Supporting Statement For Paperwork Reduction Act Submissions

Specific Instructions

A. Background

The Centers for Medicare & Medicaid Services (CMS) is requesting an extension of a currently approved tool for the collection of ambulatory care clinical performance measure data for the Office of Management and Budget (OMB) approved Medicare Demonstrations. The data will be used to continue implementation of two congressionally-mandated demonstration projects (the Physician Group Practice (PGP) Demonstration and the Medicare Care Management Performance (MCMP) Demonstration) and starting in 2011, support data collection under the new Electronic Health Records (EHR) Demonstration, an Administration high priority demonstration. Each of these demonstrations, test new payment methods for improving the quality and efficiency of health care services delivered to Medicare fee-for-service (FFS) beneficiaries, especially those with chronic conditions that account for a disproportionate share of Medicare expenditures. In addition, the MCMP and EHR Demonstrations specifically encourage the adoption of EHR systems as a vehicle for improving how health care is delivered. *The data collection tool ("PAT for Performance Assessment Tool) that we are seeking an extension for is not an EHR. Rather it is an Access form and database used to collect numerator and denominator information required to calculate specific clinical quality measures.*

The PGP Demonstration was the first pay-for-performance (P4P) initiative for physicians under the Medicare program. The demonstration rewards physicians for improving the quality and cost efficiency of health care services delivered to the Medicare FFS population. Mandated by section 412 of the Medicare, Medicaid, and SCHIP Benefits Improvement, and Protection Act of 2000, the goals of the demonstration are to encourage coordination of Part A and Part B services; promote cost efficiency and effectiveness through investment in care management programs, process redesign, and tools for physicians and their clinical care teams; and reward physicians for improving health outcomes. Payments under this demonstration are contingent upon achieving savings as well as targeted quality performance levels. PAT is used to collect the clinical quality data which is used to determine payment.

The MCMP Demonstration was authorized under section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This is a 3-year P4P pilot with physicians to promote the adoption and use of health information technology (HIT) to improve the quality of patient care for chronically ill Medicare patients. Doctors who meet or exceed performance standards established by CMS in clinical delivery systems and patient outcomes will receive additional payments for managing the care of eligible Medicare beneficiaries. In contrast to the PGP Demonstration which involves 10 large multi-specialty group practices, the MCMP Demonstration is focused on small to medium-sized primary care physicians. Approximately 650 practices in Arkansas, California, Utah, and Massachusetts are currently

participating in this demonstration which began operations on July 1, 2007. PAT is used to collect the clinical quality data that is needed to determine incentive payments for this demonstration as well.

More recently, the Secretary of Health and Human Services directed CMS to develop a new demonstration initiative using Medicare waiver authority to reward the delivery of high-quality care supported by the adoption and use of EHR. The goal of this demonstration is to foster the implementation and adoption of EHRs and 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. *However, it should be noted that CMS is not creating an EHR. Nor does the PAT tool, which is being used to facilitate the collection of data and calculation of clinical quality measure scores, serve as or substitute for an EHR.*

As part of this new demonstration, all participating 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 recognized certification authority for EHRs and their networks. However, there are numerous CCHIT-certified EHRs available in the market and the choice of the EHR is up to the individual practice. CMS will not be creating a separate EHR under this data collection effort. Physician practices must, as part of the demonstration, be utilizing their selected 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 ordering 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 coordinate care. Practices participating in this new demonstration will report the same clinical quality measures using the same core data collection methodology and tool as the PGP and MCMP Demonstrations. Although this demonstration will be operational in 2009, the first clinical data collection effort will not take place until the fall of 2011, the third year for which this Paperwork Reduction Act (PRA) approval is being sought. PAT will be used to facilitate collection and scoring of the clinical quality measure data.

The proposed ambulatory care measures being used were developed by CMS in conjunction with the American Medical Association's Physician Consortium for Performance Improvement and the National Committee for Quality Assurance. CMS worked directly with the industry and participants in the PGP Demonstration to minimize administrative burden and to align the measures with those used by commercial payers.

This renewal consolidates two existing PRA-approved electronic reporting tools into a single renewal package that will govern "PAT," the electronic reporting tool. PAT would be used to continue to collect clinical information under these two continuing and one new physician P4P demonstrations, which have been approved by OMB.

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

B. Justification

1. Need and Legal Basis

The three demonstrations for which this extension is being sought are considered a high priority for the Administration and Congress. Two of the demonstrations are being carried out under congressional mandate. The PGP Demonstration was mandated by section 412 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. The MCMP Demonstration was mandated under section 649 of the MMA. The EHR Demonstration is a major Secretarial priority being conducted under Medicare's waiver authority (Section 402(1) (1) of PL 90-248 (42 U.S.C. 1395b-1)).

2. Information Users

The proposed collection of information is strictly voluntary in nature and was developed in conjunction with the industry and demonstration participants. Only organizations that voluntarily respond and elect to participate in the demonstrations will be reporting the measures. Moreover, CMS will not be using this information to regulate and/or sanction but rather to provide financial incentives for improving the quality of care.

