Supporting Statement for Paperwork Reduction Act Submissions

A. Background

The goal of the Electronic Health Record (EHR) Demonstration is to foster the implementation and adoption of EHRs and Health Information Technology (HIT) more broadly as effective vehicles improve the quality of care provided and transform the way medicine is practiced and delivered. Adoption of HIT has the potential to provide significant savings to the Medicare program and improve the quality of care rendered to Medicare beneficiaries. This demonstration is designed to leverage the combined forces of private and public payers to drive physician practices to widespread adoption and use of EHRs. Implementation of this demonstration was a major Secretarial initiative and in February 2008, the Office of Management and Budget (OMB) gave the Centers for Medicare & Medicaid Services (CMS) the approval to proceed with implementation.

As part of this new demonstration, all participating primary care physician practices will be required to have a Certification Commission for Healthcare Information Technology (CCHIT)-certified EHR by the end of the second year. (CCHIT is the current recognized certification authority for EHRs and their networks.) Physician practices must, as part of the demonstration, utilize the EHR to perform specific minimum core functionalities that can positively impact patient care processes (e.g., clinical documentation, ordering of lab tests, recording lab tests, and recording of prescriptions). However, the core incentive payment will be based on performance on the quality measures with an enhanced bonus based on the degree of HIT functionality used to manage care.

The demonstration is being implemented in four sites, including: Louisiana, Southwest Pennsylvania (11 counties surrounding Pittsburgh), South Dakota (and some counties in bordering states), Maryland, and the District of Columbia. These four locations were initially planned to be part of Phase 1 of the demonstration. Plans to implement a second phase of the demonstration in eight additional locations were cancelled as a result of passage of the American Recovery and Reinvestment Act of 2009. However, because of the earlier timeframe for Phase 1 of the demonstration and the important data on meaningful use of EHRs that this demonstration could provide, implementation of Phase 1 of the demonstration proceeded as initially planned.

Enrollment for Phase 1 of the demonstration, which included the four sites referenced above, was completed in the fall of 2008 using a manual or paper application process that was previously approved by OMB. Approximately 400 practices are now participating in the demonstration with an additional 400 practices being assigned to the control group.

The new electronic EHR Demonstration system was first developed with the intention of having practices applying to participate in Phase 2 of the demonstration to use an on-line application form, rather than the currently approved paper application form that was used for Phase 1. However, with the cancellation of Phase 2, the system will not be used to collect new applications at this time. Instead, existing data on Phase 1 applications that was collected through the paper form and manually keyed into a PC-based Access database will be transferred to the new system. Practices participating in Phase 1 of the demonstration will be requested to use the new system to provide updated information about their practices as needed during the course of the demonstration.

The demonstration started June 1, 2009, and will continue through May 31, 2014. Throughout the 5 years of the demonstration it will be critical to be able to track accurately and on a timely basis updates to practice information. This may include providers joining or leaving the practice, changes in key identification numbers such as tax identification numbers (TINs) and national provider identifiers, new administrative contacts, changes in phone numbers and addresses, etc. Currently this is done by our contractors using a PC-based system which requires practices to send letters or other means of written communication to notify the Centers for Medicare & Medicaid Services (CMS) of updates. Often practices inadvertently send CMS sensitive information through channels such as internet email that is not secure. The EHR Demonstration system will enable practices to update critical demonstration information on line in a secure, web-enabled environment, thereby facilitating timely and more accurate updates and processing of information. We have learned through this and other similar demonstrations that a lack of timely updates can have a significant adverse impact on demonstration operations which, in turn, can negatively impact the potential incentive payment practices can earn under the demonstration.

Thus, the EHR Demonstration system (EHRDS) does not reflect a request for new or additional data beyond what practices are already providing to CMS and its contractors. Rather, it represents an effort to streamline and improve what has been more ‘ad hoc’ in terms of format for providing the same information.

The attached copies of screen prints of the system represent what an on-line user of the system will see. Depending upon what information a practice is updating, they may see/input data on only some of these screens.

The justifications provided below show that proposed collection for information pose minimal risk to the Agency, Administration, and/or the Public.

B. Justification

1. Need and Legal Basis

The EHR Demonstration is a major Secretarial priority being conducted under Medicare's waiver authority as provided in section 402 of Public Law 90-248, as amended (42 U.S.C. 1395b-1). Specifically, under 402(a) (1), the Secretary is authorized to develop and engage in demonstrations:

> "…to determine whether, and if so which, changes in method of payment or reimbursement…for health care and services under health programs established by the Social Security Act, including a change to methods based on negotiated rates, would have the effect of increasing efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services…."

Section 402(b) allows the Secretary to waive requirements in Title XVIII relating to reimbursement and payment.

The information being collected and updated has already been approved for collection using a paper form (Form CMS-10165 (8-2008). The valid Office of Management and Budget (OMB) control number for the manual (paper application) information collection is 0938-0965.

2. Information Users

The proposed collection of information is strictly voluntary and only organizations that are participating in the demonstration will be asked to use the system. Practices that wish to continue to notify us in writing through more traditional methods (e.g., U.S. mail) and have CMS and/or its contractors update their data in the system for them will still have that option and may continue to do so without penalty. In addition, CMS will not be using this information to regulate and/or sanction but rather to operate a demonstration in which participating practices are eligible to receive significant financial incentives for adopting an EHR and improving the quality of care to patients.

3. Use of Information Technology (IT)

The collection of information will be done using a secure, web-enabled system developed specifically for this demonstration. The application and collected data therein will be stored on CMS systems that meet all applicable security requirements.

Currently a PC-based system is used to track practice information. Web-enabling the form will make it easier for practices to access their practice-specific information and submit and track updates on a timely basis.

3. Duplication of Efforts

   There is no duplication of effort involved.

4. Small Businesses

   The only small businesses affected by this effort will be those small or medium-sized physician practices (<= 20 providers) that are voluntarily participating in the demonstration.

5. Less Frequent Collection

   Practices will update information on an as needed basis. This may vary from not at all for some practices to several times a year for others. On average, however, we estimate that each practice will use the system once per year to provide updated information. Although we do not expect many will elect to continue with the current manual notification process, practices that wish to continue to use the existing process may do so without penalty. In such cases CMS and/or its contractors will enter the information directly into the new system for the practices.

6. Special Circumstances

   The EHR Demonstration is a top Administration and bipartisan congressional priority. This demonstration has already been approved by OMB and is expected to produce savings to the Medicare program, as well as reward high quality providers. Only those practices participating in the demonstration will be asked to use the new system. Practices are currently asked to submit updates whenever they occur; failure to do so on a timely basis may reduce incentive payments to the practice due to our having incomplete and/or incorrect provider information. Thus, this data collection is not a new requirement and practices are not being asked to supply new data. Rather, it reflects a change and significant improvement in how this information is collected and stored.

7. *Federal Register*/Outside Consultation

   A 60-day *Federal Register* notice was published on April 30, 2010, no comments were received.

   The *Federal Register* notice soliciting public comment for the collection of this information using a paper form was originally published on November 29, 2007. One comment was received; however, it was not relevant to the proposed data collection. A subsequent notice was published on February 15, 2008.

8. Payments/Gifts to Respondents

There will be no payments or gifts to respondents for the collection of information. Using the information collected and maintained in the EHR Demonstration system, CMS will be able to administer the demonstration more effectively, thereby enabling participating practices to earn incentive payments.

9. Confidentiality

The collection of information will be done using a secure, web-enabled application form developed specifically for this demonstration. The data will be stored in CMS systems that meet all applicable security requirements.

As a matter of policy, CMS will prevent the disclosure of personally-identifiable information, i.e., TIN and Medicare Provider Identification Number. In addition, no personally identifiable information at the beneficiary, provider, or practice level will be made publicly available as part of the independent evaluation of the demonstration that will be conducted. All data presented in the evaluation will be aggregated to protect disclosure of such confidential information.

10. Sensitive Questions

Other than the information noted above in section 10, there are no sensitive questions included in the information request.

11. Burden Estimates (Hours & Wages)

The total burden estimate is summarized below. Projected costs are based on the following assumptions:

Participating practices:	400
Estimated annual average use over 5 years	313
Time per practice update:	10 minutes (.167 hour)
Estimated staff cost per hour to update:	$25
Cost/Year:	313 responses x (.167 hours/response x $25/hour) = $1,308

(The number of average annual responses is reduced based on the usage for 6 months in year 01 and 5 months in year 05. See item #10, above)

Total Cost Over 5 Years of Demo: 5 years x $1,308 = $6540

12. Capital Costs

There is no capital cost required of practices participating in this demonstration uniquely for submitting this data. The application will be available on a CMS web site accessible by any computer.

13. Cost to Federal Government

The costs to the Federal Government to implement this data collection effort include the cost of web enabling and developing the secure systems to host and store the data, as well as ongoing maintenance. Total costs for development are estimated at $4.4 million. Ongoing annual operational costs are estimated at $246,000.

It should be noted that while all of the development costs are being reflected above, this system is expected to serve as the platform for other demonstration and program-wide initiatives. No costs have been allocated to such unspecified future projects although this project does represent a significant investment in CMS' future capabilities.

14. Changes to Burden

This demonstration was approved by the Office of Management and Budget (OMB) in February 2008 and started on June 1, 2009. The original PRA approval related to this package was for the paper application form which was completed once (in the fall of 2008) by practices wishing to participate in this demonstration. The "currently approved" column in the table under Item 12 shows the approved burden for the one time collection of information on the paper application form.

Now that the demonstration is operational with approximately 400 practices participating in the treatment group, we need to be able to have accurate and timely updates to some of the data that was originally submitted on the paper application form. Practices may use the new system on an "as needed" basis. For some practices there may be no updates at all during the course of a given year. Other practices may provide updates several times in a year. Practices that wish to continue to send written notification to CMS and/or its contractors to update data (i.e. who do not wish to go on-line to update their data) will not be penalized for doing so. For purposes of calculating the burden, we estimate that each practice participating in the demonstration will update their data once per year during the course of the demonstration.

Thus, while we note in item #12 of the Paper Reduction Act Submission Worksheet/Part II: Information Collection Detail, the time that practices are expected to spend annually using the new system, we have also noted that this does not represent a new requirement. Practices are already submitting this data to CMS and/or its contractors on an 'ad hoc' basis in a variety of formats including via U.S. mail, email, etc. Thus, the net effect on practices

participating in the demonstration is expected to be minimal.

15. Publication/Tabulation Dates

There will be no publication of individual provider or practice-specific data. Any use of this data will be summarized and published only on an aggregate basis. These reports will be prepared by an independent contractor under the guidance of CMS staff.

17. Expiration Date

CMS would like approval to use this data collection tool for 3 years after the approval date. The expiration date would be printed on the data collection log-on screen (See sample screens).

18. Certification Statement

There are no exceptions to the certification statement.