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 2016 Payment Determination

CMS previously finalized in the CY 2013 OPPS/ASC final rule with comment period OP-27: Influenza Vaccination Coverage among Healthcare Personnel, a Centers for Disease Control and Prevention (CDC) measure. In the CY 2014 OPPS/ASC final rule with comment period, CMS finalized that this data would be submitted via CDC's Web-based tool located on the National Healthcare Safety Network (NHSN) website.

In the CY 2014 OPPS/ASC final rule with comment period, CMS also adopted three (3) quality measures where aggregate numerator and denominator data are submitted directly to CMS via the CMS Web-based tool (QualityNet Website). On December 31, 2013, CMS issued guidance stating that we would delay the implementation of OP-29, OP-30, and OP-31 by 3 months from January 1, 2014 to April 1, 2014 for the CY 2016 payment determination (https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228721506778). On April 2, 2014, CMS issued additional guidance stating that we would further delay the implementation of OP-31 from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination (https://www.qualitynet.org/dcs/ContentServer?c=Page& pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228721506778). In the CY 2015 OPPS/ASC final rule, we excluded OP-31 from the CY 2016 payment determination measure set.

The entire measure set for the CY 2016 payment determination is outlined in the below table:

HOSPITAL OQR PROGRAM MEASURES FOR
THE CY 2016 PAYMENT DETERMINATION

NQF No.	Measure Name	Data Collection Mode
N/A	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
N/A	OP-6: Timing of Antibiotic Prophylaxis	Chart-abstracted
0528	OP-7: Prophylactic Antibiotic Selection for Surgical Patients	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
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
N/A	OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache	Claims-based (deferred public reporting)
N/A	OP-17: Tracking Clinical Results between Visits	Web-based
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
N/A	OP-22: ED-Left Without Being Seen	Web-based
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
N/A	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	Web-based
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 (deferred by 3 months)
0659	OP-30: Endoscopy/Poly Surveillance: Colonoscopy interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Web-based (deferred by 3 months)

3. CY 2017 Payment Determination

In the CY 2015 OPPS/ASC final rule with comment period, for the CY 2017 payment determination, CMS removed two (2) measures from the Hospital OQR Program: OP-6: Timing of Antibiotic Prophylaxis and OP-7: Prophylactic Antibiotic Selection for Surgical Patients (NQF # 0528). CMS also finalized that reporting of OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) was voluntary, meaning that failure to report this measure would not affect a hospital's payment under the Hospital OQR Program.

In the CY 2016 OPPS/ASC final rule with comment period for the CY 2017 payment determination and subsequent years, CMS removed one (1) claims-based measure from the Hospital OQR Program: OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

The entire measure set for the CY 2017 payment determination is outlined in the below table:

HOSPITAL OQR PROGRAM MEASURES FOR THE CY 2017 PAYMENT DETERMINATION

NQF No.	Measure Name	Data Collection Mode
N/A	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
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
N/A	OP-17: Tracking Clinical Results between Visits	Web-based
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
N/A	OP-22: ED-Left Without Being Seen	Web-based
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
N/A	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	Web-based
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
0659	OP-30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Web-based
1536	OP-31 Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (voluntary)

4. CY 2018 Payment Determination and Subsequent Years

In the CY 2015 OPPS/ASC final rule with comment period, for the CY 2018 payment determination and subsequent years, we adopted one (1) claims-based quality measure, OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539).

In the CY 2016 OPPS/ASC final rule with comment period for the CY 2018 payment determination and subsequent years, CMS added one (1) quality measure, OP-33 External Beam Radiotherapy for Bone Metastases (NQF #1822), where aggregate numerator and denominator data are submitted directly to CMS via the CMS Web-based tool (QualityNet Website).
The entire measure set for the CY 2018 payment determination and subsequent years is outlined in the below table:

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure Name	Data Collection Mode
N/A	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
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
N/A	OP-17: Tracking Clinical Results between Visits	Web-based
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
N/A	OP-22: ED-Left Without Being Seen	Web-based
0661	OP-23: ED-Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head	Claims-based

	CT or MRI Scan Interpretation Within 45 minutes of Arrival	
N/A	OP-25: Safe Surgery Checklist Use	Web-based
N/A	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	Web-based
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
0659	OP-30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Web-based
1536	OP-31 Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Web-based (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

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.

