

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

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427-1477.

SUPPLEMENTARY INFORMATION:

Proposed Project

"Voluntary Customer Surveys Generic Clearance for the Agency for Healthcare Research and Quality"

In response to Executive Order 12962, the Agency for Healthcare Research and

Quality (AHRQ) plans to conduct voluntary customer surveys to assess strengths and weaknesses in agency program services. Customer surveys to be conducted by AHRQ may include readership surveys from individuals using AHRQ automated and electronic technology databases to determine satisfaction with the information provided or surveys to assess effect of the grants streamlining efforts. Results of these surveys will be used in future program planning initiatives and to redirect resources and efforts, as needed, to improve AHRQ program services. The current clearance will expire January 31, 2008. This is a

request for a generic approval from OMB to conduct customer surveys over the next three years.

Methods of Collection

The data will be collected using a combination of methodologies appropriate to each survey. These methodologies include:

- Evaluation forms;
- Mail surveys;
- Focus groups;
- Automated and electronic technology (e.g., e-mail, Web-based surveys, instant fax, AHRQ Publication Clearinghouse customer feedback) and,
- Telephone surveys.

ESTIMATED ANNUAL RESPONDENT BURDEN

Type of Survey	No. of respondents	Average hour burden/re-sponse	Total hours of burden
Mail/Telephone Surveys	51,200	0.15	7,680
Automated/Web-based	52,000	0.163	8,476
Focus Groups	200	1.0	200
Totals	103,400	NA	16,356

This information collection will not impose a cost burden on the respondents beyond that associated with their time to provide the required data. There will be no additional costs for capital equipment, software, computer services, etc.

Estimated Annual Costs to the Federal Government

The mail and telephone surveys and focus groups will in some cases be carried out under contract. Assuming the contract cost per survey is \$50,000-\$100,000, and for each focus group is \$20,000, total contract costs could be \$720,000 per year.

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: July 30, 2007.

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, Department of Health and Human Services.

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) allow the proposed information collection project:

"Chartering Value Exchanges for Value-driven Health Care." The information collection will take the form of narrative responses to semiannual Requests for Proposals to participate in a learning network of mature multi-stakeholder community health care collaboratives established to measure, report, and improve the quality and cost of available healthcare. 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.

DATES: Comments on this notice must be received by September 4, 2007.

ADDRESSES: Written comments should be submitted to: Karen Matsuoka 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, application form, and specific details on the estimated burden can be obtained from AHRQ's 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

“Charting Value Exchanges for Value-driven Healthcare”

This project proposes to twice annually post a public call for parties interested in becoming chartered as Value Exchanges for Value-driven Healthcare, described in the Background Section below. Anticipated benefits of being a chartered Value Exchange include (1) Participation in an AHRQ-managed Learning Network and (2) access to Medicare patient de-identified provider performance measurement results.

Background

The Secretary of Health and Human Services has created and is implementing a Value-driven Healthcare Initiative to enhance person and population-centered care by improving the quality of healthcare services and reducing healthcare costs. Related HHS goals and objectives reflect the President's Executive Order 13410: *Promoting quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs (August 2006)* and encompass (1) Promotion of the establishment of health information technology interoperability standards for exchanging price and quality healthcare data; (2) promotion of the availability and use of transparent, nationwide consensus based and endorsed quality measures; (3) promotion of the availability and use of transparent, nationwide consensus based and endorsed measures of price/cost; and (4) promotion of the use of provider and consumer incentives for high quality and cost efficient healthcare.

This Initiative's designed on three fundamental principles. The first is that at its core, healthcare is “local”—provided in uniquely constituted cultural and market-based environments. As such, improving the value of healthcare requires a critical mass of community stakeholders: Public and private purchasers, health plans, providers, and consumers, as well as other relevant community entities (e.g., local health information exchange organizations, Quality Improvement Organizations, state data organizations) investing their time and resources toward shared cost and quality improvement goals. We refer to such representative community entities as local multi-stakeholder collaboratives. Scattered across the country there are community collaboratives in various stages of development ranging from mature multi-stakeholder collaboratives (defined as ongoing collaboration among

representatives from purchasers, health plans, providers, and consumers) to communities where collaboration does not include representatives from all four groups.

