Supporting Statement – Part A

Submission of Information for the Hospital Outpatient Quality Reporting (OQR) Program

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 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, 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 (APU) factor to the hospital outpatient department fee schedule by 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 and 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 these amendments is the Hospital Outpatient Quality Reporting (OQR) Program.

Section 3014 of the Patient Protection and Affordable Care Act of 2010 (ACA) modified section 1890(b) of the Social Security 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 these requirements. 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 2016 OPPS/ASC proposed rule with comment period. This proposed rule also includes measures that were adopted for the CY 2016 and subsequent years' payment determinations. 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 these 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 National Quality Strategy: 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.

The 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 to be 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 2019 Payment Determinations

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), and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70507 through 80 FR 70511; 80 FR 70519 through 70520), CMS finalized quality measures, administrative processes and data submission requirements for the CYs 2014 through 2018 payment determinations.

CMS is not proposing any changes to the Hospital OQR Program measures for the CY 2019 payment determination in the CY 2017 OPPS/ASC proposed rule. Therefore, we do not estimate any additional burden to hospitals.

The entire measure set for the CY 2019 payment determination is outlined in the below table:

HOSPITAL OQR PROGRAM MEASURES FOR
THE CY 2019 PAYMENT DETERMINATION

NQF No.	Measure Name	Data Collection Mode
0287	OP-1: Median Time to Fibrinolysis†	Chart-abstracted
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	Chart-abstracted
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	Chart-abstracted
0286	OP-4: Aspirin at Arrival†	Chart-abstracted
0289	OP-5: Median Time to ECG†	Chart-abstracted
0514	OP-8: MRI Lumbar Spine for Low Back Pain	Claims-based
N/A	OP-9: Mammography Follow-up Rates	Claims-based
N/A	OP-10: Abdomen CT – Use of Contrast Material	Claims-based
0513	OP-11: Thorax CT – Use of Contrast Material	Claims-based
N/A	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data	Web-based (CMS)
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery	Claims-based
N/A	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	Claims-based
0491	OP-17: Tracking Clinical Results between Visits†	Web-based (CMS)
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	Chart-abstracted
N/A	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional	Chart-abstracted

0662	OP-21: Median Time to Pain Management for Long Bone Fracture	Chart-abstracted
0499	OP-22: ED-Left Without Being Seen†	Web-based (CMS)
0661	OP-23: ED-Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival	Claims-based
N/A	OP-25: Safe Surgery Checklist Use	Web-based (CMS)
N/A	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	Web-based (CMS)
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel	NHSN
0658	OP-29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients	Web-based (CMS)
0659	OP-30: Endoscopy/Poly Surveillance: Colonoscopy interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Web-based (CMS)
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (CMS; voluntary)
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	Claims-based
1822	OP-33: External Beam Radiotherapy for Bone Metastases	Web-based (CMS)

† We note that NQF endorsement for this measure was 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.

4. CY 2020 Payment Determination and Subsequent Years

In the CY 2017 OPPS/ASC proposed rule, for the CY 2020 payment determination and subsequent years, CMS is proposing a total of seven new measures – two of which are claims-based measures and five of which are Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. These measures are:

- Two claims-based measures:
  - OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy
  - OP-36: Hospital Visits after Hospital Outpatient Surgery
- Five OAS CAHPS survey-based measures:
  - OP-37a: OAS CAHPS – About Facilities and Staff
  - OP-37b: OAS CAHPS – Communication About Procedure
  - OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
  - OP-37d: OAS CAHPS – Overall Rating of Facility
  - OP-37e: OAS CAHPS – Recommendation of Facility

The entire measure set for the CY 2020 payment determination and subsequent years is outlined in the below table:

