Supporting Statement – Part A

Submission of Information for the Hospital Outpatient Quality Data Reporting Program

A. Background

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. 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. 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 its releases. The program established under these amendments is referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP).

The submission of outpatient hospital quality of care information builds on the requirement to submit such data for inpatient hospital care as required under 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173). The requirement to submit hospital quality of care information is intended to empower beneficiaries with quality of care information to make more informed decisions about their health care while also encouraging hospitals and clinicians to improve the quality of care.

In the CY 2008 OPPS final rule, seven quality measures are finalized for collection that are believed to be both applicable to care provided in hospital outpatient settings and likely to be sufficiently developed to permit data collections consistent with the timeframes defined by statute. In the proposed rule, hospitals must complete and submit the participation form to report hospital outpatient quality data by January 1, 2008, to report quality data beginning with services that occur in the time period of April 1, 2008 to June 30, 2008. The submission deadline for data for these services will be November 1, 2008; for all submissions, the deadline will be four months after the last day of the calendar quarter. The first five of these measures capture the quality of outpatient care in hospital emergency departments (EDs), specifically for those adult patients with acute myocardial infarction (AMI) or chest pain who are treated and then transferred to anther facility for further care. These five ED-AMI measures have been reported under the Inpatient Prospective Payment System (IPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.

The two remaining quality measures are directly related to surgery performed in the hospital outpatient setting; these measures are derived from measures utilized in the Physician Quality Reporting Initiative (PQRI). PQRI, established under Division B. Title I, Section 101 of the TRCHA, authorizes a financial incentive for eligible professionals to participate in a voluntary quality reporting program. Eligible professionals, who chose to participate and successfully report on a designated set of quality measures for services paid under the Medicare Physician Fee Schedule and provided between July 1 and December 31, 2007, may earn a bonus payment of 1.5% of their charges during that period, subject to a cap.

Proposed Outpatient Hospital Quality Measures for CY 2008 discharges

- ED-AMI-1 – Aspirin at Arrival Pneumonia
- ED-AMI-2 – Median Time to Fibrinolysis
- ED-AMI-3 – Fibrinolytic Therapy Received Within 30 Minutes of Arrival
- ED-AMI-4 – Median Time to Electrocardiogram (ECG)
- PQRI #20 Periperative Care: Timing of Antibiotic Prophylaxis
- PQRI #21 Perioperative Care: Selection of Prophylactic Antibiotic

As required by statute, consensus was reached by affected parties, as the measures were identified as appropriate for reporting on hospital outpatient care in collaboration with professionals and providers with experience in hospital outpatient setting as well as the with Hospital Quality Alliance (HQA). In 2002, the Secretary of HHS entered into collaboration with a hospital-industry led group established to promote voluntary hospital quality improvement and public reporting of hospital quality information. This collaboration is known as the Hospital Quality Alliance (HQA). The collaborators include the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, the Joint Commission on Accreditation of Healthcare Organizations (the Joint Commission), the National Quality Forum (NQF), the American Medical Association, the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons, the American Federation of Labor Congress of Industrial Organizations, the Agency for Healthcare Research and Quality, as well as CMS. Over time, other organizations have joined this collaboration. In addition, all of these measures have also been endorsed by the National Quality Forum (NQF) for the Inpatient or the Ambulatory Setting.

Assuring that Medicare beneficiaries receive the care they need and that such services are of appropriately high quality are the necessary initial steps to the incorporation of value-based purchasing into the OPPS. The goal is to encourage care that is both efficient and of high quality in the hospital outpatient setting through working collaboratively with the hospital community to develop and implement quality measures for the OPPS that are fully and specifically reflective of the quality of hospital outpatient services.

B. 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. 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.

2. Information Users

The information will be made available to hospitals for their use in internal quality improvement initiatives. Most importantly, this information is available to beneficiaries, as well as to the public in general, to provide hospital information to assist them in making decisions about their health care. CMS conducts focus groups or market testing prior to public reporting hospital quality data on the Hospital Compare website on the site's usability.

3. Improved Information Technology

To assist hospitals in this initiative, CMS will be employing the use of a data collection tool that builds on already established tools for data collection including the CMS Abstraction and Reporting Tool (CART). For collection of outpatient quality of care data, a free tool for hospitals for which CMS will provide training will be offered. In addition, the Agency is providing the secure data warehouse and use of the My QualityNet website for storage and transmittal of the 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 arranged for the QIOs to provide technical assistance to hospitals having difficulty with the data collection tool. CMS will work to improve this data collection tool as needed to make data submission easier for hospitals, as well as increase the utility of the data provided by the hospitals.

4. Duplication of Similar Information

The information to be collected is not duplicative of similar information collected by the Centers for Medicare & Medicaid Services. It also does not duplicate other efforts to collect quality of care data for outpatient hospital care.

Effective with fiscal year 2008, hospital will be required to complete and return a written form on which they agree to participate in the Hospital Outpatient Quality Data Reporting Program.

As outlined in the final rule, hospitals must complete and submit the participation form to report hospital outpatient quality data by January 31, 2008 to report quality data beginning with

services that occur from April 1, 2008 to June 30, 2008. The submission deadline for this time period will be November 1, 2008; for all submissions, the deadline will be 4 months after the last day of the calendar quarter.

5. Small Business

Information collection requirements were 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 reliability and validity of any calculated estimates.

7. Special Circumstances

Although participation is voluntary on the part of hospitals, all hospitals must submit this data in order to receive the full OPPS payment update for the given calendar year.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice for this collection published on October 5, 2007.

