**PATIENT PERCEPTIONS OF THE DELIVERY OF HEALTH CARE
THROUGH THE USE OF AN ELECTRONIC HEALTH RECORD STUDY**

OMB CLEARANCE APPLICATION

**OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH
INFORMATION TECHNOLOGY**

September 17, 2010

Submitted by:

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

On February 17, 2009, the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law No. 111-5 and specifically Title XIII—Health Information Technology for Economic and Clinical Health Act (HITECH), established the Office of the National Coordinator (ONC) for Health Information Technology within the U.S. Department of Health and Human Services (DHHS). Appendix A is a copy of the relevant portion of the legislation, covering health information technology (health IT).

The HITECH Act builds on existing federal efforts to encourage health IT adoption and use, and contains several provisions that are expected to promote its widespread adoption among health care providers. Recognizing the potential of health IT, Congress allocated $19.2 billion to meet the goal of meaningful use of certified electronic health records (EHRs) for each person in the United States by 2014 (U. S. Congress 2009). A central aspect of HITECH is the advancement of patient-centered medical care, and health IT experts agree that HITECH funds are likely to improve how physicians practice medicine for Medicare and Medicaid beneficiaries and, ultimately, will advance patient-centered medical care for all Americans (Blumenthal 2009). However, given the potential disruptive effect of health IT on the provider-patient relationship—a key determinant of more efficient, better coordinated, and safer care—there is a strong need for information about patients' preferences and perceptions of delivery of health care services by providers who have adopted EHR systems in their practices. The current

information gap in this area could slow the federal government's efforts to implement the goals of the HITECH Act.

With this study, ONC aims to better understand the likely role that the HITECH Act may play in fostering patient-centered medical care for all Americans by helping to fill the evidence gap about patient preferences regarding use of health IT during interactions with health care providers.

2. Purpose and Use of Information Collection

Information for the study will be collected and analyzed by Mathematica®, under Contract Number HHSP23320095642WC with ONC, titled "Patient Perceptions of the Delivery of Health Care through the Use of an Electronic Health Record" (Patient Perceptions of EHR). The goal of this study is to help policymakers understand how primary care practices' use of EHRs are related to consumers' satisfaction with (1) their medical care, (2) communication with their doctor, and (3) coordination of care.

The research questions for this study are motivated by ONC's concern that patients may have negative experiences as practices begin to use EHRs. This concern is grounded in recent evidence about the challenges of effectively using and implementing EHRs in primary care practices (Baron et al. 2005). Therefore, the research questions examine whether patients' reported experiences and satisfaction vary by a practice's stage of EHR adoption, and whether these measures improve after practices overcome transition issues related to the EHR. Our questions also explore how EHRs are related to patient satisfaction, so that our analysis can inform

policymakers about specific changes they might recommend to help practices address patient concerns.

The study addresses the following three broad research questions:

1. How is a practice's stage of EHR adoption (early, recent, or non-adopter) related to patients' current satisfaction with their care, with coordination of care, and with communication with their physician?
2. How is the length of time since EHR adoption related to the trend in patient satisfaction levels (between the time of the current visit and a visit that occurred more than a year before the current visit)?
3. What features of practices' EHR use are associated with higher levels of patient satisfaction?

To answer the first two research questions, we will compare outcome measures (such as satisfaction) across patients who are served by different types of practices in terms of whether the practice adopted an EHR and, if so, when it did so. This approach will allow us to see how the presence of an EHR is related to preferences and perceptions. The final research question will be addressed only for patients whose doctors use an EHR; we will explore which aspects of the EHR are associated most with preferences and perceptions. The specific research questions are listed in Table A.1.

