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, 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 referred to as the Hospital Outpatient Quality Reporting (OQR) Program.

Section 3014 of the 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. 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 OQR measures to be included in the CY 2014 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 ACA of 2010 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's goal of better health for individuals, better health for populations, and lower costs for health care. The National Strategy for Quality Improvement in Health Care (National Quality Strategy) was released by the U.S. Department of Health and Human Services. The strategy was required under the Affordable Care Act 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: Clinical care, Person and caregiver centered experience and outcomes, Safety, Efficiency and cost reduction, Care coordination, and Community/Population health.

B. OQR Quality Measures and Forms

1. Introduction

Hospital OQR Program payment determinations are made based on OQR 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 the health care services of appropriately high quality that are comparable to that received by those 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.

2. CYs 2014 and 2015 Payment Determinations

The CY 2013 OPPS/ASC final rule with comment period finalized quality measures, administrative processes, data submission, and validation requirements for the CYs 2014 and 2015 payment determinations.

HOSPITAL OQR PROGRAM MEASURES FOR THE CYs 2014 and 2015 PAYMENT DETERMINATIONS

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	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
0270	OP- 6: Timing of Antibiotic Prophylaxis	Chart abstracted
0268	OP- 7: Prophylactic Antibiotic Selection for Surgical Patients	Chart abstracted
0514	OP- 8: MRI Lumbar Spine for Low Back Pain	Claims-based
	OP- 9: Mammography Follow-up Rates	Claims-based
	OP-10: Abdomen CT – Use of Contrast Material	Claims-based
0513	OP-11: Thorax CT – Use of Contrast Material	Claims-based
0489	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
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	Claims-based
	OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache	Deferred
0491	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
0649	OP-19: Transition Record with Specified Elements Received by Discharged ED Patients	Removal proposed
	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
	OP-22: ED-Patient 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
0643	OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting	Removal proposed
	OP-25: Safe Surgery Checklist Use	Web-based
	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	Web-based

Chart-abstracted measures require the submission of patient-level information to be obtained through chart abstraction that is then submitted electronically to CMS.

Claims-based measures are derived through analysis of administrative claims data and do not require additional effort or burden on hospitals.

Web-based measures require hospitals to submit non-patient level data directly to CMS via a web-based tool located on a CMS website.

Two (2) measures are proposed for removal (OP-19 and OP-24) and one is proposed for continued deferral (OP-15).

3. CY 2016 Payment Determination

CMS previously finalized in the CY 2013 OPPS/ASC final rule with comment period, a Centers for Disease Control and Prevention (CDC) measure. In the CY 2014 OPPS/ASC proposed rule with comment period, CMS has proposed to have this data submitted via CDC's web-based tool located on the National Health Safety Network website.

In the CY 2014 OPPS/ASC proposed rule, CMS has also proposed to add four (4) web-based measures where numerator and denominator data are submitted directly to CMS via a web-based tool located on a CMS website.

Therefore, the entire measure set proposed for the CY 2016 payment determination is outlined in the below table:

HOSPITAL OQR PROGRAM MEASURES FOR THE CYs 2014 and 2015 PAYMENT DETERMINATIONS

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	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
0270	OP- 6: Timing of Antibiotic Prophylaxis	Chart abstracted
0268	OP- 7: Prophylactic Antibiotic Selection for Surgical Patients	Chart abstracted
0514	OP- 8: MRI Lumbar Spine for Low Back Pain	Claims-based
	OP- 9: Mammography Follow-up Rates	Claims-based
	OP-10: Abdomen CT – Use of Contrast Material	Claims-based
0513	OP-11: Thorax CT – Use of Contrast Material	Claims-based
0489	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
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	Claims-based
	OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache	Deferred
0491	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
	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
	OP-22: ED-Patient 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
	OP-25: Safe Surgery Checklist Use	Web-based
	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	Web-based
0431	OP-27:Influenza Vaccination Coverage among Healthcare Personnel	Web-based
0564	OP-28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures	Web-based
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

4. Forms Used in Hospital OQR Program Procedures

To administer the Hospital OQR Program, several forms are utilized: Notice of Participation, Extraordinary Circumstance Extension or Waiver 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, all subsection (d) hospitals reimbursed under the OPPS must complete a Notice of Participation and most have. This form explains the participation and reporting requirements of the program; this form 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 want to renew participation. This form can be found on-line and must be submitted on-line.