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure Name	Data Collection Mode
0287	OP-1: Median Time to Fibrinolysis†	Chart-abstracted
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	Chart-abstracted
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	Chart-abstracted
0286	OP-4: Aspirin at Arrival†	Chart-abstracted
0289	OP-5: Median Time to ECG†	Chart-abstracted
0514	OP-8: MRI Lumbar Spine for Low Back Pain	Claims-based
N/A	OP-9: Mammography Follow-up Rates	Claims-based
N/A	OP-10: Abdomen CT – Use of Contrast Material	Claims-based
0513	OP-11: Thorax CT – Use of Contrast Material	Claims-based
N/A	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data	Web-based (CMS)
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery	Claims-based
N/A	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	Claims-based
0491	OP-17: Tracking Clinical Results between Visits†	Web-based (CMS)
0496	OP-18: Median Time from ED Arrival to ED Departure	Chart-abstracted

	for Discharged ED Patients	
N/A	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional	Chart-abstracted
0662	OP-21: Median Time to Pain Management for Long Bone Fracture	Chart-abstracted
0499	OP-22: ED-Left Without Being Seen†	Web-based (CMS)
0661	OP-23: ED-Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival	Claims-based
N/A	OP-25: Safe Surgery Checklist Use	Web-based (CMS)
N/A	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	Web-based (CMS)
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel	NHSN
0658	OP-29: Endoscopy/Poly Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients	Web-based (CMS)
0659	OP-30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Web-based (CMS)
1536	OP-31 Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (CMS; voluntary)
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	Claims-based
1822	OP-33: External Beam Radiotherapy for Bone Metastases	Web-based (CMS)
N/A	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	Claims-based
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery	Claims-based
N/A	OP-37a: OAS CAHPS – About Facilities and Staff	Survey-based
N/A	OP-37b: OAS CAHPS – Communication About Procedure	Survey-based
N/A	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery	Survey-based
N/A	OP-37d: OAS CAHPS – Overall Rating of Facility	Survey-based
N/A	OP-37e: OAS CAHPS – Recommendation of Facility	Survey-based

† We note that NQF endorsement for this measure was 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 do not require additional effort or burden from hospitals beyond administering the survey and submitting survey data to CMS. These survey administration burdens are captured under a previously finalized PRA Package, OMB Control Number 0938-1240.

5. Forms Used in Hospital OQR Program Procedures

To administer the Hospital OQR Program, three forms are utilized: Notice of Participation, 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.

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 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 exemption or extension for meeting program requirements. For the hospital to receive consideration for an extension or exemption, an Extraordinary Circumstances Extensions/Exemptions Request must be submitted. This form can be found on-line and can be submitted electronically, by mail, or fax. We note that 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 2 percentage point reduction in their APU, 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 for the PRA (44 USC 3518(c)(1)(B)) excludes 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 by adding a new subsection (17) that affects 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 by 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 publically 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 has contributed to high levels of hospital data submissions. For example, in CY 2016, only 21 eligible hospitals did not meet program data submission requirements; of those, five hospitals failed data validation requirements. To achieve the goal of

publically reporting data, the Hospital OQR publically 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 is 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

CMS will use the information collected as to the measures selected for the Hospital OQR Program for hospital outpatient departments to either meet administrative, data collection and submission, validation, and publication requirements, or receive a 2 percentage point reduction in their annual payment update (APU) under the Outpatient Prospective Payment System (OPPS). The information will be made available to hospitals for their use in internal quality improvement initiatives. CMS uses this information to direct its contractors to focus on particular areas of improvement and to develop quality improvement initiatives. Contractors may be Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs). The information is made available to hospitals for their use in internal 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.

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.

Also, under ACA, Section 3014, 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. The findings will be formally written into the 2018 Impact Assessment Report and, pending clearance, will be posted March 1, 2018. The link to the 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.

For the claims-based measures, this section is not applicable as claims-based measures 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 APU 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 APU.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice for this data collection is scheduled to be published on July 1, 2016. The CY 2017 OPPS/ASC proposed rule with comment period can be found on the Federal Register and CMS websites. Comments are currently being submitted on this notice, and CMS will respond to those comments accordingly.

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 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. CMS maintains this information in the CMS data warehouse, which contains all information collected under this and other quality reporting and value-based purchasing programs. In addition, the tools used for transmission and storage of data are considered confidential forms of communication and are HIPAA compliant.

11. Sensitive Questions

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 by 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. The program established under these amendments is referred to as the Hospital OQR Program.

In the CY 2017 OPPS ASC proposed rule, we set out the program requirements for the CY 2019, and CY 2020 Hospital OQR Program payment determinations. 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 three forms in its administrative activities: Notice of Participation, 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. The burden associated with the Notice of Participation form is accounted for in this package under the administrative burden for each year of the program. 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.

