

III. Request for Comments

OHRP is making its draft guidance document available for public comment. OHRP's guidance document will be finalized and issued after the public comments have been considered.

Dated: November 21, 2008.

Melody H. Lin,

Deputy Director, Office for Human Research Protections.

[FR Doc. E8-28369 Filed 11-28-08; 8:45 am]

BILLING CODE 4150-36-P

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:

“Colorado Regional Health Information Exchange (CORHIO)—Point of Care Exchange System Evaluation: Point of Care Questionnaires and Focus Groups.” 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 January 30, 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

Colorado Regional Health Information Exchange (CORHIO)—Point of Care Exchange System Evaluation: Point of Care Questionnaires and Focus Groups

AHRQ proposes a case study of the point-of-care (POC) clinical exchange

system at the Colorado Regional Health Information Exchange (CORHIO). The CORHIO is an AHRQ State and Regional Demonstration Project contract which supports the administrative and technical implementation of an information technology service to provide secure electronic transmission of clinical information between partner health care entities to improve the efficiency, quality, and safety of patient care.

The key element of CORHIO is the POC clinical exchange system, which doctors can use to access information about individual patients as they care for them. The POC clinical exchange system is an Internet-based portal which allows authorized users to log in and request clinical information for a specific patient. The POC clinical exchange system is composed of two functions: The patient search function and the data exchange function. The patient search function is supported by the CORHIO master patient index, which is an index of all the patients that have been seen within a given time period at CORHIO's partner health care organizations (HCOs). The patient search function allows users to enter identifying information for a patient, such as name, date of birth, or medical record number, and searches to determine if the patient has received medical care at one of the partner HCOs. The POC clinical exchange system will then display all potential matching identities available at the CORHIO partner HCOs. Users select the appropriate match, if it exists, and request available data for the selected patient. The data exchange function aggregates and displays the available data from multiple partner HCOs for the selected patient.

This proposed information collection will provide input from clinicians at four participating HCOs regarding the usability of the system and the value of the exchanged Clinical information to inform decision-making, patient disposition and potentially redundant test ordering. Additionally, this case study will provide important information to inform future design and phase implementation of the CORHIO system.

This case study is being conducted pursuant to AHRQ's statutory mandate to conduct and support research, evaluations and initiatives to advance the creation of effective linkages between various sources of health information, including the development of information networks (42 U.S.C. 299b-3(a)(3)).

Method of Collection

This case study includes 2 distinct data collections regarding the POC clinical exchange system:

1. POC Questionnaire—a survey of end-users at three emergency departments (ED) regarding their experiences with the POC clinical exchange system and its effect on patient care. This questionnaire will be used to collect data from the EDs for one week quarterly in 2009 and for the first quarter of 2010.

2. Focus Groups—focus groups with select high- and low-use users of the POC clinical exchange system from each of the three EDs and one Call Center. Focus groups will be conducted at 4 and 8 months after users begin using the POC system.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours for the respondents' time to participate in this project. The POC questionnaire will be administered to the three participating EDs only, while the focus groups will be held at both the EDs and the one participating call center. The POC questionnaire will be administered quarterly for an entire week at each ED. There are typically two doctors per shift, 21 shifts per week and an average of 25 patients seen by each doctor per shift. One attending physician per shift will respond, resulting in about 525 patient encounters per each ED over a one week period. Since the POC questionnaire will be completed for each patient seen, 525 questionnaires will be completed each quarter, resulting in about 2,100 completed questionnaires per year (4 quarters × 525 per quarter) per ED. The POC questionnaire is estimated to require about two minutes to complete.

However, the POC clinical exchange system will be used for only about 10 percent of the visits. This means that for 90 percent of the visits providers will check off “Did not use” and select a reason why they did not use the system, which will take 5 to 10 seconds. The maximum time of two minutes was used for all responses to calculate a conservative estimate of the burden.

The focus groups will be conducted twice a year at each of the four participating facilities and are expected to take one hour or less to complete. The maximum expected time of one hour was used to calculate a conservative estimate of the burden. The total burden hours for all data collections is estimated to be 242 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
POC Questionnaire	3	2,100	2/60	210
Focus Groups	4	8	1	32
Total	7	na	na	242

Exhibit 2 shows the annualized cost burden for the respondent's time to participate in this project. The total cost burden is estimated to be \$21,775.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate* (\$)	Total cost burden (\$)
POC Questionnaire	3	210	92.03	19,326
Focus Groups	4	32	76.53	2,449
Total	7	242	na	21,775

* Based upon the weighted average of the "registered nurse" mean and the "surgeon" mean of the average wages, May 2007 National Occupational Employment and Wage Estimates, United States, U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 (accessed Nov. 1, 2008). The "surgeon" mean salary was used for the 3 ED respondents and the "registered nurse" mean salary was used for the 1 Call Center.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost of this two-year project

to the federal government. The total cost is \$34,730 and includes \$7,500 for project development, \$8,400 for data collection activities, \$6,580 for data

processing and analysis, \$1,000 for the publication of results and \$11,250 for project management.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost (\$)	Annualized cost (\$)
Project Development	7,500	3,750
Data Collection Activities	8,400	4,200
Data Processing and Analysis	6,580	3,290
Publication of Results	1,000	500
Project Management	11,250	5,625
Overhead	0	0
Total	34,730	17,365

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, quality improvement and 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: November 14, 2008.

Carolyn M. Clancy,

Director.

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BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Submission for OMB Review; Comment Request**

Title: State Council on Developmental Disabilities Program Performance Report.

OMB No.: 0980-0172.

Description: A Developmental Disabilities Council Program Performance Report is required by federal statute. Each State Developmental Disabilities Council must submit an annual report for the preceding fiscal year of activities and accomplishments. Information provided