In the event of extraordinary circumstances not within the control of the hospital, such as a natural disaster, a hospital can request a waiver or extension for meeting program requirements. For the hospital to receive consideration for an extension or waiver, an Extraordinary Circumstances Request must be submitted. This form can be found on-line and can be submitted electronically, by mail, or fax.

When a hospital is determined by CMS to not have met program requirements and has had a 2 percentage point reduction in their APU, the hospital may submit a request for reconsideration to CMS. This request must be submitted by the first business day in February in the year the payment reduction has occurred. This form can be found on-line and can be submitted by mail or fax.

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 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 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 proposed, web-based quality measures 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

This information is used by CMS to direct its contractor, including Quality Improvement Organizations (QIOs), to focus on particular areas of improvement, and to develop quality improvement initiatives. 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 My 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 other vendors to transmit the data. CMS has engaged 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 the CMS or other efforts to collect quality of care data for outpatient hospital care. As required by statute, CMS required 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

We have 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.

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 is 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, 2013. The CY 2014 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, 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 respondents 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. 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 is 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 Outpatient Prospective Payment System (OPPS) payments for services furnished by hospitals in outpatient settings on or after January 1, 2009. New 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. New 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 Outpatient Quality Reporting (OQR) Program.

CY 2014

For the CY 2014 payment determination, the burden associated with program requirements is the time and effort associated with completing the collecting and submitting the data on the required measures, and submitting documentation for validation purposes. We estimated that there will be approximately 3,200 respondents per year.

For hospitals to collect and submit the information on the chart-abstracted measures, we estimated it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and 2012 payment determinations, we estimated there will be a total of 1,628,800 cases per year, approximately 509 cases per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures is 949,590 hours (1,628,800 cases per year $\times$ 0.583 hours per case).

In addition, hospitals will incur a financial burden associated with chart abstraction and data submission where patient level data is submitted directly to CMS. We estimate the burden associated with these measures is $28,487,712 (1,628,800 cases per year $\times$ $30.00 per hour $\times$ 0.583 hours per case).

For the five (5) web-based measures, we estimated that each participating hospital will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with these measures 2,672 hours (3,200 hospitals $\times$ 0.167 hours per measure $\times$ 5 measures per hospital).

In addition, hospitals will incur a financial burden associated with data collection and data submission for these 5 measures. We estimate that the financial burden associated with these measures would be $16,032 (3,200 hospitals $\times$ $30.00 per hour $\times$ 0.167 hours per measure $\times$ 5 measures).

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; a total of up to 500 hospitals. 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 2014 requirement is the time and effort necessary to submit supporting medical record documentation. We estimated that it would take each of the selected hospitals approximately 12 hours to comply with these information request requirements. To comply with the requirements, we 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. The estimated annual burden

associated with the data validation process for CY 2014 payment determinations is approximately 6,000 hours.

In addition, hospitals will incur a financial burden associated with the required information submission requirement. We estimate that the financial burden associated with this measure would be $180,000 ($30.00 per hour × 6,000 hours).

CY 2015

For the CY 2015 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. We estimated that there will be approximately 3,200 respondents per year.

For hospitals to collect and submit the information on the chart-abstracted measures, we estimated it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and 2012 payment determinations, we estimated there will be a total of 1,628,800 cases per year, approximately 509 cases per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures is 949,590 hours (1,628,800 cases per year × 0.583 hours per case).

In addition, hospitals will incur a financial burden associated with chart abstraction and data submission where patient level data is submitted directly to CMS. We estimate the burden associated with these measures is $28,487,712 (1,628,800 cases per year × $30.00 per hour × 0.583 hours per case).