Table A.1. Key Research Questions for Patient Perceptions of EHR Study

For All Patients
How satisfied are patients with the care they receive from providers? How satisfied are patients with communication with their providers? How much time does the provider spend communicating directly with the patient during an encounter? How satisfied are patients with the coordination of care?
For Patients Who Receive Services from Providers with EHRs
How satisfied are patients with EHRs? Is provider's use of EHRs related to the length of the patient encounter (shorter, longer, no impact)? Does the entire patient encounter consist of the provider entering data into an EHR at the expense of direct communication with the patient? How do patients think EHR use by their providers affects their health and health care? Do EHRs facilitate care coordination?

For All Patients
Do EHRs facilitate referrals to other providers? Do EHRs facilitate patients' communications with their providers? If so, how? What concerns do patients have about privacy (related to providers' use of EHRs)?

A key part of this analysis will be to explore which patient concerns attenuate after doctors become more proficient at using EHRs, as consumers' views may vary depending on how long ago practices adopted EHRs. If some patient concerns persist over time (that is, even among practices that have used EHRs for several years), policymakers may need to help practices identify ways to overcome patient concerns with using EHRs.

To address these questions, we will conduct two data collection efforts: (1) a survey of 1,680 patients selected from 84 practices across the three stages of EHR adoption (early adopters, late adopters, and non-adopters), and (2) four focus groups with patients from a subset of practices that have adopted EHRs and are using them. We are requesting OMB approval of three data collection instruments: (1) a practice screener to recruit physician practices into the study and to determine the stage of EHR adoption, (2) a patient survey, and (3) a focus group protocol.

We hypothesize that patients served by early EHR adopters and non-adopters will have relatively higher levels of current satisfaction than patients of recent EHR adopters (due to transition issues and provider ease in using the EHR system). We also hypothesize that the satisfaction levels of the patients of early adopters will have improved since the visit a year ago, whereas the satisfaction level of patient of recent adopters will have declined since a year ago. Our primary analysis will test these hypotheses by comparing key measures (such as patient satisfaction with care, as shown in

Table A.2) across the three study categories: (1) patients who receive care from providers without an EHR system, (2) patients who receive care from providers that implemented an EHR system recently (in the past year), (3) and patients who receive care from providers that have used an EHR system for more than a year. Across the three study groups, we will compare measures related to patients' satisfaction with their current visit and measures related to their change in satisfaction since the previous year. Our analysis will also include descriptive statistics related to the reasons that EHR use might be related to patient satisfaction.

Table A.2. Key Measures

Measures of Satisfaction with Care and Care Coordination During Current Visit
Patient Satisfaction with Care Patient Satisfaction with Communication with Provider Patient Satisfaction with Care Coordination Whether Other Health Care Providers Have Needed Records
Measures of Change in Patient Satisfaction
Change in Patient Satisfaction with Care Since Last Year Change in Patient Satisfaction with Communication Since Last Year Change in Patient Satisfaction with Care Coordination Since Last Year
Measures of How EHR Use Might be Related to Patient Satisfaction
Effect of Doctor's Computer Use on Patient Satisfaction Effect of Doctor's Computer Use on Quality of Patient Interaction Effect of Doctor's Computer Use on Length of Visit Privacy Concerns and EHRs

While our primary analysis involves descriptive cross-tabulations, we will also estimate logit models to assess whether any differences we see among our three study groups are driven by differences in patient or practice characteristics (other than EHR implementation). For example, it is possible that large practices are more likely than small practices to adopt EHRs early; if patient satisfaction varies by practice size, a simple cross-tabulation would not be able to distinguish whether the reason for the difference in patient

satisfaction was due to differences related to practice size or to EHR adoption. The logit analysis would confirm whether or not differences we see across our three study groups persist even after we control for practice size (as well as other patient and practice characteristics). The logit models would include patient satisfaction and perception variables as outcome measures, and the following possible control variables:

- Practice size
- Geographic area of practice (that is, urban versus rural location or whether the practice is in a medically underserved area)
- Patient's age
- Patient's race/ethnicity
- Whether the patient had a chronic condition
- Patient's health status
- Patient's length of time at the practice
  - Patient's comfort level with technology

For both cross-tabulations and logit analyses, we will apply survey weights to the data according to the sample design and adjust those weights due to nonresponse.

