SUPPORTING STATEMENT

Part A

System Redesign for Value in Safety Net Hospitals and Delivery Systems

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Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances of Information Collection

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care; and
2. The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
3. Initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

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 US 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.

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 (see Attachment A). 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 (see Attachment B). 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.

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).

2. Purpose and Use of Information

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 literatures 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.

3. *Technology*

Primary data collection will be through in-person interviews with key informants. Interviews will be audio-recorded and audio recordings will be stored on password protected networks at Boston University.

4. *Efforts to Identify Duplication*

The existing literature on system redesign that focuses on SN hospitals consists of a small number of case studies of SN hospitals that have been successful at implementing large scale change. Since the scope of this project is to understand both what has worked and where the gaps are, additional data need to be collected.

5. *Involvement of Small Entities*

Collection of information will not impact small businesses or other small entities, as information will be collected for existing hospitals and health systems which are not considered to be small.

6. *Consequences if Information Collected Less Frequently*

This is a one-time study. There are no plans to repeat it. Data will be collected only once at each of the case study sites.

7. *Special Circumstances*

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. *Federal Register Notice and Outside Consultations*

8a. *Federal Register Notice*

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on February 24th, 2012 for 60 days, and again on April 26th, 2012 for 30 days. No substantive comments were received. See Attachment C.

8b. *Outside Consultations*

The prime contractor, Boston University, consulted with the National Association of Public Hospitals (NAPH) and the Cambridge Health Alliance (CHA) to develop the project and will continue to seek their advice throughout data collection. BU project staff are experts in organizational changes and in case study design and qualitative methodology. CHA has successfully worked on redesign in a competitive SN environment. NAPH's expertise in the issues and challenges in the SN environment will assist Boston University in the identification of potential case study sites. In addition, the project team will seek advice from the project's

Expert and Stakeholder Panel on study design, site selection, findings, recommendations, and dissemination throughout the project

9. Payments/Gifts to Respondents

We will not provide any payments or gifts to respondents.

10. Assurance of Confidentiality

The data will be stored on a password protected network at Boston University. All responses will be aggregated prior to publication and no identifying information will be reported. Respondents will be asked to sign a consent form (see Attachment D).

11. Questions of a Sensitive Nature

The interviews do not include questions of a sensitive nature. Social security numbers and/or Medicare numbers will not be collected.

12. Estimates of Annualized Burden Hours and Costs

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.

13. Estimates of Annualized Respondent Capital and Maintenance Cost

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimate of Annualized Cost to the 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
Government Oversight	$13,710	$4,570
Total	$499,877	$166,626

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication, and Analysis Plans

Boston University's contract for this project lasts from September 1st 2011 – November 30th 2013. Case study data collection will occur after OMB clearance is received.

The project team will use a structured analytic approach to facilitate the qualitative data analysis. In this approach, which has been used successfully by the BU project team in other projects, the conceptual framework is used to identify key research constructs for analysis tied directly to the interview questions. The primary focus of data collection and analyses will be at the level of the organization as a whole. Data on units within the organization will be used to provide depth to the organization-level analysis – to investigate the implementation and impact of redesign activities in different parts of the organization and to analyze interactions, spread and synergies of activities across the units. Data on the external environment, also secondary, will be used to examine the impact of external pressures on organization-level system redesign.

Following the visit to each site, the site-visit team will use this analytic approach to create a site profile organized by key research constructs in the interview guide. For each construct in the profile, the team will provide detailed evidence compiled across interviews of processes and activities in that area, citing specific examples provided by respondents. Differences in perceptions and accounts among respondents will be noted and included in the analysis. Team impressions of the broader organizational context will be noted and may also be included in the profiles under appropriate constructs but will be clearly labeled as impressions.

After development of the profiles by site-visit teams, the full study team will use them in cross case-site comparisons to identify common patterns or contrasts among study sites.

Dissemination activities will occur throughout the project. The dissemination plan will be finalized in March 2013 (after the case studies are complete) and the manuscripts, conference presentations, and other dissemination materials will be submitted and completed between April 2013 and November 2013. As stated in section 2, the findings and recommendations from this project will be disseminated through AHRQ networks and our collaborative partner NAPH. Manuscripts developed out of this project will be published in peer-reviewed and trade literature.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Interview guide

Attachment B: Collection of documentation guide

Attachment C: Federal Register Notice

Attachment D: Informed consent form