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 improvement organizations (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.

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 November 1, 2015. The CY 2016 OPPS/ASC final rule with comment period can be found on the Federal Register and CMS websites.

CMS is supported in this program's efforts by The Joint Commission, NQF, MAP, and 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.

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 2016 OPPS ASC final rule, we set out the program requirements for the CY 2016, CY 2017, and CY 2018 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. The burden associated

with submitting an Extraordinary Circumstances Extension/Exemption Request is accounted for in OMB Control Number 0938-1022, and is therefore excluded from this burden estimate. Consistent with 5 CFR 1320.4 (44 USC 3518(c)(1)(b)), the burden associated with filing a reconsideration request is excluded from this package because this collection occurs during the conduct of an administrative action.

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Administrative Burden: Administrative burden includes duties such as ensuring staffing, identifying and maintaining an active QualityNet Website Security Administrator, and filling out forms and other paperwork, For the CY 2016 payment determination, the burden associated with program requirements is the time and effort associated with collecting and submitting the data on the required measures and submitting documentation for validation purposes. As discussed in the CY 2010 OPPS/ASC final rule with comment period, for the CY 2011 payment determination, we estimated a total of 3500 hospitals[1] (74 FR 60660); in the CY 2011 OPPS/ASC final rule with comment period, for the CY 2012 payment determination, we estimated a total of 3200 hospitals; and in the CY 2012 and CY 2013 OPPS/ASC final rules with comment period, for the CY 2014 payment determination, we estimated a total of 3200 hospitals (76 FR 74552; 77 FR 68531). In the CY 2014 OPPS/ASC final rule with comment period, for the CY 2016 payment determination, we estimated a total of 3300 hospitals (78 FR 75171). CMS understands that each year, new hospitals may open, and existing hospitals may close or merge with others. In determining the estimate for the total number of hospitals, CMS estimated in 2010, there were 3500 hospitals eligible for the Hospital OQR Program, and this number includes voluntary hospitals that submitted data in 2009. In 2014, CMS determined that there were 3,266 hospitals eligible for the Hospital OQR Program, and this number does not include voluntary hospitals. From 2014, CMS has used the Hospital OQR Program eligible hospitals for estimation. The number of 3,300 hospitals is based on the actual Hospital OQR eligible hospitals. Therefore, CMS estimated that there would be approximately 3,300 hospitals per year. CMS estimated that the burden associated with these requirements was 42 hours per hospital or 138,600 hours for all hospitals. CMS estimated the financial burden for these requirements would be $4.2 million ($138,600 hours x $30 per hour[2]) for all hospitals.

Chart-abstraction Burden: With regard to chart-abstracted measures where patient-level data is submitted directly to CMS, we estimated it would take 35 minutes to abstract all measures per submitted case. Based upon the data submitted for prior payment determinations[3], CMS

[1] The unit for hospital is CCN. If a hospital has multiple campuses but share one CCN, then data submission is by the CCN.

[2] As discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimate a financial burden of $30 per hour associated with meeting program requirements for the Hospital OQR Program.

[3] In the CY 2010 OPPS/ASC final rule with comment period, for the CY 2011 payment determination, we estimated a total of 1,800,000 cases per year, or approximately 514 cases per year per hospital (74 FR 60661) The estimated annual burden associated with the submission requirements was 900,000 hours ((1,800,000 cases/year) × (0.5 hours/case)).

In the CY 2011 OPPS/ASC final rule with comment period, for the CY 2012 payment determination, we estimated a total of 930,000 cases per year, or approximately 290 cases per hospital (75 FR 72112 through 72113), and the estimated annual burden associated with the submission requirements for the

estimated there would be a total of 1,679,700 cases per year, approximately 509 cases per year per hospital. Therefore, the estimated annual hourly burden associated with the chart-abstracting for measures which are not submitted via a CMS Web-based tool is 979,265 hours (1,679,700 cases per year × 0.583 hours per case). Chart-abstracting for measures submitted via a CMS Web-based tool is 1,056,845 hours ((0.417 hours per hospital per case x 768 cases per hospital) x 3,300 hospitals.) In addition, hospitals would incur a financial burden associated with chart abstraction and data submission. Estimating that hospitals would pay $30 per hour for chart abstraction and data submission, we estimated the financial burden associated with these measures is $61,083,300 ((979,265 hours + 1,056,845 hours) x $30 per hour).

Web-based Measures Submission Burden: For the measures where data is submitted to CMS via a Web-based tool located on a CMS website, we estimated that each participating hospital would spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with these measures 3,858 hours (3,300 hospitals × 0.167 hours per measure × 7 measures per hospital) in CY 2015. In addition, hospitals would incur a financial burden associated with data collection and data submission for these 7 measures. CMS estimated that the financial burden associated with these measures would be $115,731 (3,858 hours x $30 per hour).

NHSN Measure Burden: CMS estimated that the total annual burden associated with OP:27-Influenza Vaccination Coverage among Healthcare Personnel for a hospital for data submission would be 106,940 hours (0.167 hours per response x 640,360 responses). In addition, hospitals would incur a financial burden associated with data submission for this measure. CMS estimated that the financial burden associated with this measure is $3,208,200 (106,940 hours x $30.00 per hour).

Validation Burden: For validation of hospital self-reported data, a random sample of 450 participating hospitals is selected plus up to 50 additional hospitals based upon targeting criteria;

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chart-abstracted data was 542,500 hours (930,000 cases per year × 0.583 hours/case). For the CY 2013 payment determination, the estimated annual burden associated with the aforementioned submission requirements for the chart-abstracted data was 1,084,380 hours (1,860,000 cases per year × 0.583 hours/case).

In the CY 2012 OPPS/ASC final rule with comment period, for the CY 2014 payment determination, we estimated a total of 1,947,429 cases per year, or approximately 509 cases per year per hospital (76 FR 74552). The estimated annual burden associated with the submission requirements for these chart-abstracted measures was 1,136,000 hours (1,947,429 cases per year × 0.583 hours per case).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68531), for the CY 2014 payment determination, we estimated a total of 1,628,800 cases per year, or approximately 509 cases per year per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures was 949,590 hours (1,628,800 cases per year × 0.583 hours per case).

In the 2014 OPPS/ASC final rule with comment period (78 FR 75171), for the CY 2016 payment determination, we estimated a total of 1,679,700 cases per year, with approximately 509 cases per year per hospital. We estimated the financial burden associated with these measures for all hospitals as $29,377,953 (1,679,700 cases per year × $30.00 per hour × 0.583 hours per case).

In the 2015 OPPS/ASC final rule with comment period (79 FR 67013 through 67014), for the CY 2017 payment determination, for the chart-abstracted measures, for the chart-abstracted measures, we estimate a total burden for all participating hospitals of 3.23 million hours (2.02 million hours + 105,685 hours + 1.1 million hours) and $96.9 million (3.23 million hours × $30/ hour).

a total of up to 500 hospitals, as detailed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965).[4] For each selected hospital, up to 48 patient encounters will be selected from the total number of cases that the hospital successfully submitted to CMS. The burden associated with the CY 2016 requirement is the time and effort necessary to submit supporting medical record documentation. CMS estimated that it would take each of the sampled hospitals approximately 12 hours to comply with these information request requirements. To comply with the requirements, CMS estimated each hospital must submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements each year, which would result in a total of up to 24,000 charts being submitted by the sampled hospitals (500 hospitals $\times$ 48 cases per hospital). The estimated annual hourly burden associated with the data validation process for CY 2016 payment determinations is approximately 6,000 hours. In addition, hospitals would incur a financial burden associated with the required information submission requirement. CMS estimated that the financial burden associated with this would be $180,000 (6,000 hours x $30.00 per hour).

