 31, 2018
OP-36	Risk-standardized Hospital Visits within 7 Days after Hospital Outpatient Surgery	2687	January 1, 2018 – December 31, 2018
Measures Submitted via a Web-based Tool			

Short Name	Measure Name	National Quality Forum Number	Data Collection Period
OP-12	The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified electronic health record System as Discrete Searchable Data±	N/A	January 1, 2018 – December 31, 2018
OP-17	Tracking Clinical Results between Visits±	0491	January 1, 2018 – December 31, 2018
OP-22	Patient Left Without Being Seen±	0499	January 1, 2018 – December 31, 2018
OP-25	Safe Surgery Checklist Use*	N/A	January 1, 2018 – December 31, 2018
OP-26	Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures*	N/A	January 1, 2018 – December 31, 2018
OP-29	Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	0658	January 1, 2018 – December 31, 2018
OP-30	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use	0659	January 1, 2018 – December 31, 2018
OP-31	Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	1536	January 1, 2018 – December 31, 2018
Patient Survey Measures			

Short Name	Measure Name	National Quality Forum Number	Data Collection Period
OP-37	OAS CAHPS Survey OP-37a: About Facilities and Staff** OP-37b: Communication about Procedure** OP-37c: Preparation for Discharge and Recovery** OP-37d: Overall Rating of Facility** OP-37e: Recommendation of Facility**	N/A	January 1, 2018 – December 31, 2018

*Measure removed beginning with the CY 2020 payment determination
** Measure delayed beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking.
[±] NQF endorsement removed

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.

Web-based measures labeled as "CMS" require hospitals to submit aggregate chart-abstracted data directly to CMS via a web-based tool located on a CMS website. The web-based measure labeled as "NHSN" is submitted through the CDC's National Healthcare Safety Network (NHSN); CDC then supplies this information to CMS.

One measure, OP-31, is reported voluntarily; reporting or not reporting data for this measure does not affect a hospital's payment determination under the program.

Measures labeled as having an information collection mode of "Claims" 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 more of "Survey-based" have information derived through analysis of data submitted via the 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. In the CY 2018 OPPS/ASC final rule, CMS is finalizing the delayed implementation of the five OAS CAHPS Survey-based measures until further action.

3. Forms Used in Hospital OQR Program Procedures

To administer the Hospital OQR Program, four forms are utilized: Notice of Participation, Validation Review, Extraordinary Circumstances Extensions/Exemptions Request, and Reconsideration Request. None of these forms is 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.

We note however that the burden associated with completing and submitting an Extraordinary Circumstance Extension/Exemption Request is already accounted for under OMB Control Number 0938-1022. Additionally, 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 reconsiderations. Therefore, the burden associated with submitting a reconsideration request is not accounted for in this PRA package; accordingly, only the Notice of Participation and Validation Review forms are included here.

To begin participation in the Hospital OQR Program for the first time, all subsection (d) hospitals reimbursed under the OPPS must complete a Notice of Participation. This form explains the participation and reporting requirements of the program, and can be submitted electronically through on-line completion, by mailing, or via fax. The NOP form explains the participation and reporting requirements of the program, and can be submitted electronically through on-line completion, by mailing, or via fax. The form explains that to receive the full annual payment update, the hospital acknowledges that data submitted under the program can be made publicly available. Hospitals that are not subsection (d) or are not reimbursed under the OPPS may voluntarily participate in the program; these hospitals have the option to submit data with or without public release of the information. Hospitals that want to withdraw from participation or those who do not want their data made publicly available may withdraw from participation using the same Notice of Participation form. This form can be found on the QualityNet website. Once this form is submitted for a hospital, it remains in effect. A hospital would need to resubmit this form only if it has withdrawn and wants to renew participation. Hospitals must submit a withdrawal form no later than August 31 of the year prior to the affected annual payment update.

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. This form can be found on-line and can be submitted electronically, by mail, or by fax. We note that this process was previously referred to as an extraordinary circumstances “extension/exemption”. However, in the CY 2018 OPPS/ASC final rule, we note that we intend to begin referring to the process as the extraordinary circumstances exceptions process. The burden associated with completing and submitting an Extraordinary Circumstance Extension/Exemption Request is already accounted for in a separate PRA package, OMB Control Number 0938-1022.

