

## Supporting Statement – Part A

### Supporting Statement For Paperwork Reduction Act Submissions

#### **A. Background**

The Centers for Medicare and Medicaid Services (CMS) has indicated through statements in proposed and final rulemaking for the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program that it is actively seeking to pursue quality measurement based on alternative sources of data that do not require manual chart abstraction or that utilize data already being reported by many hospitals for other programs, as doing so would potentially reduce the burden associated with the collection and reporting of measures for the program. Over the years, we have encouraged hospitals to take steps toward the adoption of electronic health records (EHRs) that would allow for reporting of clinical quality data from the EHRs directly to a CMS data repository beginning with the FY 2006 Inpatient Prospective Payment System (IPPS) Rule (70 FR 47420 through 47421). We have also encouraged hospitals that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by the Department of Health and Human Services (HHS).

Hospitals should own a system capable of capturing and producing quality measures now or in the future as the ARRA/HITECH legislation allows for incentives to widely implement Electronic Health Records. We stated our intention to explore mechanisms for data submission using EHRs in the FY 2009 IPPS Rule (73 FR 48614) and in the FY 2010 IPPS Rule posted July 31, 2009. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and

the adoption of standards for the capturing, formatting, and transmission of data elements that make up the measures. We believe that EHR submission testing is an important and necessary step toward establishing the ability of EHRs to report clinical quality measures and the capacity of CMS to receive such data. We intend to begin testing the reporting and acceptance of data elements needed to calculate quality measures as early as July 2010.

In September 2008, we initiated work directed toward enabling EHR submission of quality measures through EHR standards development and adoption. We are working under an inter-agency agreement between CMS and the Office of the National Coordinator for Healthcare Information Technology (ONC) to identify and harmonize standards for the EHR-based submission of three NQF endorsed measure sets: Emergency Department (ED) Throughput, Stroke, and Venous Thromboembolism (VTE). Pursuant to this agreement, the Healthcare Information Technology Standards Panel (HITSP) was tasked with harmonizing the EHR data element standards for the measure sets. The proposed interoperable standards (IS 06 version 1.1.1) for these quality measures were posted by HITSP for public review and comment in July 2009 at [http://www.hitsp.org/public\\_review.aspx](http://www.hitsp.org/public_review.aspx). Current HITSP recognized Interoperability Specifications for Quality (standard IS 06 version 1.1 and 1.0) as well as the recently displayed IS 06 version 1.1.1 are currently available at: [http://www.hitsp.org/InteroperabilitySet\\_Details.aspx?MasterIS=true&InteroperabilityId=53&PrefixAlpha=1&APrefix=IS&PrefixNumeric=06](http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=53&PrefixAlpha=1&APrefix=IS&PrefixNumeric=06) .

The final interoperable standards for EHR-based submission of the Emergency Department (ED) Throughput, Stroke, and Venous Thromboembolism (VTE) measures are scheduled to be released by HITSP in late 2009. Once these final interoperable standards for EHR-based submission become available, EHR vendors and hospitals will be able to employ them in EHR systems and begin testing the electronic collection of these data. We intend to move forward

with voluntary testing of CMS' technical ability to accept data from EHRs for the ED, Stroke, and VTE measures as early as July 1, 2010, and intend to follow similar processes and procedures to those used for the Physician Quality Reporting Initiative (PQRI) EHR testing that is currently being conducted. This information collection request describes the application and selection process for EHR vendors and hospitals wishing to participate in the CMS' 2010 voluntary testing program for Inpatient EHR-based submission of data elements needed to calculate 16 quality measures for ED, Stroke, and VTE. The purpose of the program is to evaluate CMS' ability to receive data generated by EHRs accurately. We intend to evaluate success of the program by the number of participants deemed qualified to test CMS systems from which CMS is able to receive timely and valid test data in the format specified by CMS. We do not intend to analyze or publish data submitted by respondents. We only plan to publish the percent of successful participants, and a list of successful participants. Should this change, we would submit another ICR.

It should be noted that though we have previously proposed these measures for the RHQDAPU program, these test measures are not currently required under the RHQDAPU program and EHR test data that is received for these measures will not be used to make RHQDAPU program payment decisions. These non-RHQDAPU measures were selected for EHR testing because electronic specifications have been developed for them, and the selection of measures currently adopted for the RHQDAPU program for this EHR testing program would have created confusion regarding testing requirements and RHQDAPU requirements. In addition, the posting of the electronic specifications for any particular measure should not be interpreted as a signal that we intend to select the measure for inclusion in the RHQDAPU program measure set.

## **B. Justification**

## 1 . Need and Legal Basis

In the IPPS 2010 proposed rule (74 FR 24182), we described our intent to begin a voluntary testing program for the submission to CMS of standardized data elements needed to calculate inpatient hospital quality measures on the topics of Stroke, Venous thromboembolism, and Emergency department throughput. These measures have not been adopted for Reporting Hospital Quality for Annual Payment Update (RHQDAPU) program, and participation in this voluntary EHR-testing program will not substitute for submission of data elements required under the RHQDAPU program in a time, form and manner specified by the Secretary. Similarly, non-participation in this voluntary program will not incur any penalties.

The results of this voluntary testing process will enable CMS to assess the feasibility of collecting data elements via electronic health records as a future alternative to submission of manually chart abstracted data elements by hospitals, thereby potentially reducing the administrative burden associated with submission of quality measures for the RHQDAPU program. After receiving and responding to favorable public comment, we indicated our intent to proceed with the voluntary Inpatient EHR testing program in the IPPS Final Rule published July 31, 2009.

In both the Proposed and Final IPPS rules, we indicated that EHR vendors and hospitals would be able to submit an application to participate in this voluntary program via a self-nomination process, followed by a selection process. We also indicated that prior to beginning EHR testing we would publish a Federal Register notice seeking public comment on 1) the process for self-nomination; 2) the process we intend to follow to select EHR vendors/hospitals, and; 3) the procedure we plan to use for testing EHR-based data submissions.

## 2. Information Users

We intend to select several inpatient EHR vendors and hospitals to test the feasibility of generation and submission of clinical quality data elements for the ED, Stroke, and VTE measures from Electronic Health Records (EHRs) to CMS systems. Below we describe the self-nomination process for inpatient EHR vendors and hospitals wishing to participate in this voluntary testing program in 2010. We also describe the selection criteria that will be used to select applicants for testing of CMS systems, and the testing procedure. Applications can be withdrawn at any time.

### Self-Nomination Process

The self-nomination process will involve 1) submission of a letter of interest 2) submission of an application and supporting information 3) submission of test cases and test extracts in DVD format. Theoretically, this process will span roughly a six month period of time from July through December 2010. Hospitals and vendors will be notified of the opportunity to apply through CMS and industry listserves. Inpatient EHR vendors and hospitals that wish to participate in the 2010 testing process should begin the self-nomination process by sending a letter of interest either by e-mail or regular mail. The letter should be received by CMS by 6 p.m., E.S.T. on **July 1, 2010**. Letters of interest can be e-mailed to [IP\\_EHR\\_Testing@cms.hhs.gov](mailto:IP_EHR_Testing@cms.hhs.gov) or mailed to: “Inpatient EHR Testing Program” Centers for Medicare and Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244-8532.

Following submission of a letter of intent, EHR vendors and hospitals should submit an “Application to Participate in 2010 Voluntary Inpatient EHR Testing Program” by **August 1**,

**2010.** This form, currently pending OMB approval, will be made available in draft form on the [www.cms.hhs.gov/HospitalQualityInits/](http://www.cms.hhs.gov/HospitalQualityInits/) webpage. Additional documentation submitted in support of responses on the application (such as 2010 IHE Connectathon Results) should be submitted by **September 1, 2010**. Applicants will be expected to attend one to two conference calls per month, such as individual calls to obtain clarification on application responses or documentation, and all-applicant kickoff calls or support calls. Dates for individual applicant calls will be negotiated with the applicant, while dates for kickoff or support calls will be announced in advance on the [www.cms.hhs.gov/HospitalQualityInits/](http://www.cms.hhs.gov/HospitalQualityInits/) webpage.

Applicants will also be required to submit test cases and test data extracts as a prerequisite to being selected to transmit data extracts to CMS via a Portal and Gateway. Applicants will be required to submit 30 full patient test cases as would be captured in their EHR product for each of the three measure sets: ED, Stroke, and VTE. These test cases will be due to CMS by **November 1, 2010**, and will be used by CMS for verification purposes. Applicants should submit documentation describing how the test cases were generated.

Applicants will also be required to submit extracts of the patient-level data elements needed to calculate the ED Stroke and VTE measures as specified in the HITSP standards based on the test cases submitted to CMS. As mentioned earlier, the test cases will be used to verify the test extracts. These test extracts will be due to CMS by **December 1, 2010**. Both the test cases and the test extracts should be submitted to CMS on DVD.

Further details regarding application dates, submission of test cases and test data extracts, and all-applicant support calls and will be made available on the [www.cms.hhs.gov/HospitalQualityInits/](http://www.cms.hhs.gov/HospitalQualityInits/) webpage.

### Selection Process

We anticipate being able to notify applicants individually of their eligibility to participate in testing the transmission of EHR-based data elements to CMS systems by January 1, 2011.

Selection for participation will be depend upon:

- Successful completion of all self nomination milestones on time
- Responses and details provided on the application
- Supporting documentation submitted for the application
- Ability of the applicant to regularly attend all-applicant kickoff meetings and support calls
- Successful submission of 30 test cases
- Successful submission of data extracts that contain relevant data elements for the ED, Stroke and VTE measures
- Verification of test data extracts against the test cases submitted.

Some preference may be given to EHR vendors/hospitals with products which have been:

- Certified by the CCHIT
- Used to generate other quality measures
- Used to submit information via the Nationwide Health Information Network (NHIN)
- Successful in completion of IHE Connectathon 2010.

EHR vendors/hospitals that anticipate eligibility for participation in testing the submission of inpatient EHR data to the CMS-designated clinical data repository should update their EHR

products or otherwise ensure that those products can capture and submit the necessary data elements identified for an EHR-based submission once the standardized format has been finalized. We suggest that entities selected to test submission of CMS systems begin submitting EHR data promptly after CMS announces that the clinical data repository is ready to accept such data so that problems that may complicate or preclude a successful quality measure data submission can be corrected.

### Testing Process

We anticipate that testing transmission of data elements to CMS systems will occur between March and June 2011. Applicants that receive notification of eligibility to participate in testing transmission of data extracts will need to establish an IACS account with CMS (more information regarding this will be provided to those applicants who are selected to participate in CMS systems testing). This will enable the Vendor/Hospital to transmit the previously verified data extracts to CMS systems. Ultimately, CMS will receive the data extracts in its data warehouse, and will calculate quality measures from the data elements submitted. Vendors and hospitals that have the capacity to submit the data extract to CMS via a portal will be asked to do so.

### 3. Use of Information Technology

The application and testing process for voluntary Inpatient EHR testing is expected to be conducted 85% electronically. The self nomination letter can be submitted electronically, and the application form and supporting documentation can be submitted electronically and we expect that the majority of applicants will submit their self-nominations, applications and supporting documentation via e-mail. Prior to selection of applicants for direct electronic



submission we will be requesting that the test cases and test data extracts be mailed to CMS on DVD to test the applicant's ability to generate data elements accurately and in a format that CMS can decode and use to calculate quality measures. After successfully meeting this requirement, applicants would proceed to transmit data extracts via a designated system to CMS 100% electronically.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This information collection request does not have a significant impact on small businesses.

6. Less Frequent Collection

Collection of information for Inpatient EHR testing is anticipated to occur occasionally (no more than once a year) in order to enable CMS to test system readiness to accept EHR-based submissions of quality measures. Less frequent collection would jeopardize CMS efforts to offer an alternative, less burdensome means for hospital inpatient departments to submit data elements needed to calculate chart abstracted measures for inpatient quality data reporting programs.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;

- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on August 6, 2009.

9. Payments/Gifts to Respondents

None

10. Confidentiality

We pledge to hold respondent information private to the extent possible by law.

11. Sensitive Questions

None.

