

## **Supporting Statement – Part A**

### **Submission of Information for the Hospital Outpatient Quality Reporting (OQR) Program: CY 2019 OPPTS/ASC Proposed 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 2020 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 2020 and CY 2021 payment determinations, and reflects proposals to remove one measure beginning with the CY 2020 payment determination, and nine measures beginning with the CY 2021 payment determination.

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).<sup>1</sup> 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.

In this proposed rule, we are proposing a number of new policies for the Hospital OQR Program. We developed these proposals after conducting an overall review of the program under our new Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of this proposed rule.

## **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

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<sup>1</sup> 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.

Within the Hospital OQR Program, there are four modes of data submission: (1) chart-abstracted measures, which require the submission of patient-level information obtained through chart abstraction that is then submitted electronically to CMS; (2) web-based measures, which 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, which requires hospitals to submit data via the Centers for Disease Control and Prevention (CDC) web-based tool located on the NHSN website; and (4) claims-based measures, which 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**

CMS has finalized quality measures, administrative processes, and data submission requirements for the CYs 2014 through 2020 payment determinations through the following rulemaking: CY 2012 OPPTS/ASC final rule with comment period (76 FR 74458 through 74472); CY 2013 OPPTS/ASC final rule with comment period (77 FR 68481 through 68484); CY 2014 OPPTS/ASC final rule with comment period (78 FR 75096 through 75104; 78 FR 75111 through 75112); CY 2015 OPPTS/ASC final rule with comment period (79 FR 66944 through 66956; 79 FR 66984 through 66985); CY 2016 OPPTS/ASC final rule with comment period (80 FR 70507 through 70511; 80 FR 70519 through 70520); CY 2017 OPPTS/ASC final rule with comment period (81 FR 79753 through 79796); and CY 2018 OPPTS/ASC final rule with comment period (82 FR 59424 through 59445). The information collection requirements for the CY 2014 through CY 2020 payment determinations are currently approved under OMB Control Number 0938-1109.

## **3. CY 2020 and CY 2021 Payment Determinations**

In the CY 2019 OPPTS/ASC proposed rule, CMS proposes the removal of the one NHSN measure for the CY 2020 payment determination and subsequent years: OP-27: Influenza Vaccination Coverage Among Healthcare Personnel. Also in the CY 2019 OPPTS/ASC proposed rule, CMS proposes to remove nine measures for the CY 2021 payment determination and subsequent years as follows: (1) OP-5: Median Time to ECG; (2) OP-9: Mammography Follow-up Rates; (3) OP-11: Thorax CT Use of Contrast Material; (4) OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (5) OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (6) OP-17: Tracking Clinical Results between Visits; (7) OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; (8) OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use; and (9) OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

Table 1 outlines the Hospital OQR Program measure set as finalized through prior rulemaking. As further explained below, the measures currently proposed for removal are indicated by asterisk marks.

**Table 1. Previously-Finalized Hospital OQR Program Measures for the CY 2020 Payment Determination**

<b>Short Name</b>	<b>Measure Name</b>	<b>NQF No.</b>
<b>Chart-Abstracted Measures</b>		
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	0288
OP-3	Median Time to Transfer to Another Facility for Acute Coronary Intervention	0290
OP-5	Median Time to ECG **	0289
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
<b>Claims-Based Measures</b>		
OP-8	MRI Lumbar Spine for Low Back Pain	0514
OP-9	Mammography Follow-up Rates **	N/A
OP-10	Abdomen CT Use of Contrast Material	N/A
OP-11	Thorax CT Use of Contrast Material **	0513
OP-13	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	0669
OP-14	Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT **	N/A
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
<b>Web-Based Measures</b>		
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
OP-17	Tracking Clinical Results between Visits **	0491
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

Short Name	Measure Name	NQF No.
OP-30	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use **	0659
OP-31	Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery **	1536
OP-33	External Beam Radiotherapy for Bone Metastases	1822
<b>NHSN</b>		
OP-27	Influenza Vaccination Coverage among Healthcare Personnel *	0431
<b>Survey-Based Measures</b>		
OP-37a-e	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

- \* Measure proposed for removal beginning with the CY 2020 payment determination.
- \*\* Measure proposed for removal beginning with the CY 2021 payment determination.
- \*\*\* Measure 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. The one measure labeled as having an information collection mode of “NHSN” is a web-based measure requiring submission through the CDC’s National Healthcare Safety Network (NHSN); CDC then supplies this information to CMS.

