SUPPORTING STATEMENT

Part A

Barriers to Meaningful Use in Medicaid

Version
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Agency for Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see Attachment A), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of   health care;

2. the synthesis and dissemination of available scientific evidence for use by   patients, consumers, practitioners, providers, purchasers, policy makers, and   educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (a) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (b) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

AHRQ's Health Information Technology (IT) Portfolio aims to support AHRQ's mission through its efforts to create and synthesize knowledge regarding the impact of health IT on quality of care; translate that knowledge to support implementation and use of health IT; and support health IT advancement across the nation.

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5), provides for financial incentives for Medicaid providers to adopt and "meaningfully use" certified electronic health record (EHR) technologies. To help increase the ability of eligible professionals (EPs) to qualify for and access these

incentives, AHRQ proposes a 2-year project with the objective of understanding the barriers that Medicaid health providers encounter along the way to achieving the meaningful use of EHRs and providing insight on the assistance that they require to meet the incentive program requirements. This proposed information collection will allow AHRQ to synthesize knowledge regarding the barriers that EPs encounter when attempting to achieve meaningful use and translate that knowledge to develop technical assistance and support implementation and use of EHRs.

Further, health care providers who serve Medicaid beneficiaries are serving many of AHRQ's priority populations: inner city; rural; low income; minority; women; children; elderly; and those with special health care needs. The project is designed to solicit actionable recommendations on what activities can best help Medicaid providers achieve meaningful use, take advantage of incentive payments, and ultimately use health IT to improve health care for the Medicaid population. The information gathered by this project, as publicly available information, will also be available to the Centers for Medicare and Medicaid Services (CMS) to be considered in conjunction with numerous other sources of information, including public comment, to inform the development of the Stage 2 and 3 Meaningful Use criteria.

In order to gather, analyze, and synthesize information on the barriers to the meaningful use criteria experienced by Medicaid providers this research has the following goals:

1) Identify the barriers to eligibility for incentive payments; barriers to adoption, implementation, or upgrading of EHR systems; and barriers to achieving meaningful use.
2) Develop recommendations for technical assistance that can be made available to EPs and State Medicaid agencies to assist providers in overcoming the barriers identified in #1 above.

To achieve the goals of this project the following data collections will be implemented:

1) A screening questionnaire (see Attachment B) will be used to identify eligible participants, as part of the sampling procedure for the focus groups. Appended to the screening questionnaire is a series of questions for individuals who have agreed to participate in the focus groups, in order to collect descriptive and demographic information prior to the focus group session, and as part of the analysis plan.

2) A total of 15 focus groups will be conducted with eligible Medicaid providers. Eight focus groups will include a mix of pediatricians, other physicians, dentists, nurse practitioners, physician assistants, and certified nurse midwives who have adopted an EHR. Six of the focus groups will include providers who have not adopted an EHR, and the final group will be comprised of private practice dentists who have adopted an EHR. Private practice dentists are being considered separately due to the fact that their practice patterns are likely to vary substantially from those of primary care physicians and non-physician providers. Because of the range of types of EHRs and variance in EHR functionality, we will interview twice as many providers with EHRs than non-users. We expect the information provided by non-users of EHRS to become saturated twice as fast as that provided by EHR users.

The purpose of these focus groups is to gather information about adoption issues (factors in the decision to adopt an EHR), implementation issues (organizational or environmental factors that facilitate EHR implementation and training), upgrade issues (challenges to transitioning to certified EHRs), and challenges to achieving meaningful use of EHRs as defined in Federal regulations for Stage 1 (particular functions that are problematic, the source of the challenge). Responses will also address topics related to participants' knowledge of the EHR incentive program and other factors that may facilitate EHR use. The focus group moderator will use the moderator's guide (Attachments C-E) to guide discussion. The show cards (Attachment F) will provide key reminders of content for discussion; the other respondent materials are included in Attachments H, I, J and K.

This study is being conducted by AHRQ through its contractor, RTI International, pursuant to AHRQ's statutory authority to conduct and support research to advance both training for health care practitioners in the use of information systems and the use of computer-based health records. 42 U.S.C. 299b-3(a) (2) and (6).

2. Purpose and Use of Information

The information will be used to develop recommendations to overcoming barriers to meaningful use of EHRs for Medicaid providers, including but not limited to technical assistance that could be made available to Medicaid providers through Medicaid agencies or other technical assistance programs. Three types of information will be collected: list of potential focus group participants, descriptive and demographic information about focus group participants, and the information gathered at each focus group related to the barriers to

meaningful use. The information will be synthesized to provide data to the Federal government to inform the programs offered to Medicaid agencies through AHRQ's technical assistance program and will be available to CMS as a source of information to inform future meaningful use regulations

3. Use of Improved Information Technology

The data will be collected from focus group discussions, discussion notes, and audio recordings. Data will be entered into spreadsheets and analyzed. Analysis may include using a qualitative data analysis package, such as NVivo®. These are open-ended discussions, which do not lend themselves to automated data collection tools.

4. Efforts to Identify Duplication

Based on a scan of the literature and conversations with other Federal staff working on these issues, it has been determined that there are no similar data available. Other Federal agencies, including the Office of the National Coordinator for Health IT (ONC) and the Health Services Resources Administration (HRSA) have been engaged in informal data collection efforts to understand the barriers to meaningful use at a high level, among Medicare providers, and those specific to health center controlled networks. However, none of these efforts have been formalized or specifically target the barriers faced by Medicaid providers. CMS is also engaged in an ongoing telephone survey to determine the effectiveness of the dissemination of information about the EHR Incentive Programs. Although this survey does involve EPs likely to qualify for the Medicaid Incentive Program, none of the data is specific to their experience with the program or broken out in a way that allows conclusions to be drawn based on their participation with that program. The Medicaid incentive program has a wider range of provider types that are EPs. As such, this is a unique opportunity to collect information that is not collected elsewhere as other data collection efforts are focused primarily on physicians practicing in small to medium sized offices.

5. Involvement of Small Entities

No information will be collected from small businesses or other small entities.

6. Consequences if Information Collected Less Frequently

This is a one-time collection.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on January 18, 2011, page 2911 for 60 days (see Attachment G). One comment was received; see Attachment M for the full comment and Attachment N for AHRQ's response.

8.b. Outside Consultations

Consultations within the Department of Health and Human Services (HHS) to obtain their views on the data collection include consultation with a Technical Expert Panel (TEP). The TEP includes individuals from AHRQ, CMS, HRSA, and ONC who have a wide range of expertise and roles within the broader Medicaid EHR adoption environment. The TEP provides input at each critical stage of the project: development of the research plan and data collection instruments, data analysis, and development of the report and recommendations. The TEP will also provide input on the full range of project activities and help ensure communication and dissemination of information across other stakeholders, including other Federal agencies.

9. Payments/Gifts to Respondents

Participants in focus groups will receive a gift of $200 for their participation. This amount is appropriate and necessary to gain cooperation from physicians and medical personnel who have demanding work schedules and significant competing demands. Furthermore, physicians are frequently approached to participate in research projects, making them more reluctant to participate. Response rates among physicians average about 10% lower than studies with the general population (Cull et al 2005).

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other

purpose. These assurances will be both verbal and written in the "Consent to be Interviewed" form (Attachment H).

Information that can directly identify the respondent, including name, business address, email address and telephone number will be collected for the purposes of mailing instruction packets to recruited focus group participants. Participants will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose.

All materials including the verbal consent script will be reviewed and approved by the RTI IRB prior to contacting any sample members. The Office for Human Research Protections (OHRP) has granted a Federalwide Assurance (FWA #3331 effective until March 5, 2012) to RTI that grants RTI the right to review and approve studies independently. In turn, OHRP has the right to audit RTI's IRB records or any study's procedures at any time to assure that RTI complies with the Federal regulations regarding research with human subjects.

The project team will also impose several security measures to ensure protection of confidential information collected from project participants. All computers have Pointsec software installed, are password protected, and access to shared drives is limited to staff who have signed data confidentiality agreements. Any information collected in paper form will be stored in a locked file cabinet and only those staff who work with the data will have access to the file cabinet. Any paper-based data will be expediently entered into an electronic database, stored in a password- and write-protected location on the local and/or shared drives, and the paper files will be shredded. Audio recordings will be stored in electronic formats with the protections described above and any tapes will be stored in locked filing cabinets until an electronic copy can be made at which point the tapes will be erased.

11. Questions of a Sensitive Nature

The information collection does not require the collection of sensitive information.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. The screening questionnaire will be completed by 340 clinicians and will take 12 minutes to complete on average. Focus groups will be conducted with not more than 99 clinicians and will last about 2 hours. The total

annual burden hours are estimated to be 266 hours. Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annual cost burden is estimated to be $19,594.

Exhibit 1. Estimated annualized burden hours

Data Collection	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden hours
Screening Questionnaire	340	1	12/60	68
In-Person Focus Groups EHR Users only	40	1	2	80
Virtual Focus Groups EHR Users only	29	1	2	58
Virtual Focus Groups EHR Non-users only	30	1	2	60
Total	**439**	**na**	**na**	**266**

Exhibit 2. Estimated annualized cost burden

Data Collection	Number of Respondents	Total Burden hours	Average Hourly Wage Rate*	Total Cost Burden
Screening Questionnaire	340	68	73.66	$5,009
In-Person Focus Groups EHR Users only	40	80	73.66	$5,893
Virtual Focus Groups EHR Users only	29	58	73.66	$4,272
Virtual Focus Groups EHR Non-users only	30	60	73.66	$4,420
Total	**439**	**266**	**na**	**$19,594**

*Hourly wage rate is the weighted average of hourly rates of the types of professionals who will complete the screening questionnaire and participate in the focus groups. The weighted average includes the following occupational codes and wage rates: 29-1065 (Pediatricians, General), $78.67; 29-1069 (Physicians and Surgeons, all others), $97.35; 29-1021 (Dentists, General), $76.61; 29-1111 (Registered Nurses, includes Certified Nurse Midwives), $32.35; 29-1071 (Physician Assistants), $41.86. Source: "National Compensation Survey: Occupational wages in the United States 2009," U.S. Department of Labor, Bureau of Labor Statistics.