When CMS determines that a hospital has not met program requirements and receives a 2 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 Secure File Transfer using the QualityNet Secure Portal or via secure 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 reconsiderations. Therefore, the 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 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 claims-based quality measures, quality measures submitted via the CMS web-based tool, and the NHSN measure, 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 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, for the CY 2017 payment determination, only 21 eligible hospitals did not meet program data submission requirements; of those, five hospitals failed data validation requirements. To achieve the goal of publicly reporting data, the Hospital OQR publicly displays data on the *Hospital Compare* Web site (https://www.medicare.gov/hospitalcompare) as soon as feasible after measure data have been submitted to CMS. Patient-level data that are chart-abstracted are updated on *Hospital Compare*

quarterly, 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, this data has many uses beyond simple reporting. We are 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. 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 (http://www.ahqa.org/quality-improvement-organizations/qios-acti\on/texas/texas-qio-assists-critical-access-hospitals).

2. Information Users

Under the Hospital OQR Program, hospitals outpatient departments must meet the administrative, data collection and submission, validation, and publication requirements, or receive a 2 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, to provide hospital information to assist them in making decisions about their health care.[1]

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-1, -2, -3, -4, -5, -18, -20, -21, and -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. For additional details about the MBQIP project, please visit: https://www.ruralcenter.org/tasc/mbqip.

[1] Hospital Compare: https://www.medicare.gov/hospitalcompare/search.html?.

As described below, OP-1, -4, -20, and -21 are finalized for removal from the Hospital OQR Program in the CY 2018 OPPS/ASC Final Rule.

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. The next triennial Impact Assessment Report is due in 2018 and, in preparation, CMS is compiling data from the Hospital OQR Program and other CMS programs. These findings will be formally written into the 2018 Impact Assessment Report and, pending clearance, will be posted March 1, 2018. Prior 2012 and 2015 National Impact Assessment Reports 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.html.

3. Improved 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). In addition, CMS provides a secure data warehouse and use of the QualityNet website 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 also 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.

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 Similar Information

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 CMS on a quarterly basis, and are required to submit 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, 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 CY 2018 OPPS/ASC Final Rule (82 FR 52356) was published on November 13, 2017.

CMS is supported in this program's efforts by The Joint Commission, National Quality Forum (NQF), Measures Application 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 this 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 CFR Part 480. Data related to the Hospital OQR Program is housed in the Hospital Quality Reporting (HQR) application group. HQR is a part of the QualityNet which is a General Support System(GSS) housing protected health information (PHI). Users who access QualityNet are identity-managed to permit access 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)

Section 109(a) of the Tax Relief and Health Care Act of 2006 (TRCHA) (Pub. L. 109-432) establishes requirements that affect the payment rate 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 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 quality of care furnished by hospitals in outpatient settings. The program established under the above is referred to as the Hospital OQR Program.

In the CY 2018 OPPS ASC final rule, we finalize program requirements for the CY 2020 Hospital OQR Program payment determination and subsequent years. For the Hospital OQR Program, the burden associated with meeting program requirements includes the time and effort associated with completing administrative requirements; collecting and submitting data on the required measures; and submitting documentation for validation purposes. As noted previously, the Hospital OQR Program utilizes four forms in its administrative activities: Notice of

Participation, Validation Review, Extraordinary Circumstances Exception Request, and Reconsideration Request. None of these forms is 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. The burden associated with submitting an Extraordinary Circumstances Extension/Exemption Request is accounted for in OMB Control Number 0938-1022, and is therefore excluded from this burden estimate. Consistent with 5 CFR 1320.4 (44 USC 3518(c)(1)(b)), the burden associated with filing a reconsideration request is excluded from this package because this collection occurs during the conduct of an administrative action.

Burden for the CY 2020 payment determination

Administrative Burden: Administrative burden includes duties such as ensuring staffing, identifying and maintaining an active QualityNet Website Security Administrator, and filling out forms and other paperwork. For the CY 2020 payment determination and subsequent years, the burden associated with program requirements is the time and effort associated with collecting and submitting the data on the required measures and submitting documentation for validation purposes. We have previously estimated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) that the burden associated with administrative requirements including completing program requirements, system requirements, and managing facility operations is 42 hours per hospital or 138,600 hours across 3,300 hospitals.[2] We estimate that the financial burden for these requirements would be $5.1 million (138,600 hours x $36.58 per hour[3]) for all hospitals.

Chart-abstraction Burden: With regard to chart-abstracted measures where patient-level data is submitted directly to CMS, we have previously estimated it would take or 2.9 minutes, or 0.049 hours per measure to collect and submit the data for each submitted case (80 FR 70582). Additionally, based on the most recent data from CY 2015 reporting, we estimate that 947 cases[4] are reported per hospital for chart-abstracted measures. We estimate that it will take approximately 46 hours (0.049 X 947 cases) to collect and report data for each chart-abstracted measure. In the CY 2018 final rule we finalized the removal of four chart-abstracted measures for the CY 2020 payment determination and subsequent years (OP-21: Median Time to Pain Management for Long Bone Fracture, OP-1: Median Time to Fibrinolysis, OP-4: Fibrinolytic Therapy Received Within 30 Minutes of emergency department Arrival, and OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional) from the Hospital OQR Program measure set, leaving five chart-abstracted measure in the Hospital OQR Program for the CY 2020 payment determination and subsequent years (OP-2, OP-3, OP-5, OP-18, and OP-23). Accordingly, we believe that to report these five chart-abstracted measure for the CY 2020 payment determination each hospital will spend 230 hours (46 hours X 5 measures) for a total

[2] In the CY 2016 (79 FR 67013) and CY 2017 (80 FR 70582) OPPS/ASC final rules with comment period, we estimated that a total of 3300 hospitals participate in the Hospital OQR Program, based on the actual number of Hospital OQR eligible hospitals.

[3] In this final rule, we are estimating that reporting data for the Hospital OQR Program can be accomplished by staff with a median hourly wage of $18.29 per hour, based on the Bureau of Labor Statistics (BLS) median hourly wage for a Medical Records and Health Information Technician: https://www.bls.gov/oes/current/oes292071.htm.

[4] We note that our estimated number of cases has decreased from the 1,266 cases estimated for these measures in previous PRA packages.

burden of 760,441 hours (230 hours X 3,300 hospitals) and $27.8 million (230 hours X 3,300 hospitals X $36.58) across 3,300 hospitals.

In addition, CMS estimated that OP-29 and OP-30 would require 25 minutes (0.417 hours) per case per measure to chart-abstract.[5] CMS estimated that hospitals would abstract 384 cases per year for each of these measures. Therefore, we estimated a burden of 1.1 million hours (3,300 hospitals x 0.417 hours/case x 384 case per measure x 2 measures) for all participating hospitals for OP-29 and OP-30 for a total financial burden of approximately $40.2 million (1.1 million hours x $36.58 per hour). CMS estimated that OP-31 would require 25 minutes (0.417 hours) per case to chart-abstract. CMS also estimated that hospitals would abstract 384 cases per year for this measure. CMS estimated that approximately 20 percent of hospitals (660 hospitals (3,300 hospitals x 0.2)) would elect to report this measure on a voluntary basis. Therefore, we estimated that the burden for this measure would be 105,684 hours (660 hospitals x 0.417 hours per case x 384 cases) for participating hospitals for a total financial burden of approximately $3.9 million (105,685 hours x $36.58 per hour). Thus, for chart-abstracted measures, CMS estimated a total burden for all participating hospitals of 1,966,126 hours (760,441 hours + 1.1 million hours + 105,685 hours) and $71.9 million (1,966,126 hours x $36.58 per hour) for the CY 2020 payment determination and subsequent years.

Web-based Measures Submission Burden: As previously stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 10 minutes, or 0.167 hours, per measure to report web-based measures. In the CY 2018 final rule we are finalizing the removal of two web-based measures (OP-25: Safe Surgery Checklist, and OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures) for the CY 2020 payment determination and subsequent years, leaving seven measures that are submitted via a web-based tool (OP-12, OP-17, OP-22, OP-29, OP-30, OP-31, and OP-33). Accordingly, we believe that to report seven web-based measure for the CY 2020 payment determination each hospital will spend 1.17 hours (0.167 hours X 7 measures) for a total burden of 3,850 hours (1.17 hours X 3,300 hospitals) and $140,833 (1.17 hours X 3,300 hospitals X $36.58) across 3,300 hospitals.