The analysis of focus groups will provide in-depth and more-nuanced perspectives about the experiences of patients with the care they receive from providers at different stages of EHR adoption and use to help ONC understand the role that HITECH might play in fostering patient-centered medical care. After all of the focus groups have been completed, project staff will meet to identify a list of themes from the group discussions that will be used to guide data analysis. In reviewing the focus group notes from each site, we will draft short top-line reports that highlight the major findings for

each location, because results could vary from state to state. We will then synthesize responses from the focus groups and provide qualitative descriptions of patients' expectations and experiences with the implementation of EHRs.

Findings from the patient survey and focus groups will be included in a final report to ONC.

3. Use of Improved Information Technology and Burden Reduction

Data collection for the practice recruitment will rely on a telephone-administered paper-and-pencil questionnaire. Data collection for the patient survey will rely on a self-administered paper-and-pencil questionnaire. Development and use of information technology for data collection would not be cost-effective given the relatively small sample size and the expense of using computer-assisted personal interviewing (CAPI) laptops in the field.

The contractor will enter the practice recruitment data into an Excel file, and will enter the patient survey data using Viking data entry software on a SUN Ultra Enterprise 2 workstation. A data entry program specific to the survey instrument will be developed and thoroughly tested before use. The program will contain study-specific logic and range and consistency checks to produce high quality data.

Quality control and data entry of completed questionnaires will continue throughout the field period (expected to run three months for the patient survey). The data entry program will contain edit specifications and will flag errors electronically. All errors will be reviewed and resolved during data cleaning, and all entries will be 100 percent verified.

4. Efforts to Identify Duplication and Use of Similar Information

These information collections do not duplicate any other effort and will provide unique information unavailable from any other source.

5. Impact on Small Businesses or Other Small Entities

The only small businesses affected by this effort will be those small or medium-sized physician practices (defined as practices with fewer than 30 physicians) that voluntarily agree to participate in the study. Participating in the study will impose minimal burden on the practices. The medical practice screener is designed to be completed in 10 to 15 minutes. Field staff will work with physician practice staff to collect patient surveys with minimal disruption in their offices.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection effort limited to physician practices and their patients.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

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

8. Comments in Response to the Federal Register Notice/Outside Consultation

The notice required by 5 CFR 1320.8 (d), was published in the Federal Register on February 2, 2010 (Volume 75, Number 21, pages 5329-5330). Appendix B contains a copy of the notice.

Public Comment and Responses. No public comments were received in response to the first Federal Register notice.

No outside consultation for the design of the study and surveys was received. We referenced several surveys that were used in other studies while developing the patient survey instrument to identify questions that were previously used successfully with similar populations. See Table A.3 for a comprehensive list of all surveys that were consulted for survey development.

9. Explanation of any Payment/Gift to Respondents

Physician practices are busy work places that cannot afford to distract resources for purposes other than serving patients. Thus, to ensure the practices' cooperation and compensate them for whatever resources they may need to help coordinate with our field staff, we propose to offer practices an incentive of $100 (to be paid by check). The burden on practices will be minimal; however, their cooperation is essential. Practices will likely see no reason to participate – they gain nothing from cooperating – and it is very easy for them to refuse our request without giving it a moment's consideration. Our aim is to make the study appealing to them in some way. The incentive is not aimed to compensate them for their burden but to make participation appealing in a way that practice managers will approach the practice physicians for their approval to participate.

As for the respondent incentive, we believe that a small incentive will be needed to entice respondents to stay after their medical appointment and fill out the 15-minute questionnaire. This is not the kind of survey where we can

simply call back at another time when it's more convenient. We are asking them to fill out the questionnaire right then, and we believe $10 will be sufficient incentive to do that.

