Dated: January 17, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–1400 Filed 1–25–12; 8:45 am]

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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: ''Assessing the Feasibility of Disseminating Effective Health Care Products through a Shared Electronic Medical Record Serving Member Organization of a Health Information Exchange.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on November 15th, 2011 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 February 27, 2012.

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 email 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 email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Assessing the Feasibility of Disseminating Effective Health Care Products through a Shared Electronic Medical Record Serving Member Organization of a Health Information Exchange

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve under the Paperwork Reduction Act of 1995 this collection of information from users of work products and services initiated by the John M. Eisenberg Clinical Decisions and Communications Science Center (Eisenberg Center).

AHRQ is the lead agency charged with supporting research designed to improve the quality of healthcare, reduce its cost, improve patient safety, decrease medical errors, and broaden access to essential services. AHRQ's Eisenberg Center's mission is improving communication of findings to a variety of audiences (''customers''), including consumers, clinicians, and health care policy makers. The Eisenberg Center compiles research results into useful formats for customer stakeholders. The Eisenberg Center also conducts investigations into effective communication of research findings in order to improve the usability and rapid incorporation of findings into medical practice. The Eisenberg Center is one of three components of AHRQ's Effective Health Care (EHC) Program. The collections proposed under this clearance include activities to assess the feasibility of disseminating materials developed by the Eisenberg Center through the use of an electronic medical record (EMR) shared by a network of clinical care providers that are part of a Health Information Exchange (HIE) operating in multiple sites in several states. Our Community Health Information Network (OCHIN) members include 30 clinical care organizations operating more than 230 primary care clinics in six states. Data will be gathered from three different OCHIN-member organizations representing a total of 10 primary care clinics. The information generated will be provided to AHRQ to guide decision making and planning for additional efforts to foster EHC Program product distribution via EMR prompting and product linkages.

This research has the following goals:

(1) Identify facilitators and barriers to successful efforts to implement processes that: (a) Support use of EHC Program products by clinicians in practice, and (b) place relevant clinical information in the hands of patients and family members in languages and formats that are appropriate to patients' information needs;

(2) Examine ways in which EHC Program products can be used in concert with other support programs and products (*e.g.*, healthwise® resources available through the EMR; brief patient instructions and letters, including those designed for use with persons having very low literacy skills);

(3) Assess the extent to which EHC Program products are used (*e.g.*, accessed by clinicians, provided to patients in relevant formats) in settings where use is supported by automated EMR features, such as on-screen prompts and reminders; and

(4) Document the perceived value of integrating EHC Program products into systems of care supported by an EMR system as self-reported by clinicians involved in direct care of patients and clinic support personnel who interact with patients.

This study is being conducted by AHRQ through its contractor, the Eisenberg Center—Baylor College of Medicine, pursuant to AHRQ's statutory authority to conduct and support research, and disseminate information, on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and clinical practice. 42 U.S.C. 299a(a)(1) and (4).

Method of Collection

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

(1) Automated Data Capture from EMR Usage Logs. Electronic usage data will be collected to determine the extent to which EHC Program guides for clinicians and patients were accessed to support shared decision making and patient education. The data will be retrieved from the existing EMR-linked database operated by the Kaiser Permanente staff in their coordination of activities related to the OCHIN HIE. Data will include: (a) Number and frequency of retrieval of EHC resource materials; (b) specific types of materials retrieved; and (c) health topic or condition targeted in the EHC materials. These data will inform the development of follow-up questions to be administered to clinicians and patients in the interviews and surveys described below. Because the data will be obtained using automated systems already in place, no special effort will be needed to generate these data, and thus this task is not included in the burden estimates in Exhibits 1 and 2.

(2) Interviews with Clinicians. Interviews will be held with clinical service providers for the following purposes: (a) Obtain perceptions of the overall value, relevancy, currency and appropriateness of EHC Program products in addressing the health service needs of patients treated in clinical settings; (b) assess ease of use of the materials in terms of access via the EMR; (c) determine perceived success of efforts to employ EHC Program products and related materials in addressing the needs of patients with limited language skills and/or low literacy levels; and (d) describe the relative success of efforts to use the EHC Program products in concert with other tools (*e.g.*, healthwise® resources) in promoting patient engagement in their own health care or in the care of family members.