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. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59433), CMS finalized 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: (1) Notice of Participation (NOP); (2) Validation Review; (3) Extraordinary Circumstances Exception (ECE) Request; and (4) 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.

#### **(a) Notice of Participation (NOP) Form**

To begin participation in the Hospital OQR Program for the first time, all subsection (d) hospitals reimbursed under the OPSS must complete a Notice of Participation (NOP) form. This form explains the participation and reporting requirements of the program, and can be submitted electronically through online completion, by mailing, or via fax.

In the CY 2019 OPSS/ASC proposed rule, beginning with the CY 2020 payment determination, we propose to remove the NOP as a requirement for Hospital OQR Program. Specifically, we propose that submission of Hospital OQR Program data will indicate a hospital's status as a participant in the Program. If finalized as proposed, hospitals would no longer be required to submit the NOP form according to the previously finalized deadlines, even if the form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN), as was previously required. Instead, only the following previously finalized items would be requirements for participation in the Hospital OQR Program: (1) register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) submit data.

#### **(b) Validation Review Form**

CMS performs a random and targeted selection of Outpatient Prospective Payment Systems (OPSS) 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.

#### **(c) 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.<sup>2</sup> This form can be found online and can be submitted electronically, by mail, or by fax. 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.

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

### **(c) Reconsideration Request Form**

When CMS determines that a hospital has not met program requirements and so 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 Secure File Transfer using 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 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 OPPTS 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 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, 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 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, for the CY 2017 payment determination, only 36 eligible hospitals

did not meet program data submission requirements; many of these hospitals (18 of the 36), chose not to participate in the Hospital OQR Program for the CY 2018 payment determination. To achieve the goal of publicly reporting data, the Hospital OQR Program publicly displays data on the *Hospital Compare* website as soon as feasible following submission of measure data to CMS.<sup>3</sup> Patient-level data that are chart-abstracted are updated on *Hospital 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, this data has many uses beyond 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.<sup>4</sup>

## 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 2.0 percentage point reduction in their annual payment update under OPSS. 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 *Hospital 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-5,<sup>5</sup> 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

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<sup>3</sup> The *Hospital Compare* website is available at <https://www.medicare.gov/hospitalcompare/search.html>.

<sup>4</sup> 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](http://www.ahqa.org/quality-improvement-organizations/qios-action/texas/texas-qio-assists-critical-access-hospitals).

<sup>5</sup> As explained in more detail later, the CY 2019 OPSS/ASC proposed rule proposes to remove OP-5 from the Hospital OQR Program measure set for the CY 2020 payment determination and subsequent years.



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.<sup>6</sup>

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' findings were formally written into the latest triennial National Impact Assessment Report, which was released in February 2018.<sup>7</sup>

### **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**

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<sup>6</sup> For additional details about the MBQIP project, please visit: [www.ruralcenter.org/tasc/mbqip](http://www.ruralcenter.org/tasc/mbqip).

<sup>7</sup> 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](http://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).

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 2019 OPPS/ASC proposed rule was published on July 31, 2018 (83 FR 37046).

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 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 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)**

### **(a) Background**

In the CY 2019 OPPTS/ASC proposed rule, we are proposing the removal of ten measures from the Hospital Outpatient Quality Reporting Program. One of those measures, OP-27: Influenza Vaccination Coverage Among Healthcare Personnel, is proposed for removal from the Hospital OQR Program measure set for the CY 2020 payment determination and subsequent years. The other nine measures are proposed for removal for the CY 2021 payment determination and subsequent years. We are not proposing the addition of any new measures to the Hospital OQR Program measure set in the CY 2019 OPPTS/ASC proposed rule.

### **(b) Burden for the CY 2020 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.

Except for, as further explained below, the removal of OP-27, a NHSN measure, from our total burden calculations, we are not proposing any other changes to the Hospital OQR Program measure set for the CY 2020 payment determination.

Our burden estimates are calculated based on the following data:

- Unless otherwise specified, we estimate a total of 3,300 hospitals participating in the Hospital OQR Program.<sup>8</sup>
- We estimate that collecting and reporting data required under the Hospital OQR Program can be accomplished by staff with a median hourly wage of \$36.58 per hour.<sup>9</sup>

### **(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 QualityNet Website Security Administrator, and filling out forms and other paperwork.

As previously noted in Section B(3), the Hospital OQR Program utilizes four forms in its administrative activities: (1) Notice of Participation (NOP); (2) Validation Review; (3) Extraordinary Circumstances Exception (ECE) Request; and (4) 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.

Furthermore, as noted in Section B(3), we are proposing to remove the NOP form as a Program participation requirement, and we believe the burden associated with this form is negligible. In addition, 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 excluded from this package because this collection occurs during the conduct of an administrative action.

In the CY 2019 OPPTS/ASC proposed rule, we are not proposing any changes to the administrative burden for the CY 2020 payment determination. Thus, our estimates for administrative burden remain the same as those previously approved for the CY 2020 payment determination under this OMB Control Number. Specifically, we previously estimated, in the CY 2014 OPPTS/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 approximately \$5.1 million (138,600 hours x \$36.58 per hour).

### **(2) NHSN Measure Burden**

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<sup>8</sup> Consistent with prior OPPTS/ASC final rules with comment period (79 FR 67013, 80 FR 70582, 82 FR 59478), we continue to estimate a total of 3,300 participating hospitals, based on the actual number of hospitals eligible to participate in the Hospital OQR Program.

<sup>9</sup> In the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59477), we finalized an hourly wage estimate of \$18.29 per hour, plus 100 percent overhead and fringe benefits. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of \$36.58 per hour.

In the CY 2019 OPPTS/ASC proposed rule, we are proposing the removal of the OP-27: Influenza Vaccination Coverage Among Healthcare Personnel measure for the CY 2020 payment determination and subsequent years. We note, however, that the burden associated with OP-27, a NHSN measure, is accounted for under a separate PRA Package, OMB Control Number 0920-0666. Thus, regardless of whether the proposed removal of OP-27 is finalized, our burden estimates for the CY 2020 payment determination exclude the burden associated with collecting and reporting this NHSN measure.

### (3) Chart-Abstraction Burden

In the CY 2019 OPPTS/ASC proposed rule, we are not proposing any changes to the chart-abstracted measure set for the CY 2020 payment determination. Thus, our estimates for the burden associated with chart-abstracted measures remains the same as those previously approved for the CY 2020 payment determination under this OMB Control Number.

For the CY 2020 payment determination, the chart-abstracted measure set for the Hospital OQR Program is made up of the following five measures: (1) OP-2; (2) OP-3; (3) OP-5; (4) OP-18; and (5) OP-23.

- For chart-abstracted measures where patient-level data is submitted directly to CMS, we previously estimated it would take 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<sup>10</sup> are reported per hospital for chart-abstracted measures (82 FR 59478). We continue to estimate that it will take approximately 46 hours (0.049 hours x 947 cases) to collect and report data for each chart-abstracted measure.

Therefore, for all participating hospitals, we estimate an annual chart-abstraction burden of 759,000 hours (46 hours per hospital x 3,300 hospitals x 5 measures) and a financial burden of approximately \$27.8 million (759,000 x \$36.58 per hour).

- There are three web-based measures in the Hospital OQR Program measure set that also require some chart-abstraction: (1) OP-29; (2) OP-30; and (3) OP-31.

For OP-29 and OP-30, we previously estimated that these web-based measures require 25 minutes, or 0.417 hours, per case per measure to chart-abstract (78 FR 75171),<sup>11</sup> and that hospitals would abstract 384 cases per year for each of these measures (78 FR 75171). Therefore, for all participating hospitals, we continue to estimate an annual chart-abstraction burden of 1,056,845 hours (0.417 hours per hospital, per case x 384 cases per measure x 3,300 hospitals x 2 measures), and a financial burden of approximately \$38.7 million (1,056,845 hours x \$36.58 per hour).

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<sup>10</sup> We note that our estimated number of cases has decreased from the 1,266 cases estimated for these measures in previous PRA Packages for the CY 2015 and CY 2016 OPPTS/ASC final rules with comment period.

<sup>11</sup> In the CY 2014 OPPTS/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).

The reporting of data associated with the OP-31 measure is voluntary.<sup>12</sup> We previously estimated that this web-based measure would also require 25 minutes, or 0.417 hours, per case to chart-abstract (78 FR 75171), and that hospitals would abstract 384 cases per year for this measure (78 FR 75171). We also previously estimated that approximately 20 percent of hospitals, or 660 hospitals (3,300 hospitals x 0.2), would elect to report this measure on a voluntary basis (79 FR 67014). Therefore, for all participating hospitals, we continue to estimate an annual chart-abstraction burden of 105,684 hours (0.417 hours per hospital, per case x 384 cases per measure x 660 hospitals x 1 measure), and a financial burden of approximately \$3.9 million (105,684 hours x \$36.58 per hour).