Table A.3. Surveys Consulted for Patient Perceptions of EHR Survey

Consumer Assessment of Healthcare Providers and Systems (CAHPS) - Adult Primary Care Questionnaire. 1.0 – HIT Field Test Version 2009.
Gadd, C.S., L.E. Penrod. "Dichotomy Between Physicians' and Patients' Attitudes Regarding EMR Use During Outpatient Encounters. Proc AMIA Symposium. 2000, pp. 275–279.
Garrison, G.M., M.E. Bernard, and N.H. Rasmussen. "21st Century Health Care: The Effect of Computer Use by Physicians on Patient Satisfaction at a Family Medicine Clinic". Family Medicine vol. 34, 2002, pp. 362– 368.
National Cancer Institute - Health Information National Trends Survey (HINTS) 2007
John Hsu, MD, MBA, MSCE, Jie Huang, PhD, Vicki Fung, Nan Robertson, RPh, Holly Jimison, PhD, Richard Frankel, PhD. Health Information Technology and Physician-Patient Interactions: Impact of Computers on Communication during Outpatient Primary Care Visits. Journal of the American Medical Informatics Association. Volume 12, Number 4, Jul / Aug 2005. Pp. 474 – 480.
Mathematica Policy Research/Centers for Medicare & Medicaid Services - Medicare Care Management Performance (MCMP) Demonstration Beneficiary Survey, 2009.
NPR/Kaiser Family Foundation/Harvard School of Public Health - The Public and the Health Care Delivery System Survey. April 2009.
Rouf, E., J. Whittle, N. Lu, and M.D. Schwartz. "Computers in the Exam Room: Differences in Physician-Patient Interaction May be Due to Physician Experience." JGIM: Journal of General Internal Medicine, vol. 22, no. 1, 2007, pp. 43-48.
Consumer Assessment of Healthcare Providers and Systems (CAHPS) - Adult Primary Care Questionnaire. 1.0 – HIT Field Test Version 2009.
Gadd, C.S., L.E. Penrod. "Dichotomy Between Physicians' and Patients' Attitudes Regarding EMR Use During Outpatient Encounters. Proc AMIA Symposium. 2000, pp. 275–279.

Patients who complete the 15-minute self-administered questionnaire for the study will receive $10, in the form of a gift card, as a thank you for their time and willingness to participate when their medical visit is complete. Focus group participants will receive $40, in the form of a gift card, for participating in the 90-minute group discussion and as partial reimbursement for their time and travel expenses.

10. Assurance of Confidentiality Provided to Respondents

ONC and the contractor will take several steps to assure respondents that the information they provide will be kept private to the extent to which law allows and used for research purposes only. Advance letters mailed to practices will inform them that data collected during recruitment will be aggregated in reports and that no individual practice-level data will be reported.

Patients asked to participate in the patient survey will not be asked for their names and will not be identified individually in any reports. Patients will be informed that their participation in the study is voluntary, and that they have the option to refuse to answer any question in the survey. They will also be told that neither their participation nor their responses will be shared with the physician or physician practice, nor will they affect the medical treatment they receive at the practice.

Paper-and-pencil questionnaires completed by patients are treated as sensitive documents. The patient questionnaire itself will not contain names or other personally identifying information. Instead, each questionnaire will contain a unique identification number that can be linked to the physician practice only for research purposes. Respondent signatures are not required for this survey.

Recruitment data and patient survey data will be processed and stored on the contractor's password-protected local area network (LAN). The contractor, Mathematica, protects its LAN with several security mechanisms available through the network operating system. Access to private

information stored on LAN directories is restricted to authorized project staff by means of IDs and passwords. In addition, network servers containing private information are kept in a locked area.

Personally identifying information (name, telephone number, and address) will be collected by the contractor's field staff in order to recruit patients for the four focus groups. The information will then be sent to the contractor's survey director via FedEx. The information will be used to contact patients who initially volunteer to participate in a focus group, to mail directions and detailed information on when and where the focus group will be held, and to call and remind them of the time and place for the focus group on the day before it is to be held.