NHSN Measure Burden: We have previously estimated that the total annual burden associated with OP-27: Influenza Vaccination Coverage among Healthcare Personnel for a hospital for data submission would be 106,940 hours (0.167 hours per response x 640,360 responses). In addition, hospitals would incur a financial burden associated with data submission for this measure. We estimate that the financial burden associated with this measure is $3.9 million (106,940 hours x $36.58 per hour).

Validation Burden: The burden associated with the validation procedures is the time and effort necessary to submit supporting medical record documentation for validation. CMS estimates that it will take each of the sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, CMS estimates each hospital would submit up to 48 cases for the affected year for review. All selected hospitals must comply with

[5] In the CY 2014 OPPS/ASC final rule with comment period, we estimated that the time to chart abstract a single case (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) (78 FR 75171).

these requirements each year, which would result in a total of up to 24,000 charts being submitted by the selected hospitals (500 hospitals × 48 cases per hospital). CMS estimates a total burden associated with the data validation process for four quarters of data of approximately 6,000 hours (500 hospitals x 12 hours per hospital) and a total financial impact of $219,000 (6,000 hours x $36.58 per hour) for the CY 2020 payment determination and subsequent years.

In the CY 2018 OPPS/ASC final rule, CMS finalized the delayed implementation of the five OAS CAHPS Survey-based measures until further action. We do not anticipate any change in ASC burden associated with our proposal to delay implementation of the five OAS CAHPS Survey-based measures (OP-37a-e) because hospital outpatient departments are not currently administering the survey under the Hospital OQR Program; therefore, delaying implementation of these measures will not change data collection or reporting requirements.[6]

The total estimated burden for the CY 2020 payment determination is summarized in the table below. We estimate a total burden of 2.6 million hours and $98 million across 3,300 outpatient hospitals for the CY 2020 payment determination.

Table 2. Total Burden for the CY 2020 Payment Determination

	Total Hours	Total Cost
Administrative Activities	138,600	$5,069,988
Chart-Abstracted Measures	1,946,126	$71,189,289
Web-Based Measures	3,850	$140,833
NHSN Measure	106,940	$3,911,865
Validation	6,000	$219,480
Total	**2,221,516**	**$81,263,055**

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.

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 level to operate. GS-13 approximate annual salary is $92,000 for an additional cost of $276,000.

[6] In addition, we note the information collection requirements associated with measures OP-37a-e are currently approved under OMB Control Number 0938-1240; for this reason, we do not provide an independent estimate of the burden associated with the OAS CAHPS Survey administration for the Hospital OQR Program.

CMS must maintain and update existing information technology infrastructure on QualityNet and the CART. Hospitals report outpatient quality data directly to CMS through the CART or QualityNet as they already do for inpatient quality data. Tools will be revised as needed and updates will be incorporated. CMS must also provide ongoing technical assistance to hospitals and data vendors to participate in the program.

For the claims-based measures, the cost to the Federal Government is minimal. CMS uses data from the CMS National Claims History system that are 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.

15. Program or Burden Changes

In the CY 2018 OPPS/ASC final rule, we finalize the removal of four chart-abstracted measure (OP-1: Median Time to Fibrinolysis, OP-4: Aspirin at Arrival, OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and OP-21: Median Time to Pain Management for Long Bone Fracture) and two web-based measure (OP-25 Safe Surgery Checklist Use, and OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures) for the CY 2020 payment determination and subsequent years. In total, our estimates show a reduction in burden of 1,222,711 hours (3,444,227 hours approved – 2,221,516 total estimated hours) and $44 million for the CY 2020 payment determination for the Hospital OQR Program.

16. Publication or Burden Changes

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 *Hospital Compare* Web site, www.hospitalcompare.hhs.gov. We anticipate updating this 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 CFR 1320.9.