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 this initiative will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for Quality Improvement Organizations which can be found at 42 CFR Part 480. In addition, the tools used for transmission of data are considered confidential forms of communication and are HIPAA compliant. The clinical warehouse also voluntarily meets or exceeds the HIPAA standards, please see the attached HIPAA compliance summary.

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 all subsequent improvement initiatives derived from this collection and cannot be calculated without the case specific data. This sensitive data will not, however, be released to the public. Only hospital specific data will be released to the public after consent has been received from the hospital for the release. The patient specific data remaining in the data warehouse after the data is aggregated for release for public reporting will continue to be subject to the strict confidentiality regulations in 42 CFR Part 480.

12. Burden Estimate (Total Hours & Wages)

Section 109(a) of the Tax Relief and Health Care Act of 2006 (TRCHA) (Pub. L. 109-432) sets out 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 Data Reporting Program (HOP QDRP).

CY 2009

The burden associated with this section is the time and effort associated with collecting, copying and submitting the data. We estimate that there will be approximately 14,000 responses per year, since 3,500 hospitals are expected to respond on a quarterly basis. All of these hospitals must submit data required for quality measures to receive the annual payment update covering CY 2009.

1,800,000 discharges or episodes of care will be abstracted and submitted by hospitals annually for the outpatient hospital measures. This estimate assumes that hospitals sample at a minimum threshold specified in the most current version of the joint CMS/JC Hospital Quality Measures Specifications Manual.

We estimate that it will take 900,000 hours (30 minutes per sampled discharge/episode of care) to abstract and submit data for these sampled cases. We estimate that hospitals will spend $27,000,000 annually, or $15 per sampled discharge to abstract and report the data.

In addition, newly participating or withdrawing hospitals must complete participation forms; about 4 hours annually for an additional 20 hours. We estimate that hospitals will spend $100 per response, or $500 annually, to complete the form and return it to CMS. All estimates include overhead (e.g. training).

In summary, we estimate that it will take the 3,500 hospital respondents, a total of 900,020 hours (900,000 + 20) the first year to complete all activities in order to abstract and submit the HOP QDRP measures. We estimate that hospitals will spend $27,500 to collect and report all information. The total number of responses for this information collection request is 14,005 (14,000 annual responses for quarterly clinical reporting, and 5 annual participation forms).

CY 2010

The burden associated with this section is the time and effort associated with completing the notice of participation as well as collecting and submitting the data on the seven data abstracted measures. We estimate that there will be approximately 3,500 respondents per year. For

hospitals to collect and submit the information on the required measures, we estimate it will take 30 minutes per sampled case.

In summary, we estimate there will be a total of 1,800,000 cases per year, approximately 514 cases per respondent. The estimated annual burden associated with the aforementioned submission requirements is 900,000 hours ((1,800,000 cases/year) x (0.5 hours/case)).

CY 2011

The burden associated with CY requirements are the time and effort necessary with completing the notice of participation, collecting and submitting the data on seven data abstracted measures, and to submit medical record documentation to a CMS contractor for data validation.

We estimate that there will be approximately 35 hospitals that must submit a new notice of participation form; about 4 hours annually for an additional 140 hours. We estimate that hospitals will spend $100 per response, or $14,400 annually, to complete the form and return it to CMS. All estimates include overhead (e.g. training).

For hospitals to collect and submit the information on the required measures, we estimate it will take 30 minutes per sampled case. Thus, we estimate there will be a total of 1,800,000 cases per year, approximately 514 cases per respondent. The estimated annual burden associated with the aforementioned submission requirements is 900,000 hours ((1,800,000 cases/year) x (0.5 hours/case)).

The burden associated with the CY 2011 validation requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimate that it will take each hospital approximately 38 minutes to comply with these data submission requirements. To comply with the requirements, we estimate each hospital must submit between 2 to 3 cases on average for review.

In summary, we estimate that 3,200 hospitals must comply with these requirements to submit a total of 7,300 charts across all sampled hospitals. The estimated annual burden associated with the data validation process for CY 2011 is 2,026 hours.

Reconsideration and Appeals Procedures

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a mandatory reconsideration process that apply to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. Under this proposed process, the hospitals are required to must meet all of the requirements specified in section XVI.E. of this proposed rule. While there is burden associated with filing a reconsideration request, Section 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment.

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

This is a new information collection. This program change increases data collection requirement for hospitals in order to adhere to Section 109 (a) of the TRHCA. The TRHCA adds to the current hospital reporting initiative and stipulates new data collection requirements.

CMS is reducing the reporting burden for quality of care information collected by allowing hospitals to submit electronic data in lieu of submitting paper charts.

16. Publication or Burden Changes

The goal of the data collection is to tabulate and publish hospital specific data. We will continue to display quality information for public viewing as required by the Deficit Reduction Act (DRA) and 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 12/31/2010 expiration date. We note that few additions of chart abstracted measures for hospitals reporting quality of care data are planned due to the emphasis having moved to claims-based measures. Additionally,

we believe that a three year period is an appropriate time period for this data collection effort, since both CMS and the National Quality Forum regularly review the clinical appropriateness of these quality measures. We regularly review these measures on a semiannual basis to ensure that abstraction instructions, medications, and measure algorithms are consistent with the clinical evidence base. Ten of the eleven measures are endorsed by the National Quality Forum (NQF), and NQF periodically reassesses the endorsement status of quality measures for changes to clinical evidence, linkage to clinical outcomes, and other factors.

18. Certification Statement

We certify that the Hospital Reporting Initiative complies with 5 CFR 1320.9.