Finally, Mathematica 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. Justification for Sensitive Questions

The Patient Perceptions of EHR study instruments include a medical practice screener, patient survey, and focus group discussion guide. The medical practice screener asks questions about the practices' adoption and use of specific EHR functions. The questions are not considered sensitive.

The patient survey includes questions about patient satisfaction with care, communication with the doctor, and coordination of care, and about the doctor's use of electronic medical records. It also includes questions about patient health status, medical diagnoses, and medical visits that may be considered sensitive. Obtaining information about these potentially

sensitive topics is important to the study. Many of the questions were adapted without modification from other surveys of similar populations, such as the Medicare Care Management Performance Beneficiary Questionnaire, the Medicare Coordinated Care Physician Survey Questionnaire, and the Medicare Disease Management Program Evaluation Patient Questionnaire. In these surveys, there was no indication that respondents were reluctant to report on their health status, diagnoses, and health visits as well as other aspects of their health and their experiences with health care providers.

The focus groups will cover the topics of the doctor's use of electronic medical records and patients' impressions of how that affects their quality of care and interactions with their doctor. The questions are not considered sensitive.

12. Estimates of Annualized Hour and Cost Burden

Tables A.4 and A.5 present estimates of annualized respondent burden for completing the medical practice screener, the patient survey, and the focus group discussions for 2010 and 2011, respectively. It shows the expected number of respondents, the hours per response, and the annual hour and total cost burden for the data collected. The practice recruitment and patient surveys are expected to take 15 minutes to complete; the focus group discussion is estimated to take 90 minutes to complete.

Table A.4. Estimated Annualized Burden Hours

Forms	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Screening and Recruitment Form for Primary Care	Staff at Primary Care Practices	42	1	15/60	10.5

Forms	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Practices					
Patient Survey	Patients at Primary Care Practices	840	1	15/60	210
Patient Focus Groups	Patients at Primary Care Practices	20	1	1.5	30
Total		**902**	**1**		**250.5**

Data collection for this study will be conducted over a four-month period, from October 2010 through January 2011. The medical practice screener will be administered during October and November 2010. The patient questionnaires will be administered from November 2010 through January 2011. The focus groups will be conducted during December 2010 and January 2011.

Hourly estimates for the practice recruitment and patient instruments are based on pretest interviews completed with nine patients at one practice.

The cost per medical practice screener 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*0.25 = $4.81 per response. The cost per patient survey was computed using an estimated hourly wage rate of $15.88: $15.88*0.25 = $3.97 per response. The cost per focus group participant was computed using an estimated hourly wage rate of $15.88 for patients as follows: $15.88*1.5 = $23.82 per response.

Table A.5. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Staff at Primary Care Practices	10.5	19.23	201.92

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Patient Survey Respondent	210	15.88	3,334.80
Focus Group Respondent	30	15.88	476.40

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

This is a one-time data collection for research purposes. There are no direct costs to respondents or record keepers other than their time to participate in the study.

14. Annualized Cost to Federal Government

The total value for the EHR contract is $599,660 over 18 months. The annualized cost to the government is $299,830. These estimates are based on the contractor's costs for collecting and tabulating survey and focus group 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.

15. Explanation for Program Changes or Adjustments

Data collection for EHR is new; therefore, there are no changes to burden.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection for practice recruitment will begin in October 2010, approximately 13 months from the start of the project. Data collection for the patient survey will begin in November 2010, approximately 14 months from the start of the project. The final report, due March 31, 2011, will

synthesize results from all components of the study and include all necessary background information on the objectives, scope, and methodology of the project.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed on all materials sent to practices, including the advance letter and screener, and on all materials given to patients, including the self-administered questionnaire, the study fact sheet, the letter, and the focus group contact information card.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Data collection efforts for the Patient Perceptions of EHR study practice screener, patient survey, and focus group protocol will conform to all provisions of the Paperwork Reduction Act.