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MATHEMATICA
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Evaluation of the Electronic Health Records Demonstration (EHRD) and the Medicare Care Management Performance (MCMP) Demonstration: Supporting Statement for Paperwork Reduction Act Submission

Final

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A. BACKGROUND

CMS contracted with Mathematica Policy Research, Inc. (MPR) to conduct an evaluation of two pay for performance demonstration projects (the congressionally mandated Medicare Care Management Performance (MCMP) demonstration and the new Electronic Health Record Demonstration (EHRD) which is a high priority of the Administration and Secretary). Both demonstrations are testing different methods of payment for improving the quality and efficiency of care to Medicare fee-for-service beneficiaries with chronic conditions and for encouraging the use of health information technology (HIT) to improve care delivery. The demonstrations are a component of the Administration's broad HIT strategy to ensure that most Americans have access to secure, interoperable health records by 2014. They align with the goals of the Office of the National Coordinator for Health Information Technology (ONC) to inform and interconnect health care providers, personalize care, and improve population health through EHR systems (Thompson and Brailer 2004).

We are requesting approval of the Office System Survey (OSS) that will be used in the MCMP and EHR demonstrations, and approval of the in-person and telephone discussion guides for use with community partners and physician practices in the EHR demonstration.

1. Rationale for the MCMP and EHR Demonstrations

The MCMP demonstration was authorized under Section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (see Appendix A). This is a three year pay for performance demonstration with physicians to promote the adoption and use of HIT to improve the quality of care for eligible chronically ill Medicare beneficiaries. MCMP targets small to medium sized primary care practices with up to 10 physicians. Practices must provide care to at least 50 Medicare beneficiaries. Approximately 650 practices in Arkansas, California,

Massachusetts and Utah are currently participating in this demonstration which started July 1, 2007. The demonstration is expected to end June 30, 2010. Physicians will receive payments for meeting or exceeding performance standards for quality of care. They will also receive an additional incentive payment for electronic submission of performance measures via their electronic health record (EHR) system. These payments are in addition to their normal payments for providing service to Medicare beneficiaries. The OSS will be used to assess progress of physician practices in implementation and use of EHRs and related HIT functionalities.

The EHR demonstration is authorized under Section 402 of the Medicare Waiver Authority (see Appendix B). The goal of this five year pay for performance demonstration is to foster the implementation and adoption of EHRs and HIT in order to improve the quality of care provided by physician practices. The EHRD expands upon the MCMP Demonstration and will test whether performance-based financial incentives (1) increase physician practices' adoption and use of electronic health records (EHRs), and (2) improve the quality of care that practices deliver to chronically ill patients. The EHRD targets small to medium sized primary care practices with up to 20 physicians. Practices must provide care to at least 50 Medicare beneficiaries. The demonstration began operations June 1, 2009, and is expected to end May 31, 2014. Approximately 800 practices will be enrolled in the demonstration across four sites. Practices will be randomly assigned to a treatment and control group. The OSS will be used to assess progress of physician practices in implementation and use of EHRs and related HIT functionalities, and to determine incentive payments for treatment practices. In-person and telephone discussions with community partners and physician practices will be used to learn about practices' experiences and strategies in adopting and using EHRs, as well as the factors that help or hinder their efforts.

2. MCMP and EHR Demonstration Designs

MCMP Demonstration Design

The MCMP demonstration will target practices serving at least 50 traditional fee-for-service Medicare beneficiaries with selected chronic conditions for whom they provide primary care. Under this demonstration, physicians practicing primary care[1] in solo or small- to medium-sized group practices (practices with 10 or fewer physicians, although there may be exceptions) will be eligible to earn incentive payments for (1) reporting quality measures for congestive heart failure (CHF), coronary artery disease (CAD), diabetes, and the provision of preventive health services during a baseline (predemonstration) period; (2) achieving specified standards on clinical performance measures during the three-year demonstration period; and (3) submitting clinical quality measures to CMS electronically using an EMR system that meets industry standards specified by the Certification Commission for Healthcare Information Technology (CCHIT).

The legislation authorizes up to four demonstration sites to include both urban and rural areas.[2] The states of Arkansas, California, Massachusetts, and Utah were chosen as the four sites. The Quality Improvement Organizations (QIOs) in these four states recruited demonstration practices on relationships built through CMS's Doctor's Office Quality - Information Technology (DOQ-IT) project. Demonstration practices represent many organizational structures, and serve at least 50 Medicare beneficiaries. Recruitment of demonstration practices began in January 2007.

[1] The following physician specialties will be eligible to participate in the MCMP demonstration if they provide primary care: general practice, allergy/immunology, cardiology, family practice, gastroenterology, internal medicine, pulmonary disease, geriatric medicine, osteopathic medicine, nephrology, infectious disease, endocrinology, multispecialty clinic or group practice, hematology, hematology/oncology, preventive medicine, rheumatology, and medical oncology.

[2] In addition, the statute requires that one site be "in a state with a medical school with a Department of Geriatrics that manages rural outreach sites and is capable of managing patients with multiple chronic conditions, one of which is dementia."

The demonstration practices will be eligible to receive up to three incentive payments. First, demonstration practices will receive an incentive of $20 per beneficiary per category (up to $1,000 per physician to a maximum of $5,000 per practice) for reporting baseline clinical quality measures. The payment will not be contingent on the practice's score on any of these measures.

Second, for each of the three demonstration years, based on the clinical measures data that the practices report, CMS will calculate a composite score for each chronic condition (as well as the preventive measures) and compare it against performance thresholds. Physicians will be eligible for payments of up to $70 per beneficiary for meeting standards related to a specific chronic condition. Beneficiaries who have more than one condition will be counted in each of the relevant groups. For preventive services, physicians will be eligible for a payment of up to $25 per beneficiary with any chronic condition. Physicians will be eligible to earn up to $10,000 per year for performance on all clinical measures. The maximum annual payment to any single practice will be $50,000, regardless of the number of physicians in the practice.

Third, practices with a CCHIT certified EMR system that can extract and submit performance data to CMS electronically will be eligible to increase the incentive payment by up to 25 percent, or $2,500 per physician (up to $12,500 per practice) per year during the demonstration period for electronic submission. Thus, practices could receive up to $192,500 over the three years of the demonstration (including the baseline period).

EHRD Design

The EHRD targets small to medium-sized practices (20 or fewer physicians, though there may be exceptions) providing primary care[3] to fee-for-service Medicare beneficiaries with

[3] The following physician specialties will be eligible to participate in the EHRD demonstration *if they provide primary care:* general practice, allergy/immunology, cardiology, family practice, gastroenterology, internal medicine, pulmonary disease, geriatric medicine, osteopathic medicine, nephrology, infectious disease,

congestive heart failure, coronary artery disease, diabetes, or other chronic diseases. CMS plans to recruit 800 small to medium-sized practices in four selected sites (about 200 per site). CMS has identified and recruited community partners in the four sites to help with practice outreach, education, and recruitment. Community partners represent community stakeholders and have ties to primary care physicians, but they are not required to have a specific type of organizational entity or structure. (Table A.1 presents the four sites and the affiliated community partners.)

The demonstration will begin operations on June 1, 2009, and will end on May 31, 2014. In spring 2009, prior to the start of demonstration operations, practices within each site will be randomly allocated to a treatment or a control group. MPR will design the randomization approach and will conduct the randomization.

TABLE A.1

EHRD DEMONSTRATION SITES AND COMMUNITY PARTNERS

Demonstration Sites	Community Partners
Louisiana	Louisiana Health Care Quality Forum
Maryland/DC	MedChi & Maryland Health Care Commission
Pennsylvania—Pittsburgh and surrounding counties	Pittsburgh Regional Health Initiative
South Dakota and some border counties in Iowa, Minnesota, and North Dakota	South Dakota Department of Health/South Dakota E-Health Collaborative

The evaluation will use one or more tax identification numbers (TINs) to identify demonstration practices. Physicians will be linked to practices using TINs and individual provider identification number (PIN) and/or National Provider Identification (NPI). Medicare beneficiaries who live in a demonstration site and who are treated by primary care providers (or

(continued)
endocrinology, multispecialty clinic or group practice, hematology, hematology/oncology, preventive medicine, rheumatology, and medical oncology.

those medical subspecialties likely to provide primary care for the targeted conditions) and who are covered under traditional fee-for-service Medicare for both Part A and Part B will potentially be linked to these practices.[4]

Under the demonstration, treatment practices will be eligible to receive up to three types of payments, which will be distributed by ARC. The first is a payment (up to $5,000 per physician to a maximum of $25,000 per practice) for using an EHR, called the *systems* payment, in all five years of the demonstration, beginning in year 1. The systems payment will be based on the practice's use of a minimum set of functions in an EHR system certified by the Certification Commission for Healthcare Information Technology (CCHIT), as measured by the practice's responses to the OSS. Additional payment will be provided for use of more-sophisticated EHR functions, such as identifying medication interactions. Practices that have not adopted or implemented minimal use of the EHR system by the end of the first year will not receive a payment, but they may remain in the demonstration.

In year 2, practices have the opportunity to receive the systems payment and a *reporting* payment (up to $3,000 per physician to a maximum of $15,000 per practice), for reporting on specific clinical quality measures. Practices that have not adopted or implemented minimal use of the EHR system by the end of the second year will be removed from the demonstration. In years 3 to 5, practices will have the opportunity to receive the systems payment and a *quality* payment (up to $10,000 per physician to a maximum of $50,000 per practice), based on performance on specific clinical quality measures, such as blood pressure management and lipid measurement for beneficiaries with diabetes. These financial payments will be in addition to the normal fee-for-service Medicare payment that practices receive for services delivered.

[4] Beneficiaries for whom Medicare is not the primary source of insurance coverage or whose care is managed by a hospice program will be excluded from the demonstration.

Physicians could receive up to $58,000 and practices up to $290,000 over the five years of the demonstration (Wilkin et al. 2007).

3. MCMP and EHRD Evaluation Designs

MCMP Evaluation Design

The main goal of the evaluation is to provide CMS and AHRQ with valid estimates of the incremental effect, or *impact,* of providing performance-based financial incentives on the quality of care, continuity of care, use of Medicare-covered services, and Medicare costs of the chronically ill Medicare beneficiaries served by demonstration practices. To provide this information, the evaluation must generate rigorous quantitative estimates of the intervention's impacts.

The impact analysis for the evaluation will use a *matched comparison group* design (that is, it will use a comparison group or quasi-experimental design). The impact analysis will use a *difference-in-differences* approach to estimate impacts. With this approach, *changes* in quality measures and other outcomes of practices in the demonstration states and comparison states will be compared before and after the start of the demonstration. The unit of analysis will be the practice, which also is the unit of intervention.

Data for impact analysis will be collected from four sources: (1) an Office Systems Survey, (2) a physician survey, (3) a beneficiary survey, and (4) Medicare claims and eligibility data. This request for OMB clearance includes the administration, during fall 2009, of the second and final round of the OSS for the MCMP Demonstration evaluation. The first round was conducted in 2007 by another CMS contractor as part of the Quality Improvement Organization/Eighth Scope of Work and was therefore exempt from the OMB clearance process. The OSS will measure practices' adoption and use of EHRs and its specific functions, including prescribing

medications, ordering laboratory tests and other procedures, and care management and coordination (see Table A.2 for a list of key survey topics).