CY 2019 Payment Determination and Subsequent Years

In keeping with current practice, we discuss only the incremental burden associated with the proposals made for the CY 2019 payment determination and subsequent years. For the CY 2019 payment determination and subsequent years, CMS proposed to extend the submission deadline for extraordinary circumstances extensions or exemptions requests (ECE) from 45 days from the date that the extraordinary circumstance occurred to 90 days from the date that the extraordinary circumstance occurred. The proposed updates to the ECE deadlines will have no effect on burden for hospitals, because CMS is not making any changes that will increase the amount of time necessary to complete the form. CMS does not anticipate that there would be any additional burden as the materials to be submitted related to an ECE request are unchanged and the deadline does not shorten the time to submit an extension or exemption request.

CY 2020 Payment Determination and Subsequent Years

In keeping with current practice, we discuss only the incremental burden associated with the proposals made for the CY 2020 payment determination and subsequent years. For the CY 2020 payment determination and subsequent years, CMS proposed to add seven additional measures to the Hospital OQR Program. The proposed measures are:

- OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy
- OP 36: Hospital Visits after Hospital Outpatient Surgery
- OP-37a: OAS CAHPS – About Facilities and Staff
- OP-37b: OAS CAHPS – Communication About Procedure
- OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
- OP-37d: OAS CAHPS – Overall Rating of Facility
- OP-37e: OAS CAHPS – Recommendation of Facility.

Since proposed OP-35 and proposed OP-36 are claims-based measures, they use Medicare Fee-for-Service (FFS) claims data and to not require additional hospital data submissions. Therefore, they would not result in additional burden to participating hospitals.

The remaining five proposed measures, OP-37a – OP-37e, are calculated using data collected from the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS Survey). The information collection requirements associated with proposed measures OP-37a – OP-37e are currently approved under OMB Control Number 0938-1240; for this reason, we are not providing an independent estimate of the burden associated with the OAS CAHPS Survey administration for the Hospital OQR Program. The burden associated with the OP-37a – OP-37e measures is the time and effort put forth by the hospitals to submit the OAS CAHPS patient files to their approved OAS CAHPS survey vendor. All data will be collected by Center for Medicare (CM) (who maintains OMB Control Number 0938-1240) and sent to CMS's Center for Clinical Standards and Quality (CCSQ) for payment determinations and posting on the *Hospital Compare* Web site. This previously finalized Information Collection Request assumes that the full universe of Medicare-certified facilities would participate and submit the highest required number of completed surveys (that is, 300 completed surveys). While not all Medicare-certified facilities will be required to submit data for the OAS CAHPS survey-based measures for reasons such as exemption due to small facility size or electing not to participate in the Hospital OQR Program, this estimate uses the maximum burden possible. Therefore, there is no additional burden to hospitals resulting from these measures' use in the Hospital OQR Program.

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 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 is approximately $11,500,000 on an annual basis. CMS must maintain and update existing information technology infrastructure on QualityNet and the CART tool. CMS must also provide ongoing technical assistance to hospitals and data vendors to participate in the program. CMS also calculates four additional claims-based imaging efficiency measures for hospital outpatient departments, and provide hospitals with feedback reports about all of the measures.

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.

15. Program or Burden Changes

As discussed above, we are proposing to add two new claims-based measures and five survey-based new measures to the Hospital OQR Program for the CY 2020 payment determination and subsequent years. Because we calculate the claims-based measures using Medicare FFS claims

data that do not require additional hospital data submissions, we do not anticipate that the new claims-based measures would create additional burden to hospital outpatient departments for the CY 2020 payment determination and subsequent years. In addition, the information collection requirements associated with the OP-37: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems survey-based measures are currently approved under OMB Control Number 0938-1240. For this reason, we are not providing an independent estimate of the burden associated with OAS CAHPS survey administration for the Hospital OQR Program. As a result of these changes, we do not anticipate an increase or decrease in burden for hospitals.

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 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

We request a 10/31/2019 expiration date as Hospital OQR Program requirements and activities outlined are included to this date in this request.

18. Certification Statement

We certify that the Hospital OQR Program complies with 5 CFR 1320.9.