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated total and annualized cost to the government for conducting this research. The total cost is estimated to be $424,493.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$79,313	$39,657
Data Collection Activities	103,464	51,732
Data Processing and Analysis	49,732	24,866
Publication of Results	38,415	19,208
Project Management	33,601	16,801
Overhead	119,968	59,984
Total	$0	$212,247

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

This is a qualitative data collection. In order to conduct a rigorous analysis, data analysis will begin immediately after each focus group session. The moderator, technical expert, and assistant will debrief to review notes and summarize important observations that may be relevant to the interpretation of the data. The post-interview debriefing will identify topics that will facilitate analysis, such as recurring themes, group dynamics, and word choice in discussing barriers to meaningful EHR use.

Additionally, a coding structure will be applied to the systematic review of transcripts, audio files, and/or video files. A two-member team will review the transcripts, audio files, and/or video files of all focus group sessions and code the information from the files. Although we will endeavor to develop as complete a code set as possible based on the information from the pilot test, it may be necessary to add codes when coding the information from the main study. Any new codes will be prospectively or retroactively applied to all focus group sessions as appropriate, to maintain consistency across codes.

For each focus group, the code sets from each team member will be compared for consistency. In the event that the two coders differ in their interpretation of the information, the item will be reviewed to

determine if it is a clerical error or a more substantive disagreement that requires review by the full research team. In addition, at least one member of the interviewing team will review coding for accuracy in interpreting the statements made during the focus group.

Once the coding is complete, the analysis team may use NVivo® or similar software to assist in analyzing the resulting transcripts and audio files for recurring themes. This system will help the project team classify, sort and arrange concepts, as well as quantify the frequency with which they are mentioned.

At the end of the data collection period, all focus group data will be organized by theme and used as the basis to develop the final analysis. A report summarizing findings and identifying key points of agreement and disagreement both within and across groups will be developed. Major themes, typical comments, and frequency of comments will be reported in tabular form. Illustrative quotes from subjects will underscore the range, intensity, and type of attitudes, knowledge, and behaviors regarding barriers to achieving meaningful EHR use. The analysis will be structured to first account for overarching barriers and then providing a more detailed analysis by each EP type.

The final products from this body of research will include an analysis report, including methodological detail (such as, description of the location and enrollment of each focus group, our recruitment and logistic processes, and the duration of sessions) and analysis results. The analysis will specifically highlight responses to specific Stage 1 Meaningful Use criteria that could have implications for providers attempting to meet the Stage 2 Meaningful Use criteria. The report will address questions regarding barriers to achieving meaningful use among Medicaid providers. This information would highlight opportunities to provide technical assistance to agencies to assist providers. A PowerPoint slide deck summarizing the key findings will also be prepared and submitted to AHRQ.

Task Description	Performance Period	
	Start	End
Prepare and submit OMB Package for OMB Clearance	9/30/2010	12/08/2010
Prepare and submit IRB Package for IRB Approval	9/30/2010	1/31/2011
Publication of 60-day notice	1/18/2011	1/18/2011
Preparation for data collection	6/30/2010	2/28/2011

Publication of 30-day notice	6/03/2011	6/03/2011
Submission of final OMB package	6/30/2011	6/30/2011
Data Collection	8/30/2011*	10/31/2011
Draft Analysis and Recommendations	11/1/2011	1/9/2012
Analysis and Recommendations Teleconference	1/20/2011	1/20/2012
Revise Analysis Report	1/23/2012	2/6/2012
Draft and submit Final report	2/7/2012	3/30/2012
Draft and submit final presentation	2/7/2012	3/30/2012

*Data collection efforts and subsequent dates are contingent upon the receipt of OMB approval.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Healthcare Research and Quality Act of 1999
Attachment B: Screening Questionnaire and Participant Information Form
Attachment C: Moderator's Guide for Use with In-Person Focus Groups with EHR Users
Attachment D: Moderator's Guide for Use with Virtual Focus Groups with EHR Users
Attachment E: Moderator's Guide for Use with Virtual Focus Groups with EHR Non-Users
Attachment F: Show Cards
Attachment G: Federal Register Notice
Attachment H: Consent Form
Attachment I: Study Announcement
Attachment J: Confirmation Letter
Attachment K: Fact Sheet
Attachment L: Pretest Study Report
Attachment M: Public Comments
Attachment N: AHRQ's Response to Public Comments

References

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