CY 2017

Administrative Burden: For the CY 2017 payment determination, the burden associated with program requirements is the same as for CY 2016; it is the time and effort associated with collecting and submitting the data on the required measures, and submitting documentation for validation purposes. CMS estimated that there would be approximately 3,300 hospitals per year. CMS estimated that the burden associated with these requirements was 42 hours per hospital or 138,600 hours for all hospitals. CMS estimated the financial burden for these requirements would be $4.2 million ($138,600 hours x $30 per hour) for all hospitals.

Chart-abstraction Burden: With regard to chart-abstracted measures where patient-level data is submitted directly to CMS, in the CY 2015 OPPS/ASC final rule with comment period, CMS removed OP-6 and OP-7 from the Hospital OQR Program for the CY 2017 payment determination and subsequent years. CMS previously estimated that each participating hospital would spend 35 minutes (or 0.583 hours) per case for 12 chart-abstracted measures (OP-1, OP-2, OP-3, OP-4, OP-5, OP-6, OP-7, OP-18, OP-20, OP-21, OP-22, OP-23). Since CMS removed two of these measures, we believed that the time to chart-abstract measures would be reduced by 16.7 percent (2 of 12 measures). Therefore, CMS estimated that hospitals would spend

[4] For the CY 2013 payment determination and subsequent years, CMS reduced the number of randomly selected hospitals from 800 to 450. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), CMS finalized their intent to select a random sample of hospitals for validation purposes, and to select an additional 50 hospitals based on specific criteria designed to measure whether the data these hospitals have reported raises a concern regarding data accuracy In the CY 2013 OPPS/ASC final rule, CMS finalized specifically, a hospital will be preliminarily selected for validation based on targeting criteria if it: Fails the validation requirement that applies to the previous year's payment determination. For example, if a hospital was selected for validation for the CY 2013 payment determination year, either on a random or targeted basis, and the hospital did not meet the 75 percent validation score for the designated time period, based upon our validation process, for the designated time period, the hospital would be included in the targeted sample pool for the CY 2014 payment determination); or Has an outlier value for a measure based on the data it submitted, based on finalized criteria from the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485).

approximately 29 minutes (0.483 hours) per case, or 2.9 minutes per measure, to collect and submit the data for these 10 measures. Based upon the data submitted for the CY 2014 payment determination, hospitals would submit approximately 1,266 cases per year for these measures. Therefore, CMS estimated that the time it would take a hospital to abstract data for all of the chart-abstracted measures would be 612 hours per year (1,266 cases x 0.483 hours), resulting in a burden of 2.02 million hours (612 hours x 3,300 hospitals) for all participating hospitals, for a total financial burden of approximately $61 million (2.02 million hours x $30 per hour).
In addition, CMS estimated that OP-29 and OP-30 would require 25 minutes (0.417 hours) per case per measure to chart-abstract.[5] CMS estimated that hospitals would abstract 384 cases per year for each of these measures. Therefore, for the CY 2017 payment determination and subsequent years, we estimated a burden of 1.1 million hours (3,300 hospitals x 0.417 hours/case x 384 case per measure x 2 measures) for all participating hospitals for OP-29 and OP-30 for a total financial burden of approximately $33 million (1.1 million hours x $30 per hour). CMS estimated that OP-31 would require 25 minutes (0.417 hours) per case to chart-abstract. CMS also estimated that hospitals would abstract 384 cases per year for this measure. Because this is a new measure for the CY 2017 payment determination and subsequent years, CMS estimated that approximately 20 percent of hospitals (660 hospitals (3,300 hospitals x 0.2)) would elect to report this measure on a voluntary basis. Therefore, we estimated that the burden for this measure would be 105,684 hours (660 hospitals x 0.417 hours per case x 384 cases) for participating hospitals for the CY 2017 payment determination and subsequent years, for a total financial burden of approximately $3.2 million (105,685 hours x $30 per hour). Thus, for chart-abstracted measures, CMS estimated a total burden for all participating hospitals of 3.23 million hours (2.02 million hours + 1.1 million hours + 105,685 hours) and $96.9 million (3.23 million hours x $30 per hour) for the CY 2017 payment determination and subsequent years.