The second principle is that broad access to accurate, meaningful information will improve the value of healthcare services by (1) stimulating provider improvement, (2) engaging consumers in provider selection and treatment choices, and (3) enabling purchasers to align consumer and provider incentives. Generating the information needed to accomplish this is maximized when performance measures can be calculated based on all payer data.

The third principle is that establishing a nation-wide learning network will accelerate market-based health care improvement. Learning networks are an evidence-based organizational mechanism to achieve rapid identification, dissemination and adoption of best practices. They are comprised of individuals or groups focused on achieving common broad goals.

Based on the above, AHRQ plans to (1) identify and designate qualified mature community-based multi-stakeholder groups as Chartered Value Exchanges and establish a nation-wide learning network for them.

Chartered Value Exchanges (CVEs)

AHRQ envisions Chartered Value Exchanges as having four core and three important non-core functions as described below.

Four (4) Core Functions

Engagement of Stakeholders in Collaboration:

Effectively engaging representatives from all four critical stakeholders: purchaser, health plan, provider, and consumer representatives as well as from Health Information Exchanges, Quality Improvement Organizations, state data organizations and other community stakeholders in *ongoing* collaboration is a core CVE function.

Use of Measures:

Getting nationwide consensus based and endorsed performance measures locally adopted and used is a core CVE function. Developing new measures is not. Measures could be generated nationally or generated locally based on clear protocols. Optimally, measures would be constructed by pooling information from all relevant sources and would ultimately address all six Institute of Medicine performance domains of safety, timeliness,

effectiveness, efficiency, equitableness, and patient-centeredness.

Provider Engagement in Improvement:

Directly engaging providers to use performance information is a core CVE function and is not limited to informing providers of results. Engagement requires active ongoing dialogue that includes but is not limited to improving data accuracy and data interpretability. While provider engagement is anchored locally, CVEs will operate in a national environment and should encourage involvement, support and ongoing dialogue between national, regional, and local entities.

Consumer Engagement:

Engaging consumers to use performance information is a core CVE function and is not limited to reporting of information. This function may be met, however, by assuring usable information is made available to other entities that would use and distribute that information to consumers.

Three (3) Important (Non-core) Functions

Promoting HIT and HIE

The role of the CVE is to: (1) Facilitate the use of interoperable health information technologies and health information exchange either directly or through alignment with regional health information networks and (2) promote the ongoing migration of measure calculation based solely on aggregated claims data to measure calculation that includes aggregated electronic clinical data and fosters real time patient care improvement.

Facilitating Rewards for Better Performance

The role of the CVE is to *facilitate or enable* the use of performance measures to reward and foster better provider performance and consumer behavior. The function may be met by serving as a catalyst attempting to influence regional or national health plans and purchasers.

Supporting Knowledge Transfer and Conducting Ongoing Improvement of Efforts

Sharing discoveries and lessons learned within the CVE community, the CVE learning network, and interested public at large is an expectation of how a CVE conducts itself. Likewise, it is an expectation that a CVE will practice continues quality improvement in all that it does.

The Chartered Value Exchange designation will be applied to the collective work occurring within a

community regardless of how many organizations divide up the work. AHRQ does not plan, however, to impose a particular definition of community based on geography or population density. AHRQ recognizes the need to respect local culture, relationships, and priorities, and will maintain a flexible and inclusive approach to selection and designation. AHRQ does not require a Value Exchange to be an incorporated non-profit entity. AHRQ expects CVEs to adopt nationwide consensus based and endorsed principles and standards where they exist and as they are made available. To be eligible, interested parties must first be recognized by HHS Secretary Michael O. Leavitt as a Community Leader for Value-driven Healthcare. For additional information on Community Leader recognition, see <http://www.hhs.gov/transparency/communities/communityleaders/communities.html>.

Learning Network

Goals of the Learning Network will be to facilitate sharing of CVE experiences and lessons learned; identify and share promising practices that improve healthcare value; identify gaps where innovation is needed; raise issues to be addressed by national consensus-building organizations; and provide on-the-ground perspective to inform and participate in setting national priorities for healthcare quality and cost improvement. The Learning Network will provide technical assistance in such areas as collaborative production of public reports, effective pay for performance, and use of consumer incentives, and will ultimately work with CVEs to implement a core measure set derived from nationwide consensus based and endorsed measures.

Method of Collection

Each RFP will be posted on the AHRQ public Web site (<http://www.ahrq.gov>) with a link to the AHRQ site on the HHS transparency Web site as well. The RFP instructions will direct interested parties to electronically submit narrative information (maximum 3000 words) to AHRQ that describes their current activities and/or plans to perform the four core functions and three important non-core functions. In addition, applicants will be asked to describe their staff/consultant/in-kind resource arrangements to provide needed expertise; their ability to raise funds or in-kind support from multiple stakeholders; and their ability to manage projects and finances as indications of their organizational capacity to accomplish the four core functions. Review teams comprised of purchaser, health plan, provider, consumer, and federal representatives will be assembled. Review teams will include experts from Health Information Exchanges and the Quality Improvement Organization community. Each enrollment period will be open for two months. Applications will be assigned and scored as they are received at AHRQ. AHRQ staff will screen the application for Community Leader status, then distribute it to each member of the 5 member review team. The application will be individually scored by each of the review team members within two weeks. The completed scoring forms will be returned to AHRQ who will then generate the team's average scores per function for that applicant. The Scoring Form uses the following rating scale and definitions to guide the evaluations:

Evaluation Guide: To standardize the interpretation of the rating scale, please use the following definitions to guide your choices:

- *Excellent (5 points):* Clear demonstration of activity already in progress.
- *Very Good (4 points):* Activity partially in progress and effective plan to further mature articulated.
- *Average (3 points):* Effective plan articulated.
- *Fair (2 points):* Attempts to address but hasn't effectively articulated plan or success.
- *Poor (1 point):* Ignores issue.

Minimum *average* scores have been set for each function, and are weighted to reflect the importance of the particular function. Engagement of critical stakeholders has a minimum *average* score of 4.5 while engagement of others, use of performance measures, provider engagement and consumer engagement each have minimum *average* scores set at 3.0. Non-core functions including promotion of HIT and HIE, facilitation of rewards for better performance, participation in knowledge transfer, and ongoing improvement of efforts each have minimum *average* scores set at 2.0. Organizational capacity requires a minimum *average* score of 2.0 also. Individual application scores can range from a possible high of 27 to a low of 10, but the acceptance of any applicant will be based on meeting the minimum *average* score required for each function as well as organizational capacity. A grid of *all* applicants' *average* scores by function will be presented to the AHRQ Executive Leadership Team to make final decisions on how many and which applicants will be chartered at the end of the first month and at the close of the enrollment period. Attempts will be made to maximize geographical and population diversity. Successful applicants will be notified within one month of review.

Estimated Annual Respondent Burden

EXHIBIT 1.—ESTIMATE OF COST BURDEN TO RESPONDENTS

Data collection effort	Number of estimated respondents	Estimated time per respondent in hours	Estimated total burden hours	Average hourly wage rate	Estimated annual cost burden to respondents
Draft narrative response to RFP by Collaborative Manager	50	8	400	\$34.67	\$13,868
Narrative reviews by 1–2 members of Collaborative executive committee	75	1	75	57.90	4,342.50
Narrative revisions by Collaborative Manager	50	8	400	34.67	13,868
Assembly of narrative with any supporting documents by Collaborative Assistant	50	2	100	12.58	1,258
Total	225		950		33,336.50

This information collection will not impose a cost burden on the respondent beyond that associated with the above

estimates of the time needed to provide the application-requested information. There will be no additional substantial

costs to respondents anticipated, e.g. for capital equipment, software, computer services.

Estimated Costs to the Federal Government

The total cost to the government for its proposal review activity is estimated to be \$500,000 annually.

Request for Comments

In accordance with the above-cited legislation, comments on the 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 health care improvement and information dissemination functions of AHRQ, including whether the information requested 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 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 request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 30, 2007.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety and Security Monitoring Project—Radiological Health; Availability of Cooperative Agreements Under a Limited Competition; Request for Applications: FD07-005; Catalog of Federal Domestic Assistance Number: 93.448

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations, is announcing the availability of cooperative agreements for equipment, supplies, personnel, training, and facility upgrades to Food Emergency Response Laboratory

Network (FERN) radiological laboratories of State, local, and tribal governments. The cooperative agreements are to enable the analyses of foods and food products in the event that redundancy and/or additional laboratory surge capacity is needed by FERN for analyses related to radiological terrorism or other emergency situations. These cooperative agreements are also intended to expand participation in networks to enhance Federal, State, local, and tribal governmental food safety and security efforts. This notice supersedes the request for applications that published in the **Federal Register** of August 24, 2006 (71 FR 50068).

A. Background

ORA is the primary inspection and analysis component of FDA and has approximately 1,600 investigators, inspectors, and analysts who cover the country's approximately 95,000 FDA-regulated businesses. These investigators inspect more than 15,000 facilities per year and ORA laboratories analyze several thousand samples per year. ORA conducts special investigations, conducts food inspection recall audits, performs consumer complaint inspections, and collects samples of regulated products. Increasingly, ORA has been called upon to expand the testing program that addresses the increasing threat to food safety and security through intentional radiological terrorism events. Toward this end, ORA has developed radiological screening and analysis methodologies that are used to evaluate foods and food products in such situations. However, in the event of a large-scale emergent incident, analytical sample capacity in ORA field laboratories has a finite limit. Information from ongoing relationships with State partners indicates limited redundancy in State food testing laboratories; both in terms of analytical capabilities and analytical sample capacity. Several State food testing laboratories lack the specialized equipment to perform the analyses, and/or the specific methodological expertise in the types of analyses performed for screening foods and food products involving radiological terrorism events.

The events of September 11, 2001, reinforced the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act, which President George W. Bush signed into law on June 12, 2002. The Bioterrorism Act is divided into the following five titles:

Title I—National Preparedness for Bioterrorism and Other Public

Health Emergencies,
Title II—Enhancing Controls on Dangerous Biological Agents and Toxins,

Title III—Protecting Safety and Security of Food and Drug Supply,
Title IV—Drinking Water Security and Safety, and
Title V—Additional Provisions.

Subtitle A of the Bioterrorism Act, "Protection of Food Supply," section 312, "Surveillance and Information Grants and Authorities," amends part B of Title III of the Public Health Service Act to authorize the Secretary of Health and Human Services to award grants to States and Indian tribes to expand participation in networks to enhance Federal, State, and local food safety efforts. This may include meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

FDA will support the projects covered by this document under the authority of section 312 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107-188). This program is described in the Catalog of Federal Domestic Assistance under number 93.448.

B. Program Research Goals

The goal of ORA's cooperative agreement program is to complement, develop, and improve State, local, and Indian tribal food safety and security testing programs. This will be accomplished through the provision of equipment, supplies, personnel, facility upgrades, training in current food testing methodologies, participation in proficiency testing to establish additional reliable laboratory sample analysis capacity, analysis of surveillance samples, and, in cooperation with FDA, participation in method enhancement activities designed to extend analytical capabilities. In the event of a large-scale radiological terrorism event affecting foods or food products, the recipient may be required to perform selected radiological analyses of domestic and imported food samples collected and supplied to the laboratory by FDA or other Federal agencies through FDA. These samples may consist of, but are not limited to, the following: Vegetables and fruits (fresh and packaged), juices (concentrate and diluted), grains and grain products, seafood and other fish products, milk and other dairy products, infant formula, baby foods, bottled water, condiments, and alcoholic products (beer, wine, scotch).