(3) Interviews with Support Staff. Interviews will be held with non-clinical support staff to characterize perceptions of how the introduction of EHC Program products: (a) Affected clinic workflows and influenced the work that staff was required to do in supporting clinician-patient interactions; and (b) facilitated or impeded efforts to inform patients about actions they could take in being more fully involved in their own health care.

(4) Interviews with Patients. Interviews will be held with recruited patients to determine if they: (a) Viewed the EHC Program products that they were provided as useful to them in understanding their health issues; (b) were able to understand the EHC Program-related information that was provided to them sufficiently to take actions in their own health care; and (c) have suggestions about how the EHC Program materials could be changed or the delivery of them done in a different way to make the materials more useful and/or accessible to patients.

(5) Survey of Clinicians. A questionnaire will be administered to clinical care providers near the end of the study to gather quantitative data around their assessments of: (a) The relevancy of the EHC Program materials to the patients they serve; (b) the appropriateness of the products in addressing specific clinical issues; (c) the ease of use of the system created to provide access to EHC Program products through the EMR; and (d) overall ratings of the approach in addressing patient needs with regard to specific conditions addressed by the products available.

The interviews with clinicians, clinical staff, and patients will be conducted throughout the project period, approximately every three months with different sets of participants, to inform and refine delivery mechanisms and monitor progress.

This information will be used to determine the feasibility of: (a) Mounting broader efforts to distribute clinician and consumer guides, as well as other EHC products using EMRs as the primary vehicle for providing product access at the point of care; and (b) initiating additional studies to identify factors that encourage or deter effective integration of EHC products into care processes using electronic tools and care delivery support systems, like the EMR, that are increasingly common in clinical work settings.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden for the respondents' time to participate in this research. Three rounds of interviews will be conducted during the project period (each round of interviews to be held approximately every three months with separate sets of participants) to assess progress and adjust methods or refine materials as needed. Interviews will be conducted with 100 patients, 50 clinicians and 50 clinical support staff. Each interview is estimated to last no more than 30 minutes. All clinicians in each participating clinic will have access to the EMR and will be invited to participate in an online questionnaire. Approximately 200 clinicians will complete the 10-minute questionnaire.

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 $6,274.

EXHIBIT 1—ESTIMATED ANNUALIZED TOTAL BURDEN HOURS

Type of data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Interviews with Clinicians	50	1	30/60	25
Interviews with Support Staff	50	1	30/60	25
Interviews with Patients	100	1	30/60	50
Survey of Clinicians	200	1	10/60	33
Total	400	na	na	133

EXHIBIT 2—ESTIMATED ANNUALIZED TOTAL COST BURDEN'>

Type of data collection	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Interviews with Clinicians	50	25	$83.59	$2,090
Interviews with Support Staff	50	25	14.31	358
Interviews with Patients	100	50	21.35	1,068
Survey of Clinicians	200	33	83.59	2,758
Total	400	133	na	6,274

Based upon the mean wages for clinicians (29–1062 family and general practitioners), clinical team members (31–9092 medical assistants) and patients/consumers (00–0000 all occupations), National Compensation Survey: Occupational wages in the United States May 2010, ''U.S. Department of Labor, Bureau of Labor Statistics.''

Estimated Annual Costs to the Federal Government

The maximum cost to the Federal Government is estimated to be $217,451 annually for two years.

Exhibit 3 shows the total and annualized cost by the major cost components.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$153,750	$76,875
Data Collection Activities	162,465	81,233
Data Processing and Analysis	33,563	16,781
Project Management	22,625	11,313
Overhead	62,500	31,250
Total	434,903	217,451

Request for Comments

In accordance with the Paperwork Reduction Act, 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 healthcare research and healthcare 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: January 17, 2012.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on the Use of Natriuretic Peptide Measurement in the Management of Heart Failure

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for scientific information submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from medical device manufacturers of natriuretic peptide measurement assays. Scientific information is being solicited to inform our Comparative Effectiveness Review of Use of Natriuretic Peptide Measurement in the Management of Heart Failure, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173.

DATES: Submission Deadline on or before February 27, 2012.

ADDRESSES: Online submissions: *http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/*. Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

Email submissions: ehcsrc@ohsu.edu (please do not send zipped files—they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW. Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239–3098.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: (503) 494–0147 or Email: *ehcsrc@ohsu.edu*.

SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for use of natriuretic peptide measurement in the management of heart failure.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (*e.g.,* details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on natriuretic peptide measurement assays, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=899#4210.*

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific