Supporting Statement for Paperwork Reduction Act Submissions
Specific Instructions

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.

As part of the implementation of this demonstration, several key functions were automated. A new electronic EHR demonstration "Practice Application and Profile" system (EHRDS) was developed to help manage practice and provider data for this system. OMB approval for this system was covered under OMB Control Number 0938-0965 granted October 18, 2010.

The second module of EHRDS to be developed is for the collection of ambulatory clinical quality measures. Starting in the fall of 2011, the 400 treatment group practices will be required to report 26 clinical quality measures on an annual basis for years two through five of the demonstration. The original method for collecting quality measure data in the Physician Group Practice (PGP), Medicare Care Management Performance (MCMP) and Electronic Health Records (EHR) Demonstrations was approved under OMB Control Number 0938-0941(expiration date: January 31, 2012). This is the "Performance Assessment Tool" (PAT). The second EHRDs module was developed to replace the original PAT with a web enabled, secure (3-zone architecture) methodology for collecting the same exact data. This current request for approval under the Paperwork Reduction Act is for this web-enabled version of PAT and extension of the expiration date to cover the next three years of data collection under the EHR Demonstration. The EHR Demonstration system (EHRDS) PAT module does not reflect a request for new or additional data beyond what has been previously approved. There should be no increase in burden for respondents. In fact, because all of the practices participating in the EHR Demonstration and submitting data will have EHRs, it is possible that the originally estimated burden will decrease.

The attached copies of screen prints of the system represent what an on-line user of the system will see

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. The valid Office of Management and Budget (OMB) control number for the manual (paper application) information collection is 0938-0941.

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. 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.

4. Duplication of Efforts

There is no duplication of effort involved.

5. 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.

6. Less Frequent Collection

The information is to be collected on an annual basis. If the information were collected less frequently, CMS would not be able to obtain the information necessary to process payments

and otherwise implement and evaluate this demonstration.

7. 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. 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.

8. *Federal Register*/Outside Consultation

The 60-day Federal Register notice published on March 11, 2011.

The existing tool has been used successfully with over 600 practices in the MCMP and PGP demonstrations. The new tool will function in a manner almost identical to the currently used tool with the exception that it will be web-enabled, hosted on CMS computers, and meet all federal security requirements.

9. Payments/Gifts to Respondents

There will be no payments or gifts to respondents for the collection of information. However, based on how well physician practices electing to participate in the demonstration perform on the clinical measures, they will be eligible to earn incentive payments under the terms of the demonstration.
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10. 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, (e.g., TIN and Medicare Provider Identification Number for providers; Medicare HIC, date of birth, for beneficiaries, etc.). 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 private information to the fullest extent provided by law..

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

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

Participating Practices	400
Time per practice to update	24 hours per submission
Frequency of Updates	Once per year for 4 years (Reporting occurs after years 2,3,4 & 5 of the demonstration)
Estimated staff cost per hour to update	$55 /hour
Cost per year per practice	$1320.00
Total Cost per year (all practices)	$528,000.00

Please note that the burden estimated above represents no change from the burden estimated and approved under OMB 0938-0941for the EHR Demonstration.

13. 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.

14. 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 $2 million. Ongoing annual operational costs are estimated at $400,000.

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.

15. Changes to Burden

There is no projected change in the estimated burden for practices participating in the EHR Demonstration from the burden estimated and approved under OMB 0938-0941 January 8, 2009. Rather this request reflects a change in the structure of the tool being used from one that is written in Access and downloaded through QNet (a secure email transmission system used by the QIOs) to one that is web based and hosted by CMS computers in a secure 3-zone environment meeting all federal security requirements.

16. 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.