12. Burden Estimates (Hours & Wages)

For the voluntary Inpatient EHR Testing program, we estimate a total of 55 applicants for 2010. We anticipate that prior to self-nomination, potential applicants will have examined the specifications for the 16 ED, Stroke, and VTE measures for which electronic standards are available, and will have assessed their ability to capture, generate and submit data elements needed to calculate the 16 measures using their Inpatient EHR product. We anticipate that the types of applicants we will receive will be large EHR vendors with Inpatient EHR products and large Hospitals who have developed their own inpatient EHR systems. We estimated the burden hours for the tasks associated with submitting an application to participate and successfully participating in the 2010 voluntary EHR testing program as shown in Table 1 below.

**Table 1. Burden Hours per applicant**

	<b>Burden Hour Estimate</b>
Self Nomination Letter	10
Submission of Application Form	10
Submission of Supporting Documentation for Application	40
Clarification questions	40
Support Calls	25
Generation of Test Cases	40
Extract Test Data from EHR System	160
Generation and Submission of Test Extract on DVD	80
Apply for Access to CMS Systems	16

Submit Data Extract via Portal	40
Setting up system to pull dummy vs. real data	20
Correction and Resubmission of data	40
<b>Total</b>	<b>521</b>

Though programming of Inpatient EHR products is expected to have occurred prior to submission of an application, we anticipate that some programming refinement may be needed prior to testing, and we have included programming refinement burden hours into support calls, generation and submission of test cases, and generation and submission of test extract. We also estimate that the average hourly wage for staff involved in these tasks for EHR testing is \$50 per hour. Therefore, the cost associated with participating in 2010 voluntary EHR testing is estimated at \$26,050.00 (\$50 per hour x 521 hours per applicant). Based on the assumptions discussed above and shown in Table 1, we provide an estimate of total annual burden hours and total annual cost burden associated with an Inpatient EHR vendor or hospital self-nominating to participate and successfully participating in voluntary 2010 inpatient EHR testing.

**Table 2. Total Annual Burden Hours and Cost**

	<b>Burden Estimate</b>
<b>Estimated # of EHR Vendors and Hospitals Self-Nominating for 2010 voluntary inpatient EHR testing (a)</b>	55
<b>Estimated Total Annual Burden Hours Per applicant (b)</b>	521
<b>Estimated Total Annual Burden Hours for EHR Vendors and hospitals (c) = (a)*(b)</b>	<b>28,655</b>
<b>Estimated Cost Per applicant (d)</b>	\$26,050
<b>Estimated Total Annual Burden Cost for EHR Vendors and</b>	<b>\$1,432,750</b>

<b>hospitals (e) = (a)*(d)</b>	
--------------------------------	--

### 13. Capital Costs

CMS requirements do not require the acquisition of new systems or the development of new technology to participate in the 2010 voluntary inpatient EHR testing program. Participants should not need to hire additional staff in order to participate. However, we anticipate that participants will need to refine the programming of their EHR products once final HITSP standards become available in late 2009 in order to successfully participate. It is also possible that some participants may need to perform systems upgrades in order to successfully participate.

### 14. Cost to Federal Government

We anticipate that the cost to the Government to conduct voluntary Inpatient EHR Testing of quality measure submission will be \$2.5 Million. This cost accounts for the following:

- Vetting of applicants over 5 month period
- QIO data warehouse infrastructure upgrade
- Decoding DVD extracts
- Use of Patient Test Files to verify DVD test extracts
- Resubmission of test files and extracts (as needed)
- Calculation of numerator, denominator and exclusion flags from test extracts
- Support Calls with participants and troubleshooting
- Coordination of applications for portal system accounts to submit test data
- Resubmission of test extracts (as needed)
- Retrieval of data from portal accounts
- Data processing (Calculation of numerator, denominator and exclusion flags from portal test data)

### 15. Changes to Burden

This is a new information collection.

### 16. Publication/Tabulation Dates

CMS will post on the Hospital Quality Initiatives website at

<http://www.cms.hhs.gov/HospitalQualityInits/> the names of those Inpatient EHR vendors (and their products) and Hospitals that successfully complete the 2010 voluntary Inpatient EHR testing program. We anticipate being able to post this information by December 31, 2010.

17. Expiration Date

CMS would like approval for this information collection for a period of 3 years from the date of publication of the final notice. We will display the expiration date on information collection instruments. We anticipate an expiration date of May 2013

18. Certification Statement

There are no exceptions to the certification statement.