It should be emphasized that CMS is not creating an EHR. Rather, PAT is used to facilitate collection and scoring of the clinical quality measure data which can be provided by a physician practice from either a paper chart of an EHR system.

The collection of information to be used under this extension is being used to test quality data collection systems and determine incentive payment levels to participating physician practices participating in the PGP and MCMP Demonstrations. It will similarly be used when the EHR Demonstration is implemented.

In addition, this data will be used to evaluate the effectiveness of these payment models and provide insight into the most appropriate way for the agency to collect clinical information. Each of the demonstrations will be reviewed by an independent evaluation contractor. As congressionally-mandated demonstrations, both the PGP and MCMP Demonstrations have mandated reports to Congress and this data will be critical to those evaluations and reports.

3. Use of Information Technology (IT)

The collection of information will be done using an automated, electronic tool developed and refined with industry input. Referred to as "PAT," it was developed explicitly for these demonstrations and has been used successfully over the past 3 years. It should be

emphasized that CMS is not creating an EHR. Rather, PAT is used to facilitate collection and scoring of the clinical quality measure data which can be provided by a physician practice from either a paper chart of an EHR system. Initially, PAT will be pre-populated by our contractor based on claims data. Demonstration participants will only have to provide information that is available only from a medical record. The tool will reduce the administrative burden in collecting and reporting information.

Practices participating in the demonstration may input the data directly into the tool using their computer or, alternatively, the tool is able to import data electronically from an EHR, patient registry, or other electronic file. In the MCMP Demonstration, practices that submit the data electronically from a CCHIT-certified EHR are eligible for additional financial incentives. Once completed, the PAT file is then returned to CMS for scoring using "Quality Net Exchange," a secure method for transmitting data that is approved for use by the Quality Improvement Organizations.

4. Duplication of Efforts

The collected information will be used by CMS to demonstrate alternative physician payment models that might move CMS further in the direction of being a value-based payer and achieving its vision of capturing clinical information from providers for use in payment policy. In 2007, after CMS had already implemented the PGP and MCMP Demonstrations, CMS began a Physician Quality Reporting Initiative (PQRI) in which all Medicare physicians could participate. This latter program collects data via the submission of special codes on Medicare claims, whereas these demonstrations are testing alternative payment models using more sophisticated methodologies for use in calculating quality measures. In addition, the demonstrations reward not just the reporting of data but actual performance by physicians on quality-related process and outcome measures. Nonetheless, CMS recognizes the importance of minimizing reporting burden on physicians. Towards this end, in 2007 CMS' Office of Research, Development, and Information sought, and were granted from OMB, a waiver for practices participating in demonstrations that would allow these practices to earn PQRI incentives as well as demonstration payments through their participation in the demonstration. By doing so, we are rewarding those practices that have voluntarily agreed to participate in the demonstration and reduced the reporting burden they would otherwise have had if they had to submit duplicate clinical quality data using two different systems.

5. Small Businesses

The only small businesses affected by this effort will be those small or medium-sized PGPs that voluntarily elect to participate in the demonstrations. The MCMP Demonstration involves small to medium-sized primary care practices with 10 or fewer physicians. The EHR Demonstration will be focused on primary care practices with 20 or fewer providers. While some of these practices are affiliated with larger organizations, many are small businesses consisting of one or only a few physicians and their office staff. To assist

practices participating in the demonstration, we have contractors who are available to provide technical assistance in using PAT. Our experience, to date, is that PAT is user-friendly for practices. Again, participation in all of these demonstrations is voluntary.

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 these congressionally-mandated and high priority demonstrations.

7. Special Circumstances

The PGP and MCMP Demonstrations are congressionally-mandated demonstrations. The EHR Demonstration is a top Administration and Secretarial priority. All of these demonstrations have been approved by OMB and are expected to produce savings to the Medicare program as well as reward high quality providers. Only those practices volunteering to participate will be required to submit the requested information. Practices generally have 8-10 weeks to submit this data. We reiterate that CMS is not creating an EHR. Rather, PAT is used to facilitate collection and scoring of the clinical quality measure data.

8. *Federal Register*/Outside Consultation

The Emergency *Federal Register* notice soliciting public comment for this collection was originally published on August 19, 2005. A subsequent notice was published on June 26, 2008.

CMS consulted with key stakeholders in designing and implementing the standardized quality measures to be used in this demonstration and reported as part of this data collection effort. For example, the standardized ambulatory care measures were developed by CMS in conjunction with the American Medical Association's Physician Consortium for Performance Improvement and the National Committee for Quality Assurance. The data being collected for the MCMP Demonstration is substantially the same as that being collected for the PGP Demonstration and reflects a consensus agreement between physicians and CMS, as well as comments and suggestions offered by stakeholders during the consultative process. In addition, over the past 3 years, in response to comments and suggestions by practices participating in the demonstrations, we have provided additional pre-populated data in the tool, reports to facilitate their data collection efforts, and refinements to PAT to minimize administrative burden. We have also worked with IT staff and the practices and EHR vendors to make the measures specifications available so that practices could more readily create files from their EHRs that the data collection tool could import electronically, thereby reducing the amount of manual effort involved. The data

being collected for the EHR Demonstration, starting in 2011, will be the same as that for the MCMP Demonstration.