The sum total of the estimated chart-abstraction burdens calculated above results in a total annual chart-abstraction burden of 1,921,529 hours (759,000 hours + 1,056,845 million hours + 105,684 hours) and approximately \$70.3 million (1,921,529 hours x \$36.58 per hour) for all participating hospitals.

#### **(4) Web-Based Measures Burden**

In the CY 2019 OP/ASC proposed rule, we are not proposing any changes to the web-based measure set for the CY 2020 payment determination. Thus, our estimates for the burden associated with web-based measures remains the same as those previously approved for the CY 2020 payment determination under this OMB Control Number.

For the CY 2020 payment determination, the web-based measure set for the Hospital OQR Program is made up of the following five measures: (1) OP-12; (2) OP-17; (3) OP-22; (3) OP-29; (4) OP-30; (5) OP-31; and (6) OP-33.

We previously estimated, in the CY 2016 OP/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. Therefore, for all participating hospitals, we continue to estimate an annual web-based burden of 3,858 hours (0.167 hours per hospital x 3,300 hospitals x 7 measures), and a financial burden of approximately \$141,115 (3,858 hours x \$36.58 per hour).

#### **(5) Claims-Based Measures Burden**

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-9, OP-10, OP-11, OP-113, OP-14, OP-32, OP-35, and OP-36) do not influence our burden calculations.

#### **(6) Survey Measures Burden**

In the CY 2018 OP/ASC final rule with comment period (82 FR 59433), CMS finalized the delayed implementation of the five OAS CAHPS survey-based measures (OPs-37a-e) until

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<sup>12</sup> Hospitals may voluntarily submit data for OP-31 but will not be subject to a payment reduction with respect to this measure for the CY 2020 payment determination or during the voluntary reporting period.

further action. In the CY 2019 OPPI/ASC proposed rule, we are not proposing any changes to our delayed implementation of the five OAS CAHPS survey-based measures. As hospital outpatient departments are not currently administering the survey under the Hospital OQR Program, these survey-based measures do not influence our total burden calculations.<sup>13</sup>

**(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 × 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 \$219,480 (6,000 hours x \$36.58 per hour).

**(8) Total Burden for the CY 2020 Payment Determination**

Based on the burden estimates calculated above for the CY 2020 payment determination, for all participating hospitals, we estimate a total annual burden of 2,069,987 hours, and a total financial burden of approximately \$75.7 million. The table below summarizes our calculations.

**Table 2. Total Burden for the CY 2020 Payment Determination**

	<b>Total Hours</b>	<b>Total Cost</b>
Administrative Activities	138,600	\$5,069,988
NHSN Measure	N/A	N/A
Chart-Abstracted Measures	1,921,529	\$70,289,541
Web-Based Measures	3,858	\$141,115
Claims-Based Measures	N/A	N/A
Survey-Based Measures	N/A	N/A
Validation	6,000	\$219,480
<b>Total</b>	<b>2,069,987</b>	<b>\$75,720,124</b>

**(c) Burden for the CY 2021 Payment Determination**

<sup>13</sup> In addition, we note the information collection requirements associated with measures OPs-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.

As discussed above, in the CY 2019 OPPS/ASC proposed rule, we are proposing the removal of nine measures from the Hospital OQR Program measure set for the CY 2021 payment determination and subsequent years as follows:

- One chart-abstracted measure: OP-5
- Five web-based measures: OP-12; OP-17; OP-29; OP-30; and OP-31
- Three claims-based measures: OP-9; OP-11; OP-14

We are not proposing the addition of any new measures to the Hospital OQR Program measure set for the CY 2021 payment determination.

We note that our calculations for the following burden estimates for the CY 2021 payment determination do not change from the estimates calculated above, for the CY 2020 payment determination:

	<b>Total Hours</b>	<b>Total Cost</b>
Administrative Activities	138,600	\$5,069,988
Survey-Based Measures	N/A	N/A
Validation	6,000	\$219,480

Accordingly, we do not repeat our calculations for these particular burden estimates, as they are discussed, above, in Section 12(b). Below, our total burden estimates reflect the proposed removals of one chart-abstracted, three claims-based, and five web-based measures from the Hospital OQR Program measure set for the CY 2021 payment determination and subsequent years.

