

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Healthcare Research and Quality****Agency Information Collection Activities: Proposed Collection; Comment Request**

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Building an Implementation Toolset for E-Prescribing." In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on April 24th, 2009 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by July 30, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (*attention:* AHRQ's desk officer) or by e-mail at OIRA_submission@omb.eop.gov (*attention:* AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:**Proposed Project**

"Building an Implementation Toolset for E-Prescribing"

AHRQ proposes to develop and test an electronic prescribing (e-prescribing) toolset to provide information and tools of sufficient detail to act as a "how-to guide" for implementing e-prescribing across various organizational settings.

The current system of prescribing and dispensing medications in the United States poses widespread safety and efficiency problems. E-prescribing systems have the potential to avert some of the more than 2 million adverse drug

events (ADEs) annually, of which 130,000 are life threatening. E-prescribing also has enormous potential to create savings in health care costs, both through reducing ADEs and through more efficient work processes of prescribers and pharmacists. One recent study estimated the potential savings at \$27 billion per year in the United States. [Johnston D, Pan E, Middleton B, Walker J, Bates DW. The value of computerized provider order entry in ambulatory settings. 2003 [cited 2003/12/10]. Available from: http://www.citl.org/research/ACPOE_Executive_Preview.pdf.]

The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003, Public Law 108-173, provided that Medicare Part D sponsors are required to establish electronic prescription drug programs to provide for electronic transmittal of certain information to the prescribing provider and dispensing pharmacy and the dispenser. There is no requirement that prescribers or dispensers implement e-prescribing, but those who do electronically transmit prescription and certain other prescription-related information for Medicare Part D covered drugs prescribed for Medicare Part D eligible individuals, either directly or through an intermediary, are required to comply with any applicable final standards that are in effect.

However, adoption of e-prescribing technology remains limited. On the surface, e-prescribing involves getting a prescription from point A to point B. In reality, the complexity of e-prescribing reflects all aspects of the process from appropriate prescribing, through dispensing, to correct patient use.

Much current work has been on the adoption of technical standards that establish a common language, contain technical specifications, and provide other specific criteria designed to be used consistently as rules or definitions. While standards are a necessary foundation for e-prescribing systems, they are insufficient in themselves to insure a successful implementation. Of equal importance to successful e-prescribing implementations are appropriate workflows and sustainable commitment from the various organizations that must participate in such a system.

This Accelerating Change and Transformation in Organizations and Networks (ACTION) project will produce a toolset to help a diverse range of provider organizations, from small independent offices to large medical groups to "safety net" clinics, to adopt e-prescribing systems and use them

effectively in ways that advance the organization's goals. By enabling the greater adoption of e-prescribing systems that are effective in improving safety, quality and reducing prescription drug costs, the project will advance each of the priorities embodied in AHRQ's mission, which is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.

This work is being conducted by the RAND Corporation under AHRQ ACTION contract HHSA290200600017, Task Order #4, period of performance—8/1/08–1/31/10. It is being conducted pursuant to AHRQ's statutory authority to conduct research and evaluations (1) on health care and systems for the delivery of such care, including activities with respect to health care technologies, facilities and equipment, 42 U.S.C. 299a(a)(5), and (2) to advance training for health care practitioners and researchers in the use of information systems. 42 U.S.C. 299b-3(a)(2).

Method of Collection

In order to evaluate the draft toolset's usability and usefulness, we will pilot test the toolset by studying its effects among 6 practices that are attempting to implement e-prescribing for the first time. Field researchers will visit each practice before and after the e-prescribing implementation effort to conduct semi-structured interviews and observations of work processes. Finally, selected members of the practices will be surveyed via a Web-based instrument regarding the effort's success and the degree to which elements of the toolset were helpful.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in this project. Pre-test and post-test interviews will be conducted with 3 physicians, 3 nurses or clinical support staff and 3 other staff from each of the 6 test sites. The pre-test and post-test observations will involve no more than 1 physician, 1 nurse or clinical support staff and 2 other staff from each of the 6 test sites. Eight physicians from each of the 6 test sites will complete the physician survey and 12 other staff from each site will complete the other staff survey. The total annual burden is estimated to be 186 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in this project. The total cost burden is estimated to be \$8,297.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of sites	Number of responses per site	Hours per response	Total burden hours
Pre-Test Interviews and On-Site Observations				
Pre-test interview guide	6	9	1	54
Pre-test on-site observation guide	6	4	15/60	6
Post-Test Interviews and On-Site Observations				
Post-test interview guide	6	9	1	54
Post-test on-site observation guide	6	4	30/60	12
Web-Based Survey				
Physician questionnaire	6	8	30/60	24
Other staff questionnaire	6	12	30/60	36
Total	36	na	na	186