Web-based Measures Submission Burden: With regard to measures for which data is submitted to CMS via a Web-based tool, CMS estimated that each participating hospital would spend 10 minutes per measure per year to collect and submit the data for the six measures (OP-12, OP-17, OP-22, OP-25, OP-26, OP-29, and OP-30). Therefore, the estimated annual burden associated with these measures for all participating hospitals is 3,858 hours (3,300 hospitals x 0.167 hours per measure x 7 measures per hospital) for the CY 2017 payment determination and subsequent years. In the CY 2015 final rule, CMS made reporting for OP-31 voluntary. We estimated that approximately 20 percent of hospitals (660 hospitals (3,300 hospitals x 0.2)) would elect to report OP-31 on a voluntary basis. Therefore, CMS estimated that the burden for this measure for all participating hospitals would be 110 hours (660 hospitals x 0.167 hours) for the CY 2017 payment determination and subsequent years. Thus, CMS estimated that the financial burden incurred for the web-based submission of these measures for all participating hospitals would be $119,040 ((3,858 hours + 110 hours) x $30 per hour) for the CY 2017 payment determination and subsequent years.

NHSN Measure Burden: As for CY 2016, CMS estimated a total burden for all participating hospitals of 106,940 hours (0.167 hours per response x 640,360 responses) and a total financial

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

burden of $3,208,200 (106,940 hours x $30 per hour) associated with the NHSN measure (OP-27) for the CY 2017 payment determination and subsequent years.

Validation Burden: For prior payment determinations, CMS sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. For the CY 2017 payment determination, CMS is proposing transitioning to a new payment determination timeframe; as a result, only three quarters of data will be used for determining the CY 2017 payment determination. Therefore, CMS estimates that data submission for three quarters would reduce the number of hours required by 25 percent (from 12 hours to 9 hours per hospital.) CMS estimates a total burden of approximately 4,500 hours (500 hospitals x 9 hours per hospital) and a total financial impact of $135,000 ($30 per hour x 4,500 hours) for the CY 2017 payment determination and subsequent years.

CY 2018

For the CY 2018 payment determination, the burden associated with program requirements is the time and effort associated with collecting and submitting the data on the required measures, and submitting documentation for validation purposes. CMS estimated that there would be approximately 3,300 participating hospitals per year. Below, we discuss only the incremental burden associated with the proposals made for the CY 2018 payment determination and subsequent years. We have not included the burden discussed in the sections above that continue for future years.

Chart-abstraction Burden: With regard to chart-abstracted measures where patient-level data is submitted directly to CMS, for the CY 2018 payment determination, we did not propose to add or remove any chart-abstracted measures for the Hospital OQR Program. Therefore, the chart-abstraction burden for the CY 2018 payment determination is the same as CY 2017 payment determination.