### **(1) Chart-Abstraction Burden**

In the CY 2019 OPPS/ASC proposed rule, we are proposing the removal of one chart-abstracted measure from the Hospital OQR Program measure set for the CY 2021 payment determination and subsequent years: OP-5. If finalized, this will leave four chart-abstracted measures in the Hospital OQR Program for the CY 2021 payment determination and subsequent years (OP-2, OP-3, OP-18, and OP-23).

As stated above, for chart-abstracted measures where patient-level data is submitted directly to CMS, we previously estimated it would take 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 estimated that 947 cases<sup>14</sup> are reported per hospital for chart-abstracted measures (82 FR 59478). We continue to estimate that it will take approximately 46 hours (0.049 x 947 cases) to collect and report data for each chart-abstracted measure.

<sup>14</sup> We note that our estimated number of cases has decreased from the 1,266 cases estimated for these measures in previous PRA Packages for the CY 2015 and CY 2016 OPPS/ASC final rules with comment period.



Therefore, for all participating hospitals, we estimate an annual chart-abstraction burden of 607,200 hours (46 hours per hospital x 3,300 hospitals x 4 measures), and a financial burden of approximately \$22.2 million (607,200 hours x \$36.58 per hour).

## (2) Web-Based Measures Burden

In the CY 2019 OPPS/ASC proposed rule, we are proposing the removal of five web-based measures from the Hospital OQR Program measure set for the CY 2021 payment determination and subsequent years: OP-12, OP-17, OP-29, OP-30, and OP-31. If finalized, this will leave two web-based measures in the Hospital OQR Program for the CY 2021 payment determination and subsequent years: OP-22 and OP-33.

As stated above, 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.

Therefore, for all participating hospitals, we estimate an annual web-based burden of 1,102 hours (0.167 hours per hospital x 3,300 hospitals x 2 measures), and a financial burden of approximately \$40,318 (1,102 hours x \$36.58 per hour).

## (3) Claims-Based Measures Burden

In the CY 2019 OPPS/ASC proposed rule, we are proposing the removal of three claims-based measures from the Hospital OQR Program measure set for the CY 2021 payment determination and subsequent years: OP-9, OP-11, and OP-14.

As stated above, claims-based measures are derived through analysis of administrative claims data and do not require additional effort or burden on hospitals. As a result, we do not expect these proposals to influence our burden calculations for the CY 2021 payment determination.

## (4) Total Burden for the CY 2021 Payment Determination

Based on the burden estimates calculated above for the CY 2021 payment determination, for all participating hospitals, we estimate a total burden of 752,902 hours, and a financial burden of approximately \$27.5 million.

**Table 3. Total Burden for the CY 2021 Payment Determination**

	<b>Total Hours</b>	<b>Total Cost</b>
Administrative Activities	138,600	\$5,069,988
Chart-Abstracted Measures	607,200	\$22,211,376
Web-Based Measures	1,102	\$40,318
Claims-Based Measures	N/A	N/A
Survey-Based Measures	N/A	N/A
Validation	6,000	\$219,480
<b>Total</b>	<b>752,902</b>	<b>\$27,541,162</b>

### **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.

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 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.

### **15. Program or Burden Changes**

In the CY 2019 OP/ASC proposed rule, we propose the removal of the one NHSN measure (OP-27) for the CY 2020 payment determination and subsequent years. As explained above, although the burden associated with NHSN measures is accounted for under a separate PRA Package, OMB Control Number 0920-0666, the burden associated with OP-27 was included in our previous total burden estimates under this OMB Control Number. We also propose the removal of one chart-abstracted measure (OP-5); three claims-based measures (OP-9, OP-11, and OP-14); and five web-based measures (OP-12, OP-17, OP-30, and OP-31) for the CY 2021 payment determination and subsequent years.

In total, for the CY 2021 payment determination for the Hospital OQR Program, our estimates show an annual reduction in hourly burden of 1,468,614 hours (2,221,516 hours approved – 752,902 total estimated hours for CY 2021), and a financial reduction of approximately \$53.7 million (\$81,263,055 approved – \$27,541,162 total estimated cost for CY 2021).

### **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* website. 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 C.F.R. § 1320.9.