TABLE A.2

MEASURES COLLECTED ON THE MCMP OFFICE SYSTEMS SURVEY

Office Practices and Work Flows
Proportion of patient visits where paper charts are pulled; providers dictate notes into a tape recorder or phone; use computerized system to manage office work flows
Use of Electronic Health Records
Availability of EHR system
Whether EHR system is CCHIT certified
Proportion of paper records that have been transitioned to HER
Use of EHR system to perform functions (for example, documenting office visits, e-prescribing, polypharmacy, or issuing laboratory orders or patient reminders)
Use of stand-alone systems for e-prescribing or patient registries
Practice Characteristics
Practice contact information (name, address, telephone number)
Affiliations with IPAs, PHOs, other medical groups
Participation in other quality improvement or pay-for-performance initiatives
Provider Characteristics
Provider name and identification number
Credentials
Specialty
Languages spoken (other than English)
Medicare billing number (provider identification number or PIN)

EHRD Evaluation Design

The main goal of the EHRD evaluation is to provide CMS with valid estimates of the incremental effect, or *impact,* of providing performance-based financial incentives on the adoption and use of EHR, quality of care, continuity of care, use of Medicare-covered services, and Medicare costs of chronically ill Medicare beneficiaries served by demonstration practices. To provide this information, the evaluation must generate rigorous quantitative estimates of the intervention's impacts.

The impact analysis will compare regression-adjusted outcome measures for the treatment and control groups in order to test hypotheses concerning the impact of the *combined* financial incentives (that is, the systems, reporting, and quality performance payments). The evaluation also includes a descriptive quantitative analysis of the chart-based quality measures, which are available only for the treatment group.

The impact analysis will assess impacts on outcomes measured at the practice, physician, and beneficiary levels, whereas the intervention is implemented only at the practice level. Because the practice—not the beneficiaries—receives the demonstration payments, it is the *unit of analysis.* When sample sizes permit, the impact analysis will use *hierarchical linear models* that nest beneficiaries within practices to assess the impact of the demonstration on outcomes (for example, quality of care, service use, and Medicare expenditures) that are measured at the beneficiary level.

Because physician practice regulations, practice styles, practice settings, adoption of EHRs, and pay-for-performance penetration are likely to differ across sites and may render data pooling infeasible, the impact analysis will estimate impacts separately for each demonstration site. However, for certain analyses, such as those based on survey data, the analysis will explore pooling data across sites. Where sample sizes permit, we will estimate impacts for subgroups defined by practice features (such as size or patient mix) and by beneficiary characteristics.

Data for the impact analysis will be collected from five sources: (1) the demonstrations' practice application form, (2) the OSS, (3) a beneficiary survey, (4) a physician survey, and (5) Medicare claims and eligibility data.

A second goal of the evaluation is to provide CMS with a detailed understanding of practices' experiences and strategies in adopting and using EHRs, and the factors that help or hinder their efforts. To provide this information, the evaluation will use qualitative techniques

and descriptive quantitative methods to gather and analyze information gathered from practice staff and community partners. Data for the implementation analysis will come from in-person and telephone discussions with practice staff and community partners, and practice responses to the OSS.

A third goal of the evaluation is to provide CMS with a synthesis of quantitative and qualitative findings to answer three questions: (1) What are the overall impacts of the demonstration? (2) What is the relationship between the *level* of the systems and quality performance payments and *changes* in quality-of-care indicators and use of EHRs? and (3) What is the relationship between the quality-of-care indicators and health outcomes? Data sources for the overall impact analysis include site-specific findings from all four sites and outcome measures from both the implementation and the impact analyses. The analysis will rely on an implementation synthesis to summarize how the intervention was implemented across the four sites, an exploratory analysis to compare the characteristics of successful and unsuccessful sites, a confirmatory analysis to test for differences in impacts between groups of sites, and a synthesis of findings on the types of beneficiaries for whom the intervention was most effective.

Data sources for the analysis of the relationship between system levels and quality factors include practice-level data for treatment group practices in each site (systems and quality performance payments and scores, chart-based quality measures and scores, measures of use of EHRs, and health outcomes derived from claims data); when appropriate, data across all sites will be pooled to maximize the available sample size. This analysis will use linear regression models to estimate the association between changes in quality of care and use of EHRs and the level of systems and quality performance payments. We will use similar models to estimate the association between quality-of-care indicators and health outcomes.

This request for OMB clearance relates only to the design and conduct of the EHRD's OSS and the in-person and telephone discussions with practice staff and community partners, since these activities are expected to begin in 2010.[5] The OSS will measure practices' use of EHRs and their specific functions, including prescribing medications, ordering laboratory tests and other procedures, and care management and coordination (see Table A.3 for a list of key survey topics). Treatment group practices will be required to complete an annual OSS for each of the five demonstration years. To minimize respondent burden, control group practices will be asked to complete the survey at the end of demonstration years 2 and 5 only. In addition, MPR will conduct a yearly validation with 25 percent of the responding treatment practices to validate their responses to the OSS.

Discussions with staff of participating practices will gather their perspectives on the demonstration and incentives; their experience in adopting and implementing HIT, including barriers and facilitators; their use of HIT functions; and their view of the effect of new HIT on care management, quality measures and improvement activities, and practice operations. These discussions will take place during years 1 and 5 of the demonstration's operations. Discussions with staff of practices that have withdrawn from the demonstration will provide information on their reasons for participation and withdrawal, their participation and attitudes toward pay-for-performance programs, and factors that would have encouraged them to remain in the demonstration. Discussions with community partners will provide information on the recruitment and operational experiences of the practices, which will inform the interpretation of the

[5] We will submit a separate request for OMB clearance for the beneficiary and physician surveys, since we expect these to be fielded about 36 months after practice enrollment in the demonstration, starting roughly in June 2012.

interviews with the practices (see Table A.4 for a list of key discussion topics by respondent type).

TABLE A.3

MEASURES COLLECTED ON THE EHRD OFFICE SYSTEMS SURVEY

Use of Electronic Health Records
Availability of EHR system
Whether EHR system is CCHIT certified
Number of providers in the practice who use the EHR system
Proportion of paper records that have been transitioned to EHR
Use of EHR system to perform functions (for example, documenting office visits, e-prescribing, polypharmacy, or issuing laboratory orders or patient reminders)
Use of stand-alone systems for e-prescribing or patient registries
Practice Characteristics
Practice contact information (name, address, telephone number)
Affiliations with IPAs, PHOs, other medical groups
Participation in other quality improvement or pay-for-performance initiatives
Provider Characteristics
Provider name and identification number
Credentials
Specialty
Languages spoken (other than English)
Medicare billing number (provider identification number or PIN)

The overall timeline for the demonstration and evaluation activities is presented in Figure I.1.

TABLE A.4

EHRD QUALITATIVE DISCUSSION TOPICS BY TYPE OF RESPONDENT

Practices

Administrative Staff

- Practice demographics
- Practice perspective on the demonstration and early response
- Adaptation of practice operations as HIT is implemented
- Facilitators and barriers to adopting and implementing HIT
- Other incentives, reporting programs, and HIT initiatives
- Use of HIT for care management
- Plans for change

Physicians

- Demonstration participation and operational response
- HIT experience and effect on practice change
- Care management views and experience
- Quality measures and improvement activities

Medical Director

- Physicians' use of HIT functions
- Physicians and other clinical staff attitudes toward HIT
- Other issues related to HIT adoption, such as the effect on malpractice insurance premiums
- Changes in job responsibilities or patient interface
- Critical factors for success and closing

Nurse or Other Staff Member Performing Care Management

- Effect of new HIT, or changes in use, on job responsibilities
- Adoption of care management
- Greater use of data to refine the care process
- Enhanced practice orientation to quality and safety

Senior Administrative Personnel (CEO, CFO, Marketing Director)

- Demonstration's fit with practice goals
- Effects of HIT on the practice
- Expectations/thinking regarding incentive payments
- Market factors

Community Partners

- Experience recruiting practices to the demonstration
- Practice needs for the demonstration to be successful
- Plans for working with and facilitating assistance to practices
- Perceptions of practices' progress under the demonstration
- Other (non-EHRD) HIT activities in the site

FIGURE I. 1

TIMELINE FOR THE EHR DEMONSTRATION AND EVALUATION AND FOR THE MCMP OSS ADMINISTRATION

Note: Medicare claims data will be collected annually for treatment and control groups.

[a] In spring 2009, practices will be randomly allocated within each site to a treatment or control group.

B. JUSTIFICATION

1. Need and Legal Basis

The MCMP demonstration was authorized under Section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This three year, pay for performance demonstration with physicians will promote the adoption and use of HIT to improve the quality of care for eligible chronically ill fee for service Medicare beneficiaries. The MMA authorized up to four demonstration sites to include urban and rural areas; CMS chose Arkansas, California, Massachusetts, and Utah. The legislation mandated an independent evaluation of the MCMP Demonstration. The evaluation must include an assessment of the impact of providing pay-for-performance financial incentives on quality of care, care coordination, and continuity of care, thereby reducing Medicare expenditures and improving health outcomes. This evaluation requires an OSS to determine adoption and use of HIT in physician practices.

The EHRD is authorized under Section 402 of the Medicare waiver authority. The EHRD expands upon the MCMP Demonstration and will test whether systems and performance-based financial incentives (1) increase physician practices' adoption and use of EHRs, and (2) improve the quality of care that practices deliver to chronically ill patients with fee-for-service Medicare coverage. This demonstration requires an OSS to determine HIT use and financial incentives. In addition, in-person visits and telephone calls with practices and community partners are necessary to learn how HIT and care management are implemented within practices and across sites.

Both demonstrations are a component of the Administration's broad HIT strategy to ensure that most Americans have access to secure, interoperable health records by 2014. The

demonstrations align with the goals of the Office of the National Coordinator for Health Information Technology (ONC) to inform and interconnect health care providers, personalize care, and improve population health through EHR systems (Thompson and Brailer 2004).

2. Information Users

Information for the evaluation of the MCMP Demonstration will be collected and analyzed by MPR, under Contract Number 500-00-0033, Task Order 05 with CMS, titled "Evaluation of the Medicare Care Management Performance Demonstration." Findings from the impact analysis will be included in the Report to Congress (due within 12 months of the conclusion of the demonstration) and other internal reports to CMS.

Information for the evaluation of EHRD will be collected and analyzed by MPR, under Contract Number HHSM-500-2005-00025I (0006) with CMS, titled "Evaluation of the Electronic Health Records Demonstration." Findings from the implementation analysis, impact analysis, and synthesis of findings will be included in the internal reports to CMS.

3. Use of Information Technology

The MCMP and EHR demonstrations will use a web-based survey instrument (OSS) as the primary method of data collection with practices, supplemented by paper-and-pencil questionnaires for those practices that either request a paper version or do not have internet access early on in the demonstration. Multiple attempts will be made to encourage practices to complete the web-based survey. While we expect that most practices will complete the web survey, a small number of practices may prefer to complete a paper version. MCMP OSS data collection will take place in 2009, one year prior to the end of the demonstration. The EHRD OSS data collection with treatment group practices will take place at the end of each demonstration year; data collection with control group practices will be at the end of

demonstration years 2 and 5. All participating demonstration practices will receive an advance letter instructing them how to log onto the website to complete the OSS online. The letter will also provide a toll-free number to call if a practice has a question or prefers to complete a paper-and-pencil questionnaire. A toll-free help desk and general email address will be established to assist practices in completing the online survey. We expect that 90 percent of responding practices will complete the web-based version of the OSS, and 10 percent will complete a paper-and-pencil version.

In-person and telephone discussions with EHRD practices and community partners will take place in 2010 and 2014. Discussions with practices that have withdrawn from the demonstration will occur during spring 2012. All the discussions will be conducted using semi-structured, paper-and-pencil discussion guides. Information gathered from the practice discussions will be entered into Atlas.ti software (a commercial tool for analyzing qualitative data) to help identify themes and illustrative examples.

4. Duplication of Effort

These information collections do not duplicate any other effort, and the information cannot be obtained from any other source.

5. Small Businesses

For the MCMP Demonstration, small to medium-sized practices (with 10 or fewer physicians) were targeted. For the EHRD, small to medium-sized practices (with 20 or fewer physicians) will be targeted. Participating in the OSS for the MCMP and EHR demonstrations will impose minimal burden, as the surveys are designed to be completed in 29 minutes. The web-survey format permits practice staff to complete the survey at their convenience. Furthermore, only one survey is needed from each practice at each data collection point.

Respondent signatures are not required for either of the demonstrations' OSSs. However, we will collect from respondents, once they have completed the survey, a data attestation that verifies the accuracy of the information they provided, along with their name and title.

Two rounds of discussions (in-person or telephone) will be conducted with up to 24 practices and 4 community partners during demonstration years 1 and 5. Each round of contacts will include site-level discussions with 4 treatment group practices, up to 2 control group practices, and the community partner. At each of the 24 practices, discussions with three key staff members will be scheduled at the convenience of the practice, during physicians' off-hours if necessary. Most discussions with practice staff and community partners will last 30 minutes, and none will be scheduled to exceed one hour. In addition, discussions with up to 6 practices that have withdrawn from the demonstration will be conducted during spring 2012. Each discussion will last 30 minutes.

6. Less-Frequent Collection

Collecting OSS data at regular intervals is critical for tracking changes in the adoption and use of HIT, and for conducting a credible evaluation of both the MCMP and EHR demonstrations. Conducting a second round of the OSS for the MCMP demonstration is necessary to measure changes in the use of EHR and HIT over time. For the EHRD, the OSS must be administered annually to treatment group practices in order to determine the amount of the demonstration incentive payment. Yearly payments to treatment practices would be impossible with less-frequent administration. Administering the survey to the control group at years 2 and 5 is necessary to measure changes in the use of EHRs over time in the absence of demonstration incentives. Less-frequent collections of OSS data would limit CMS's understanding of the impact of the MCMP and EHR demonstrations.

For the EHRD, conducting two rounds of discussions with practice staff and community partners is necessary to provide details of how practices are evolving in their use of technology to support care quality. Conducting discussions with practice staff and community partners at only one point would make it impossible to describe these changes over time. Conducting discussions with practices that have withdrawn from the demonstration is necessary to capture the characteristics and reasons for withdrawal.

7. Special Circumstances

There are no special circumstances related to the proposed data collection.

8. Federal Register/Outside Consultation

The notice required by 5 CFR 1320.8 (d), was published in the *Federal Register* on January 23, 2009**.** A copy of the notice is in Appendix C.

a. Public Comment and Responses

Public comments were received at the conclusion of the first 60-day period and written responses have been submitted.

Outside consultation for the design of the studies and surveys was received from a variety of experts (see Table B.1 for a list of consultants).

The OSS instruments developed for the second (and final) round of administration for the MCMP and for the EHR demonstration evaluations drew heavily upon the OSS instrument that was designed and administered in 2007 under the MCMP evaluation. In fact, the current MCMP OSS instrument is nearly identical; the only difference is the removal of a short set of questions that are no longer applicable (those pertaining to experience and satisfaction with Quality Improvement Organizations). The MCMP OSS questionnaire was pretested with less than nine respondents.

TABLE B.1

CONSULTANTS

Individual	Affiliation/Agency/Division	Telephone Number
	Within the Department of Health and Human Services	
James Sorace	Assistant Secretary for Planning and Evaluation	(202) 205-8678
Jody Blatt	Centers for Medicare & Medicaid Services	(410) 786-6921
Debbie Vanhoven	Centers for Medicare & Medicaid Services	(410) 786-6625
Karen Bell	Office of the National Coordinator for Health Information Technology	(202) 690-7151
David Hunt	Office of the National Coordinator for Health Information Technology	(202) 690-7151
	Outside the Department of Health and Human Services	
John Wilkin	Actuarial Research Corporation	(703) 941-7400

For the EHRD, we used the 2007 MCMP OSS to identify questions that were asked successfully of a similar population. We added questions to capture EHR functions and use in greater detail. The EHRD OSS questionnaire was pretested with less than nine respondents.

9. Payments/Gifts to Respondents

No incentive payment was offered for the initial round of the MCMP OSS in 2007. Therefore, we will not offer an incentive to practices for participating in the second round of the OSS for the MCMP demonstration.

For the EHRD, treatment group practices must participate in the OSS to receive the systems payments (described in Part A of the OMB submission package). For this reason, treatment practices will have a strong motivation to participate in the OSS and an incentive payment will not be needed to ensure a high response rate. On the other hand, control group practices receive no demonstration payment for adoption and use of an EHR, so they will have no clear incentive

to complete the OSS. We therefore plan to offer a $50 incentive to control group practices to ensure a comparably high response rate to the survey. Without an incentive for the control group, there is a risk of obtaining a lower response rate for control group practices, which could bias the study results.

No incentive payment will be offered for participation in the EHRD discussions with practice staff and community partners.

10. Confidentiality

MPR will take several steps to assure respondents that the information they provide will be treated as confidential and used for research purposes only. Advance letters to practices will inform respondents that data collected from the OSS or practice discussions will be aggregated in reports and that practice-level data will not be reported. MPR will restrict access to the OSS web instrument to protect the confidentiality of respondents and the preloaded practice-level information the instrument contains. Each practice will be assigned a unique ID and password that will be included in the advance letter addressed to the person who completed the demonstration application form (for the initial round of the survey) or the prior OSS (for subsequent rounds).

The OSS web instrument will be hosted on MPR's web servers. Data will be processed and stored on MPR's password-protected local area network (LAN). MPR protects its LAN with several security mechanisms available through the network operating system: Novell Netware 5.1, IntraNetware, and a firewall from Cisco Systems. Novell Netware 5.1 is compliant with the C2/E2 Red Book security specifications. IntraNetware is certified at the National Computer Security Center's Trusted Network Interpretation Class C2 level at the network level. All LAN servers containing confidential information are located in a controlled-access area, which is also protected from unauthorized external electronic access by a firewall from Cisco Systems. This

firewall is located between the T1 line, which connects to the Internet, and the rest of MPR's network. Access to confidential information stored on LAN directories is restricted to authorized project staff by means of ID and password. In addition, network servers containing confidential information are kept in a locked area. All staff working with extremely sensitive data are required to change their password at least every 90 days. In addition, LAN access privileges for staff leaving the project are revoked within 24 hours.

Completed paper-and-pencil questionnaires are sensitive documents, since they contain both personal identifiers (name, phone number, address) and survey data. MPR staff will create a detailed plan for tracking and protecting the OSS paper-and-pencil instruments through the data collection process (that is, quality control, data entry, and coding). Once the paper questionnaires are received at MPR, personal identification information will be removed and separated from the respondent's survey data as soon as possible. A unique identification number will be used to link or connect the personal identifiers to the respondent's survey data. The linking methodology will be secured to prevent unauthorized linkage of the survey data and the personal identifiers.

Finally, MPR staff assigned to work on the project all sign confidentiality pledges as a term of employment. The confidentiality pledge requires that staff maintain the confidentiality of all information collected.

11. Sensitive Questions

The MCMP and EHR OSS instruments include questions about practices' use of EHRs and the EHRs' specific functions, including prescribing medications, ordering laboratory tests and other procedures, and care management and coordination. These questions are not considered sensitive. Many of the questions were adapted without modification from the previous round of the OSS administered for the MCMP demonstration.

For the EHRD, the questions asked during discussions with practice staff cover their perspectives on the demonstration and incentives; experience in adopting and implementing an EHR, including barriers and facilitators; use of HIT functions; and the effect of new HIT on care management, quality measures and improvement activities, and practice operations. These questions are not considered sensitive. The questions asked during discussions with practices that have withdrawn from the demonstration cover the reasons for enrollment and withdrawal from the demonstration, participation and attitudes toward pay-for-performance programs, and factors that could have encouraged them to remain in the demonstration. These questions are not considered sensitive.

12. Burden Estimates (Hours and Wages)

Table B.2 presents estimates of respondent burden for completing the OSS for the MCMP and EHR demonstration evaluations. It shows the expected number of respondents, the hours per response, and the annualized hour and cost burden for each year that OSS data are collected. The OSS for the MCMP Demonstration will be administered in fall 2009. Practices enrolled in the EHRD will be surveyed beginning in Spring 2010, and treatment group practices will be surveyed annually thereafter; control group practices will be surveyed in the Spring of years 2 and 5 of the demonstration. Hourly estimates for the OSS are based on pretest interviews completed with less than nine practices. Interview completion times ranged from 24 to 35 minutes for the MCMP OSS and 25 to 37 minutes for the EHRD OSS, with an average length of 29 minutes for each survey instrument. The cost per practice was computed using an estimated annual salary of $40,000 for practice managers and 2,080 annual work hours as follows: $40,000/2,080*0.48 = $9 per response.

TABLE B.2

EHRD OSS ANNUAL RESPONSE BURDEN

Study (Year)	Number of Respondents*	Frequency of Response	Hours Per Response	Annual Hour Burden	Cost Per Response	Annual Cost Burden
MCMP Demonstration (2009)	980	1	0.48	470	$9	$8,820
EHRD (2010)	400	1	0.48	192	$9	$3,600
EHRD (2011)	680	1	0.48	384	$9	$7,200
EHRD (2012)	380	1	0.48	192	$9	$3,600
EHRD (2013)	380	1	0.48	192	$9	$3,600
EHRD (2014)	660	1	0.48	384	$9	$7,200

*Assumes that 5 percent of treatment group practices will withdraw at the end of demonstration year 2, and that 70 percent of control group practices will complete a survey in demonstration year 2 and 5.

Table B.3 presents estimates of respondent burden for completing a validation of OSS responses for the EHRD. It shows the expected number of respondents, the hours per response, and the annualized hour and cost burden for each year that OSS data are collected. The validation will take place each year the OSS is conducted, with 25 percent of the treatment practices that completed a survey, and will occur after the OSS data have been collected. Hourly estimates for the OSS are based on pretest interviews completed with less than nine practices. Interview completion times ranged from 60 to 105 minutes, with an average length of 83 minutes. The cost per practice was computed using an estimated annual salary of $40,000 for practice managers and 2,080 annual work hours as follows: $40,000/2,080*1.38 = $26 per response.

TABLE B.3

EHRD OSS VALIDATION OF SURVEY RESPONSES ANNUAL RESPONSE BURDEN

Study (Year)	Number of Respondents	Frequency of Response	Hours Per Response	Annual Hour Burden	Cost Per Response	Annual Cost Burden
EHRD (2010)	100	1	1.38	138	$26	$2,600
EHRD (2011)	100	1	1.38	138	$26	$2,600
EHRD (2012)	95	1	1.38	131	$26	$2,470
EHRD (2013)	95	1	1.38	131	$26	$2,470
EHRD (2014)	95	1	1.38	131	$26	$2,470

Discussions with EHRD practice staff and community partners will be conducted during years 1 and 5 of the evaluation. Within each site, discussions will be held with 4 treatment practices, up to 2 control practices, and a community partner, for a total of 24 practices and 4 community partners. Discussions will be conducted at two points in time and both rounds will be conducted in person. In each round, discussions with each practice will last two to three hours, depending on practice size and staffing structure. MPR staff will meet with three key staff members at each practice for discussions using semi-structured guides, which vary in length from 30 minutes to one hour each depending upon the staff member's involvement in the implementation of HIT. An additional 45-minute group discussion may be scheduled for larger practices that have additional administrative personnel who could inform the project. Discussions with community partners will be 60 minutes long.

Telephone discussions will be held with up to 6 practices that have withdrawn from the demonstration. These 30-minute discussions will occur in year 1 of the evaluation.

Table B.4 presents estimates of respondent burden for completing the discussions with EHRD practices and community partners. It shows the expected number of respondents, hours

per response, and the annualized hour and cost burden for each year that discussions are conducted. Hourly estimates for the discussions are based on mock interviews completed with MPR staff. Interview completion times ranged from 30 to 60 minutes, with an average length of 45 minutes. The cost per discussion was computed using an estimated annual salary of $40,000 for practice managers and community partners; $160,000 for physicians, medical directors and CFOs; and $47,000 for nurses, with 2,080 annual work hours as follows: practice managers and community partners: $40,000/2,080*1.0 = $19 per response; physicians, medical directors and CFOs: $160,000/2,080*0.75 = $58 per response; and nurses: $47,000/2,080*0.5 = $11 per response.

13. Capital Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Cost to Federal Government

The total current value for the MCMP evaluation contract is $2,299,876 over seven years. The estimated annualized cost to the government for conducting the OSS is $141,369. This figure is based on the contractor's costs for collecting and tabulating the survey data, including labor; other direct costs for computer, telephone, postage, reproduction, fax, printing, and survey facilities; and indirect costs for fringe benefits, general and administrative costs, and fees.

The total current value for the EHRD contract is $5,225,643 over eight years. The estimated annualized cost to the government for conducting the OSS is $158,457, and for conducting the practice discussions is $125,486. These estimates are based on the contractor's costs for collecting and tabulating survey and practice contact data, including labor and travel; other direct costs for computer, telephone, postage, reproduction, fax, printing, and survey facilities; and indirect costs for fringe benefits, general and administrative costs, and fees.

TABLE B.4

EHRD DISCUSSIONS WITH PRACTICE STAFF, COMMUNITY PARTNERS AND PRACTICES THAT WITHDREW FROM THE DEMONSTRATION

ANNUAL RESPONSE BURDEN

Round 1 Discussions (Evaluation year 1)

Type of Respondent	Number of Respondents	Frequency of Response	Hours per Response	Annual Hour Burden	Annual Cost per Response	Cost Burden
Discussions with Practice staff**	72	1	0.75	54	$29	$2,088
Discussions with Community Partners	4	1	1.0	4	$19	$76
Discussions with Withdrawn Practices	6	1	0.5	3	$19	$114

Round 2 Discussions (Evaluation year 5)

Type of Respondent	Number of Respondents	Frequency of Response	Hours per Response	Annual Hour Burden	Annual Cost per Response	Cost Burden
Discussions with Practice staff**	72	1	0.75	54	$29	$2,088
Discussions with Community Partners	4	1	1.0	4	$19	$76

*Total number of respondents over both years
--Practice staff: 144
--Community Partners: 8
--Practices that withdrew: 6

**Number of practices per round: 24; Number of respondents per practice: 3

15. Changes to Burden

Data collection for EHRD is new; therefore, there are no changes to burden. For the MCMP demonstration, there is a slight reduction in burden for the second round of the OSS, a result of the removal from the 2007 version of a short series of questions that pertained to Quality Improvement Organizations and are no longer relevant.

16. Publication/Tabulation Dates

MCMP Demonstration Evaluation Reports

The MCMP Demonstration evaluation will produce several reports, including an interim and a final evaluation report that synthesize findings across states and analytic components. The evaluation reports will be adapted to develop the Report to Congress. Table B.5 summarizes the delivery schedule. A summary of each report follows.

TABLE B.5

MCMP DEMONSTRATION DELIVERY SCHEDULE OF REPORTS

	Due Date	
Report	Project Month[a]	Calendar Month
First Interim Evaluation Report	19	January 2009
Cost Neutrality Monitoring Report	25	July 2009
Second Interim Evaluation Report	30	December 2009
Report to Congress (Third Interim Evaluation Report)	43	January 2011
Final Evaluation Report	53	November 2011

[a] Refers to the number of months after the start of the demonstration (July 1, 2007).

a. Cost Neutrality Monitoring Report

OMB has requested that CMS monitor cost neutrality over the first 18 months of the demonstration. This analysis will require comparing regression estimates of the demonstration's effects on Medicare savings to the incentive payments made to demonstration practices. Assuming the data for this analysis are available by month 22 (that is, 22 months after the demonstration begins), we will deliver a draft report to CMS in month 25 (July 2009).

b. Interim and Final Evaluation Reports

Three interim evaluation reports (drafts due 19, 30, and 43 months after the start of the demonstration) and a final evaluation report (draft due 53 months after the start of the demonstration) will be prepared for CMS, all of which will synthesize those findings available at different times during the demonstration.

The first interim evaluation report, due January 2009 (19 months after the start of the demonstration), will provide qualitative descriptions of practice changes made in response to the intervention, including changes to the processes associated with the adoption of HIT and how it is used.