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of sites	Total burden hours	Average hourly wage rate*	Total cost burden
Pre-Test Interviews and On-Site Observations				
Pre-test interview guide	6	54	\$41.79	\$2,257
Pre-test on-site observation guide	6	6	41.79	251
Post-Test Interviews				
Post-test interview guide	6	54	41.79	2,257
Post-test on-site observation guide	6	12	41.79	501
Web-Based Survey				
Physician questionnaire	6	24	79.33	1,904
Other staff questionnaire	6	36	31.31	1,127
Total	36	186	na	8,297

*Based upon the national average hourly wages for physicians and surgeons, all others (29–1069; \$79.33), registered nurses (29–1111; \$31.31), and health care support workers, all others (31–9099; \$14.74), National Compensation Survey: Occupational wages in the United States May 2008, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annual costs of this project. Since

data collection will not exceed one year, the total and annual costs are the same. The total cost is estimated to be \$119,976.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUAL COST

Cost component	Total cost	Annualized cost
Instrument Development	\$12,533	\$12,533
Data Collection Activities	33,422	33,422
Data Processing and Analysis	16,711	16,711
Report Preparation/Publication	16,711	16,711
Project Management	4,178	4,178
Overhead	36,421	36,421
Total	119,976	119,976

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to

any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination

functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of

information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and, (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: June 22, 2009.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Health IT Community Tracking Study 2009." In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by August 31, 2009.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at doris.lefkowitz@ahrq.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Health IT Community Tracking Study 2009

Electronic prescribing (e-prescribing) is a central focus of efforts to promote health information technology (IT) and is of particular interest to AHRQ because of its potential to improve patient safety by reducing medication errors. Despite many public- and private-sector initiatives to support e-prescribing, to date, physician adoption and use has been limited (Friedman, Schueth and Bell 2009). Recently, section 132 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Public Law 110-275, authorized a new incentive program for eligible individual providers who are successful e-prescribers. In addition, section 4101 of the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111-5, provides incentives for meaningful use of electronic health record technology, which includes the use of e-prescribing.

The potential gains from e-prescribing assume that prescribers and pharmacists have access to the required features and use them. Limited research on the topic suggests, however, that not all e-prescribing systems currently have the full range of e-prescribing features required under MIPPA; that even when the features are available, physician practices face barriers to implementing them effectively; and even when they are implemented at the practice level, physicians may not use them. For example, in a small, exploratory qualitative study by Grossman, et al. (2005), physicians did not routinely have access to patient medication histories or formulary data for a significant portion of their patients and when they did, physicians often did not use the information, instead continuing to rely on patients for medication history and pharmacists to identify formulary issues. Several studies have identified that IT system limitations, workflow and training issues, and real or perceived regulatory barriers present obstacles in both the physician and pharmacy settings to electronic transmission of prescriptions (Grossman et al. 2007; NORC 2007; Rupp and Warholak 2008; Warholak and Rupp 2009).

AHRQ proposes to conduct a qualitative research study designed to help build knowledge on how the e-prescribing features required under MIPPA are actually being implemented and used by physicians and pharmacies in 12 nationally representative communities. These communities have

been studied longitudinally since the mid-1990s as part of the Center for Studying Health System Change (HSC) Community Tracking Study (CTS) (Center for Studying Health System Change 2007). This qualitative study will collect data from physician practices and pharmacies that are using electronic transmission of prescriptions to allow a focus on both the facilitators of and barriers to this critical aspect of e-prescribing. The study will be the first to ask questions of physician practices and pharmacies in the same communities on the same topics, providing a much more complete picture of e-prescribing implementation. For example, in addition to gaining physician and pharmacy perspectives on electronic transmission, the study will explore how physician practices use patient formulary data and how pharmacies perceive changes in the communication with physician practices around formulary issues with e-prescribing.

Information collected by this study will inform strategies to promote the adoption and effective use of e-prescribing being developed by AHRQ and other Department of Health and Human Services agencies, including the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health IT, as well as State and local governments and private health care organizations. In particular, while physician adoption has been the focus of most policy efforts, findings from the study can help identify and shape strategies to promote more effective implementation of e-prescribing in retail and mail-order pharmacies. This work will be conducted by AHRQ's contractor, the Center for Studying Health System Change (HSC), under contract number 290-05-0007-03. This study is being conducted pursuant to AHRQ's statutory authority to conduct and support research on health care and systems for the delivery of such care, including activities with respect to health care technologies, facilities and equipment, 42 U.S.C. 299a(a)(5).

Method of Collection

The study will use qualitative methods, including telephone interviews with physician practices and pharmacies, as well as State pharmacy associations, IT vendors and other e-prescribing experts. Using semi-structured interview protocols, the following specific research questions will be addressed to provide an in-depth look at unexplored barriers to effective e-prescribing use in physician practices and pharmacies, including: