

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:22 p.m. on Monday, April 23, 2012, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Director Thomas M. Hoenig (Appointive), seconded by Director Richard Cordray (Director, Consumer Financial Protection Bureau), concurred in by Director Thomas J. Curry (Comptroller of the Currency), Director Jeremiah O. Norton (Appointive), and Acting Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street NW., Washington, DC. Federal Deposit Insurance Corporation.

Dated: April 23, 2012.

Robert E. Feldman,
Executive Secretary.

[FR Doc. 2012-10161 Filed 4-24-12; 11:15 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: "System Redesign for Value in Safety Net Hospitals and Delivery Systems." 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 February 24th, 2012 and allowed 60 days for public comment. No substantive 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 May 29, 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

System Redesign for Value in Safety Net Hospitals and Delivery Systems

This proposed project is a case study of 8 safety net (SN) hospitals. The goals of the project are to:

- (1) Identify the tools and resources needed to facilitate system redesign in SN hospitals and;
- (2) Identify any barriers to adoption of these in SN environments, or any gaps that exist in the available resources.

These goals are consistent with The National Strategy for Quality Improvement in Health Care, published by the U.S. Department of Health and Human Services in March 2011, which articulated a need for progress toward three goals: (1) Better Care, (2) Healthy People/Healthy Communities and (3) Affordable Care. SN hospitals and systems are critical to achieving all three. SN hospitals are hospitals and health systems which provide a significant portion of their services to vulnerable, uninsured and Medicare patients. While all hospitals face challenges in improving both quality and operating efficiency, safety net (SN) hospitals face even greater challenges due to growing demand for their services and decreasing funding opportunities.

Despite these challenging environmental factors, some SN hospitals and health systems have achieved financial stability and implemented broad-ranging efforts to improve the quality of care they deliver. However, while there have been successful quality improvement initiatives for SN providers, most initiatives aim at specific units within large organizations. The improvements introduced into these units have not often been spread throughout the organization. Additionally, these improvements often are hard to sustain. "System redesign" refers to aligned and synergistic quality improvement efforts across a hospital or health system leading to multidimensional changes in the management or delivery of care or strategic alignment of system changes with an organization's business strategy. System redesign, if done successfully, will allow SN providers to improve their operations, remain afloat financially, and provide better quality healthcare to vulnerable and underserved populations. Resources, as defined here, may include learning materials and environments developed to support, advance, and facilitate quality improvement efforts (e.g., tools, guides, webinars, learning collaboratives, training programs). The term "resources" should not be interpreted here to imply financial support for routine staffing or operations of Safety Net systems, but may include quality improvement grants, fellowships, collaboratives and trainings.

Many tools, guides, and other learning environments have been developed to support the implementation of individual quality improvement initiatives. However, the development of resources to support alignment across multiple domains of a health system has been limited. Furthermore, the applicability of existing resources to SN environments is unknown.

This study is being conducted by AHRQ through its contractor, Boston University, pursuant to AHRQ's statutory authority to conduct and support research 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 with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

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

(1) In-person interviews will be conducted during a 2-day site visit with senior medical center leaders, clinical managers and staff involved in system redesign from each of the 8 participating SN hospitals. These interviews may be conducted one-on-one or in small groups, depending upon the participants' availability. The purpose of these interviews is to learn directly from hospital leadership and staff about the resources they have used to support and guide their system redesign efforts and what, if any, gaps there are in the resources available to them.

(2) Collection of documentation from each SN hospital. The documentation to be collected includes annual reports, performance dashboards, reports on specific system redesign and quality improvement projects and hospital newsletters. The purpose of this task is to provide supplementary information

about the hospitals and their quality improvement and system redesign efforts. Collection of documentation from participating hospitals will allow the research team to collect additional information that is readily available in hospital documents, but may not be known or readily accessible to interview subjects during their interviews.

The findings and recommendations developed from this project will be disseminated through AHRQ networks and through our partnership with the National Association of Public Hospitals and its membership group to ensure that findings are reaching administrators at public and SN hospitals directly. In addition, findings will be published in peer-reviewed and trade literature so that they will be available to a wide range of SN delivery system managers and clinicians for use in hospitals and healthcare systems. Findings will be

presented as illustrative of the issues facing SN hospitals engaging in system redesign—rather than as representing the quantity or distribution of conditions and practices within SN hospitals. All presentations and publications will state the limitations of our case-study methodology.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this data collection. In-person interviews will be conducted with a total of 160 hospital staff members (20 from each of the 8 participating SN hospitals) and will last about 1 hour. The collection of documentation will require 2 hours work from 1 staff member at each hospital. The total burden is estimated to be 176 hours.

EXHIBIT 1—ANNUALIZED BURDEN HOURS

Data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
In-person interviews	160	1	1	160
Collection of documentation	8	1	2	16
Total	168	n/a	n/a	176

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to provide the

requested data. The total cost burden is estimated to be \$9,242 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED BURDEN COST

Data collection	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
In-person interviews	160	160	\$56.23	\$8,997
Collection of documentation	8	16	15.30	245
Total	168	176	na	9,242

* The hourly rate of \$56.23 is an average of the clinical personnel hourly wage of \$91.10 for physicians and \$32.56 for registered nurses, and the administrative personnel hourly wage of \$45.03 for medical and health services managers. The hourly rate of \$15.30 is median hourly rate for medical administrative support staff. All hourly rates are based on median salary data provided by the U.S. Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the government

for this 3 year project. The total cost is \$499,877 and includes the cost of data collection, data analysis, reporting, and government oversight of the contract. The costs associated with data

collection activities are not all for the primary data collection of the case studies but include the review of existing literature and other available data sources.

TABLE 3—COST TO THE FEDERAL GOVERNMENT

Cost component	Total cost	Annualized cost
Project Development	\$49,161	\$16,377
Data Collection Activities	123,478	41,159
Data Processing and Analysis	109,433	36,478
Publication of Results	81,836	27,279
Project Management	18,438	6,146
Overhead	117,531	39,177

TABLE 3—COST TO THE FEDERAL GOVERNMENT—Continued

Cost component	Total cost	Annualized cost
Government Oversight	13,710	4,570
Total	499,877	166,626

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: April 19, 2012.

Carolyn M. Clancy,
Director.

[FR Doc. 2012-10007 Filed 4-25-12; 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: "American Recovery and Reinvestment Act "Developing a Registry of Registries"." 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 February 23, 2012 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 May 29, 2012.

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SUPPLEMENTARY INFORMATION:

Proposed Project

American Recovery and Reinvestment Act "Developing a Registry of Registries"

The Food and Drug Administration Modernization Act of 1997, Public Law 105-115, provided for the creation of a Clinical Trials Data Bank, known as *ClinicalTrials.gov*. Since its launch in 2000, the *ClinicalTrials.gov* system has registered over 90,500 trials. The large volume of studies currently listed in *ClinicalTrials.gov* and the high usage numbers suggest that the system has been successful at improving access to information about clinical studies. However, while *ClinicalTrials.gov* supports the listing of observational studies, such listing is not required.

Patient registries are a distinct type of observational study. Patient registries may be designed for many purposes, such as to observe the natural history of disease, examine comparative effectiveness, or fulfill post-approval commitments. Patient registries have specific characteristics that are not

currently captured on *ClinicalTrials.gov*. To date, some registry sponsors have attempted to leverage the observational study model to post patient registry-type records on *ClinicalTrials.gov*. However, stakeholders have noted that the system does not fully meet their needs.

Patient registries have received significant attention and funding in recent years. Similar to controlled interventional studies, patient registries represent some burden to patients (e.g., time to complete patient reported outcome measures, risk of loss of privacy), who often participate voluntarily in hopes of improving knowledge about a disease or condition. Patient registries also represent a substantial investment of health research resources. Despite these factors, registration of patient registries in *ClinicalTrials.gov* is not currently required, presenting the potential for duplication of efforts and insufficient dissemination of findings that are not published in the peer-reviewed literature. To ensure that resources are used in the most efficient manner, registries need to be listed in a manner similar to that of trials in *ClinicalTrials.gov*.

By creating a central point of collection for information about all patient registries in the United States, the Registry of Patient Registries (RoPR) helps to further AHRQ's goals by making information regarding quality, appropriateness, and effectiveness of health services (and patient registries in particular) more readily available and centralized.

The primary goal of this project is to engage stakeholders in the design and development of a RoPR database system that is compatible with *ClinicalTrials.gov* and meets the following objectives:

(1) Provides a searchable database of patient registries in the United States (to promote collaboration, reduce redundancy, and improve transparency);

(2) Facilitates the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage);

(3) Provides a public repository of searchable summary results (including