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 Demonstration. The data will be used to continue implementation of the congressionally-mandated Physician Group Practice Transition Demonstration (PGP-TD) (PGP) project. The demonstration will 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.

The PGP-TD Demonstration, an extension of the original Physician Group Practice (PGP) demonstration involving 10 large multi-specialty group practices, is a 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. For the two performance periods of the PGP TD, data will be collected in the summers of 2012 and 2013.

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-TD Demonstration to minimize administrative burden and to align the measures with those used by commercial payers.

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 Demonstration for which this extension is being sought is considered a high priority for the Administration and Congress. The PGP Demonstration was mandated by section 412 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 and is the

precursor to the Medicare Shared Savings Program. Section 1899(k) of the Social Security Act, as added by section 10307(k) of the Affordable Care Act (as amended by section 10307 of the Health Care and Education Reconciliation Act of 2010), states "the Secretary may enter into an agreement with an ACO under the Demonstration under section 1866A, subject to rebasing and other modifications deemed appropriate by the Secretary." The Demonstration extension is entitled the PGP Transition Demonstration.

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 Demonstration 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.

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 group practices participating in the PGP-TD.

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.

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 Medicare Demonstrations and has been used successfully over the past 5 years. It should be emphasized that CMS is not creating an electronic health record (her). Rather, PAT is used to facilitate collection and scoring of the clinical quality measure data which can be provided by a physician group 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.

Groups 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. 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 Demonstration, CMS began a Physician Quality Reporting Initiative (PQRI) in which all Medicare physicians could participate. This program collects data via the submission of special codes on Medicare claims. In 2010, CMS began offering physician groups the opportunity to submit via a similar data collection tool as included in this request part of the Physician Quality Reporting System (PQRS) Group Practice Reporting Option (GPRO). A distinction is that the Demonstration rewards 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 group practices participating in Demonstrations that would allow these practices to earn PQRS 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 medium-sized PGPs that voluntarily elect to participate in the Demonstration, though the minimum requirement for participation is 200 physicians. 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 group practices. Again, participation in this Demonstration 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 this congressionally-mandated and high priority Demonstration.

7. Special Circumstances

The PGP TDis a congressionally-mandated Demonstration that, has been approved by OMB and is expected to produce savings to the Medicare program as well as reward high quality providers. Only those group practices volunteering to participate will be required to submit the requested information. Group 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 *Federal Register* notice soliciting public comment for this collection was originally

published on August 19, 2005. A subsequent notice was published on September 12, 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. In addition, over the past 5 years, in response to comments and suggestions by group practices participating in the Demonstration, 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.

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 solely to facilitate the collection and scoring of clinical quality measure data. Any reports pertaining to the collected information by an independent evaluator will be in aggregate form.

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 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. Group practices will only have to report once each year and we assume an average hourly personnel cost of $65.

The PGP-TD Demonstration involves 10 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.

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 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.

		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

- Removing the Medicare Care Management Performance (MCMP) Demonstration from the application. The Combining the PRA application for the PGP and MCMP Demonstrations into a single application. Data collection under the MCMP Demonstration has ended so the extension request is only for the additional two years of the PGP Transition Demonstration.
- An increase in the estimated cost per hour (salary + fringe) for collecting the data from $55 to $60 due to the general increase in labor costs over the past 3 years.

16. Publication/Tabulation Dates

The terms of the PGP TD include that CMS may publicly report the site-specific results of the quality measures. This is an option, but CMS may also elect to only publish the data at the aggregate level.

17. Expiration Date

CMS would like approval to use this data collection tool for a period of 2 years from the expiration of the current 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 12/31/2011 date).

18. Certification Statement

There are no exceptions to the certification statement.