For the five (5) web-based measures, we estimated that each participating hospital will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with these measures 2,672 hours (3,200 hospitals × 0.167 hours per measure × 5 measures per hospital).

In addition, hospitals will incur a financial burden associated with data collection and data submission for these 5 measures. We estimate that the financial burden associated with these measures would be $16,032 (3,200 hospitals × $30.00 per hour × 0.167 hours per measure × 5 measures).

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; a total of up to 500 hospitals. 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 2014 requirement is the time and effort necessary to submit supporting medical record documentation. We estimated that it would take each of the selected hospitals approximately 12 hours to comply with these information request requirements. To comply with the requirements, we 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. The estimated annual hourly

burden associated with the data validation process for CY 2014 payment determinations is approximately 6,000 hours.

In addition, hospitals will incur a financial burden associated with the required information submission requirement. We estimate that the financial burden associated with this measure would be $180,000 ($30.00 per hour × 6,000 hours).

CY 2016.

For the CY 2016 payment determination, the burden associated with program requirements is the time and effort associated with completing the collecting and submitting the data on the required measures, and submitting documentation for validation purposes. We estimated that there will be approximately 3,300 respondents per year.

For hospitals to collect and submit chart-abstracted measures where patient-level data is submitted directly to CMS, we estimate it will take 35 minutes per submitted case. Based upon the data submitted for the CY 2012 and CY 2013 payment determinations, we estimate there will 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 aforementioned data submission requirements is 979,265 hours (1,679,700 cases per year × 0.583 hours per case).

In addition, hospitals will incur a financial burden associated with chart abstraction and data submission where patient level data is submitted directly to CMS. We estimate the burden associated with these measures is $29,377,953 (1,679,700 cases per year × $30.00 per hour × 0.583 hours per case).

For the measures where data is submitted to CMS via a web-based, on-line tool located on a CMS website, we estimate 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 4,960 hours (3,300 hospitals × 0.167 hours per measure × 9 measures per hospital) in CY 2015.

In addition, hospitals will incur a financial burden associated with data collection and data submission for these 9 measures. We estimate that the financial burden associated with these measures would be $148,797 (3,300 hospitals × $30.00 per hour × 0.167 hours per measure × 9 measures).

For the NHSN HAI measure: Influenza Vaccination Coverage among Healthcare Personnel, we estimate that the total annual burden associated with this measure for a hospital for data submission would be 27,555 hours (3,300 hospitals × 0.167 hours per measure × 50 workers per hospital).

In addition, hospitals will incur a financial burden associated with data submission for this measure. We estimate that the financial burden associated with this measure would be $826,650 ($30.00 per hour × 27,555 hours).

We are not proposing to make any changes to our validation procedures. As a result, the burden associated with the validation procedures for the CY 2016 payment determination is the same as for CY 2015 payment determination and is the time and effort necessary to submit supporting medical record documentation for validation. We estimate that it would take each of the sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, we estimate 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). The estimated annual burden associated with the data validation process for the CY 2015 payment determination is approximately 6,000 hours.

In addition, hospitals will incur a financial burden associated with the required information submission requirement. We estimate that the financial burden associated with this measure would be $180,000 ($30.00 per hour $\times$ 6,000 hours).

Reconsideration and Appeals Procedures

While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

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 My 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 provides hospitals with feedback reports about all of the measures.

Hospitals will be reporting outpatient quality data directly to CMS through a CART or My QualityNet as they already do for inpatient quality data. An abstraction tool is under development that is based upon the current tool for collecting inpatient quality data. The tools will be revised as needed and updates will be incorporated.

15. Program or Burden Changes

The program has increased the number of measures included in its data collection requirements. However, the newly proposed measures have data submission via a web-based tool, either

directly to CMS or via the NHSN. These increases are in adherence to section 3013 of ACA which requires CMS to identify gaps where no quality measures exist and existing quality measures that need improvement, updating, or expansion.

16. Publication or Burden Changes

The goal of the data collection is to tabulate and publish hospital specific data. We 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.

17. Expiration Date

We request a 10/31/2015 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.