New Web-based Measure Burden: For the CY 2018 payment determination and subsequent years, CMS adopted one new measure: OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF # 1822) where aggregate numerator and denominator data are submitted directly to CMS via the CMS Web-based tool (QualityNet Website). CMS previously estimated that it would take hospitals approximately 2.92 minutes (or 0.049 hours) per case to collect chart-abstracted data for a single Web-based measure. Based on our most recent data (Quarter 4 2013 through Quarter 3 2014) for the Hospital OQR Program measures, CMS estimates that the average hospital will submit 48 cases per year for the EBRT measure. Therefore, CMS believes that the average hospital will spend 2.352 hours (0.049 hours/measure/case x 48 cases) chart-abstracting data for this measure. In addition, consistent with prior years, CMS estimated that each participating hospital will spend 10 minutes (0.167 hours) per measure per year to collect and submit the data via the Web-based tool. Therefore, CMS estimates that, in total, the proposed measure will increase burden by 2.519 hours (2.352 hours + 0.167 hours) per hospital per year. As stated above, approximately 3,300 hospitals participate in the Hospital OQR Program. Therefore, CMS estimates a total increase in burden across all participating hospitals of 8,312.7 hours (2.519 hours/hospital x 3,300 hospitals) per year associated with this measure. Finally, consistent with prior years, we estimate that a hospital pays an individual approximately $30 per hour to abstract and submit these data. Therefore, we estimate a total financial increase in burden to be $75.57 per hospital (2.519 hours x $30 per hour) or $249,000 (8,312.7 hours x $30 per hour) across all participating hospitals as a result of this measure for the CY 2018 payment determination and subsequent years.

Validation Burden: For the CY 2018 payment determination and subsequent years, the Hospital OQR Program returns to its four-quarter payment determination cycle. The burden associated with the validation procedures is the time and effort necessary to submit supporting medical record documentation for validation. CMS estimates that it will take each of the sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, CMS estimates each hospital would submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements each year, which would result in a total of up to 24,000 charts being submitted by the selected hospitals (500 hospitals $\times$ 48 cases per hospital). CMS estimates a total burden associated with the data validation process for four quarters of data of approximately 6,000 hours (500 hospitals x 12 hours per hospital) and a total financial impact of $180,000 (6,000 hours x $30 per hour) for the CY 2018 payment determination and subsequent years. The increase in burden associated with reporting on four quarters instead of three results in an incremental increase in burden of 1,500 hours between CY 2017 and CY 2018.

Accordingly, we estimate the total annual hourly burden for CY 2016 to be 2,291,508. We estimate the total annual hourly burden for CY 2017 to be 3,434,415. We estimate the total annual hourly burden for reporting all measure data for CY 2018 to be 3,444,227. Therefore, the average annual hourly burden for CY 2016, CY 2017, and CY 2018 is approximately 3,056,717. Accordingly, we estimate the total annual financial burden for reporting measure data for the Hospital OQR Program for CY 2016 payment determination to be $68.7 million, for the CY 2017 payment determination to be $104.5, million and for the CY 2018 payment determination to be $106.9 million. Therefore, the average annual financial burden for CY 2016, CY 2017, and CY 2018 is approximately $93.4 million.

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 and software. 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 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, in the CY 2015 OPPS/ASC final rule with comment period, for the CY 2017 payment determination, CMS removed two chart-abstracted measures, finalized the reporting of one new measure, and for the CY 2018 payment determination, CMS adopted one claims-based quality measure for the Hospital OQR Program. In the CY 2016 OPPS/ASC final rule with comment period for the CY 2017 payment determination and subsequent years, CMS removed one claims-based measure from the Hospital OQR Program, and added one web-based measure for the CY 2018 payment determination and subsequent years. As we noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530), CMS calculates claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions. Therefore, we estimate that there will be no change in burden based on finalizing the adding or removal of claims-based measures. Since submitting a measure through a CMS Web-based tool has two burden components: the time required to abstract the measure data; and second, the time required to enter these data into a CMS Web-based tool, we anticipate an increase in burden for submission of the web-based measure for the Hospital OQR Program.

For the CY 2017 payment determination, CMS also finalized conforming changes to the validation scoring process to reflect proposed changes in the APU determination timeframes. In addition, for the CY 2017 payment determination, we finalized that validation will be based on three quarters of data (quarter 2, quarter 3, and quarter 4 of 2015). For this transition year, we estimate that the burden associated with validation reporting will be reduced by 25 percent because hospitals will submit validation data for three quarters instead of four. As a result, there will be an increase 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 an annual basis.

17. Expiration Date

We request a 10/31/2017 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.