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.

10. Confidentiality

As a matter of policy, CMS will prevent the disclosure of personally identifiable information contained in the data submitted. It should be emphasized that we are not creating a comprehensive EHR or an individual personalized health record for beneficiaries as part of these demonstrations. Rather, PAT is being used to facilitate the collection and scoring of clinical quality measure data. Moreover, any reports pertaining to the collected information by an independent evaluator will be in aggregate and anonymous form. Neither individual specific nor practice specific data will be published.

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 annual burden estimate is calculated separately for each of the demonstrations and is summarized in the table provided.

The estimate is based on the number of participating physician practices in each demonstration, the estimated number of hours to load PAT, the estimated hourly cost including fringe benefits, and when reporting will begin. For all of the demonstrations, practices will only have to report once each year and we assume an average hourly personnel cost of $55.

The PGP Demonstration involves 10 very large multi-specialty group practices. Because of the size of these practices and the number of patients they serve, it is expected that it will take 79 hours, on average, per respondent.

The MCMP Demonstration involves 650 small to medium sized primary care practices. Because these practices each serve fewer patients, it is expected that reporting will take only 24 hours on average per response.

The EHR Demonstration will not begin collecting clinical quality data until 2011. Although that demonstration will ultimately involve 1,200 small to medium-sized primary care practices, it will be implemented in phases. Phase I will include 400 practices and will conduct its first clinical data collection period in 2011. Phase II will include the remaining 800 practices but will not collect clinical data collection until the following year.

Based on the above assumptions, we estimate the total burden for 2009 through 2011 to be as follows:

Demonstration	# Respondants per Year					Total Cost Per Year		
	2009	2010	2011	Hours/ Response	Cost/ Hour	2009	2010	2011
PGP Demonstration	10	10	10	79	$ 55	$ 43,450	$ 43,450	$ 43,450
MCMP Demonstration	650	650	650	24	$ 55	$ 858,000	$ 858,000	$ 858,000
EHR Demonstration	0	0	400	24	$ 55	$ -	$ -	$ 528,000
Total	660	660	1060			$ 901,450.00	$901,450.00	$ 1,429,450.00

13. Capital Costs

There is no capital costs required for the collection of this information. The data abstraction tool will be provided to demonstration participants at no cost. Demonstration participants will not be required to purchase or maintain any systems or capital equipment solely for the collection of this data.

14. Cost to Federal Government

The costs to the Federal Government to implement this data collection effort include CMS staff resources to manage the project (.35 full-time equivalent per demonstration per year) and contractor costs (paid for under CMS' administrative budget) to collect the data, program reports, and provide technical assistance to practices participating in the demonstration. The difference in contracting costs per demonstration is a function of the number of practices participating in each demonstration, as well as the level of technical assistance required for the specific demonstration.

		PGP Demonstration	MCMP Demonstration	EHR Demonstration	TOTAL
CMS Staff*	2009	$ 52,500	$ 52,500		$ 105,000
	2010	$ 54,075	$ 54,075		$ 108,150
	2011	$ 55,697	$ 55,697	$ 55,697	$ 167,092
Contractor Costs	2009	$ 240,000	$ 450,000		$ 690,000
	2010	$ 240,000	$ 450,000		$ 690,000
	2011	$ 240,000	$ 450,000	$ 268,366	$ 958,366
Total	2009	$ 292,500	$ 502,500	$ -	$ 795,000
	2010	$ 294,075	$ 504,075	$ -	$ 798,150
	2011	$ 295,697	$ 505,697	$ 324,063	$ 1,125,457
Grand Total		$ 882,272	$ 1,512,272	$ 324,063	$ 2,718,607
Average/ Year					**$ 906,202**

* *Estimated as .35 FTE per year, GS 14 ($150,000 / year including all salary and fringes); 3% annual inflation*

15. Changes to Burden

The changes in the estimated burden in this PRA application, since the original submission, are due to the following changes

- Combining the PRA application for the PGP and MCMP Demonstrations into a single application. Initially, there were two separate approvals for the same data collection effort.
- Reduction in the number of practices participating in the MCMP Demonstration from a projected 800 to an actual of 650.
- An increase in the estimated cost per hour (salary + fringe) for collecting the data from $50 to $55 due to the general increase in labor costs over the past 3 years.
- The implementation of the new EHR Demonstration which will begin collecting clinical quality data starting in 2011 with 400 Phase I practices.

16. Publication/Tabulation Dates

There will be no publication of individual practice specific data. As mandated by the legislation authorizing the demonstrations, there will be a Report to Congress for the PGP and MCMP Demonstrations. All 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 and submitted to Congress under established schedules.

17. Expiration Date

    CMS would like approval to use this data collection tool for a period of 3 years from the expiration of the current MCMP Demonstration approval (12/31/2011). There are no paper forms involved in this data collection activity. Any expiration date would be printed on the data collection log on screen (See current sample with 12/31/2008 date).

18. Certification Statement

    There are no exceptions to the certification statement.