The second interim evaluation report, due in December 2009 (30 months after the start of the demonstration), will focus on impact estimates for the first year of program operations. Although the report will compare impacts on use of Medicare-covered services and costs across practices and states, we will not attempt to draw inferences from them at this stage of the evaluation. In addition, the report will summarize findings from telephone discussions with highly successful practices and with those that withdrew, if any, in year 2 of demonstration operations.

The third interim evaluation report, due to CMS in January 2011 (43 months after the start of the demonstration), will focus on impact estimates for the second year of program operations. The report will also include findings on the impacts of pay-for-performance on physician-beneficiary interactions (that is, access to care, care coordination, and satisfaction with care) from the beneficiary survey.

The final evaluation report, due in November 2011 (53 months after the start of the demonstration), will provide final impact estimates from claims data from the third, and final, year of demonstration operations. In addition, the report will present impact estimates from the

physician survey on processes associated with the adoption of HIT to improve quality of care. It will also incorporate our synthesis analysis, including data from the last wave of the OSS.

c. Report to Congress

MPR will produce one Report to Congress based on the independent evaluation. The report is due in January 2011, about six months after the end of demonstration operations. This report will analyze implementation experiences and findings of the MCMP Demonstration across the four states.

EHRD Evaluation Reports

The EHRD evaluation will produce several reports, including implementation reports, final site visit reports, and interim and final evaluation reports. Table B.6 summarizes the delivery schedule. A description of each report follows.

d. Implementation Report

The results from the analysis based on the first round of site visits will be presented in the implementation report, due to CMS in June 2010 (13 months after the start of the demonstration). The implementation analysis report will provide an overview of practice characteristics and demonstration implementation in the first year of operation. It will rely on data from reports for the first round of site visits to practices, and will include data from practice applications for the demonstration and the OSS, as available.[6]

6 Most treatment group practices will not yet have completed the first annual OSS, and OSS data for the control group practices will not be available for the implementation analysis report, since they will not be collected from control group practices until the second year of the demonstration.

TABLE B.6

EHRD DELIVERY SCHEDULE OF REPORTS

Report	Due Date	
	Project Month[a]	Calendar Month
Implementation analysis report	13	June 2010
Interim evaluation report	40	September 2012
Evaluation summary report	58	March 2014
Final site visit report	70	March 2015
Evaluation final report	79	December 2015
Final cost monitoring report	81	February 2016

[a] Refers to the number of months after the start of the demonstration (June 1, 2009).

e. Final Site Visit Report

Results from the second round of contacts to practices will be reported in the final site visit report, due to CMS in March 2015 (70 months after the start of the demonstration). The final site visit report will draw implementation-related conclusions, related primarily to EHR use and care management activities.[7] It will synthesize information from the implementation report, the 8 site visit reports, and descriptive analyses of OSS data. The analysis of OSS data will examine changes in use of EHR functions over time, while the qualitative analysis of the site contact information will offer insights about how practices responded to demonstration incentives.

7 The final site visit report may be delayed if the second round of site visits is postponed. Contact with practices may be postponed to fully capture the potential effects of the quality performance payments, which will first be received by practices in the third year of the demonstration.

f. Cost Neutrality Monitoring Reports

The cost-monitoring reports, due annually between December 2010 and 2014 (19 to 67 months after the start of the demonstration), will analyze whether the demonstration is generating cost savings and will include annual and cumulative estimates of the impact of the demonstration payments on use of Medicare-covered services and expenditures. The final cost-monitoring report, due in February 2016 (81 months after the start of the demonstration), will summarize findings for the demonstration's impacts on Medicare expenditures; it will draw from the evaluation final report described below. The cost-monitoring reports will rely primarily on data from Medicare claims and on the levels of the demonstration payments made to treatment group practices for each year of demonstration operations.

g. Interim Evaluation Summary and Final Evaluation Reports

The interim evaluation report, due in September 2012 (40 months after the start of the demonstration), will provide descriptions of practice changes made after three years of intervention and will discuss the initial perceived effects of the demonstration on EHR use, quality of care, and costs from the implementation analysis. It will summarize findings from the first round of site visits to practices, as reported in the implementation report, and telephone interviews with practices that withdrew, if any. The report will also include findings from the first cost reports, which will draw on Medicare claims data and the incentive payments.

The evaluation summary report, due in March 2014 (58 months after the start of the demonstration), will provide qualitative descriptions of practice changes made after 4.5 years of intervention and will discuss impact estimates on quality of care, use of EHR, use of Medicare-covered services, and costs across sites. The report will synthesize findings from the practice contacts, interviews with representatives of withdrawn practices, and OSS data (including year 2 data for treatment and control group practices). Finally, the report will include impact analyses of

OSS-based systems scores, use of Medicare-covered services and expenditures, and claims-based quality measures, as available.

The final evaluation report, due in December 2015 (79 months after the start of the demonstration), will provide final impact estimates on the use of Medicare-covered services and expenditures, claims-based quality measures, survey-based measures, and OSS-based systems scores, using data from the final year of demonstration operations.[8] The report will also include a synthesis analysis of the overall effects of the systems and performance financial incentives on quality measures, and EHR use. It will rely on findings from the final site visit reports, the fifth cost-monitoring report, the last year of the OSS, the beneficiary and physician survey analysis reports, and the interim and summary evaluation reports.

17. Expiration Date

The OMB expiration date will be displayed on all materials sent to practices, including the advance letter and a paper version of the OSS questionnaire.

18. Certification Statement

Data collection efforts for the MCMP and EHRD OSS and for the EHRD discussions with practice staff and community partners will conform to all provisions of the Paperwork Reduction Act.

8 Completion of the final evaluation report may require an extension to allow for final collection of quality performance data and claims run out.