

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 24, 2014.

Richard Kronick,
AHRQ 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, 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: "Updating and Expanding the AHRQ QI Toolkit for Hospitals." 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.

This proposed information collection was previously published in the **Federal Register** on May 12th 2014 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 September 3, 2014.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email 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 email at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Updating and Expanding the AHRQ QI Toolkit for Hospitals

AHRQ has developed sets of Quality Indicators (QIs) that can be used to document quality and safety conditions at U.S. hospitals. Three sets of QIs are particularly relevant for hospitals and include: The Inpatient Quality Indicators (IQIs), the Patient Safety Indicators (PSIs), and the Pediatric Quality Indicators (PDIs). The IQIs contain measures of volume, mortality, and utilization for common medical conditions and major surgical procedures. The PSIs are a set of measures to screen for potentially preventable adverse events that patients may experience during hospitalization. The PDIs measure the quality of pediatric health care, mainly focusing on preventable complications that occur as a consequence of hospitalization among pediatric patients. These QIs have been previously developed and evaluated by AHRQ, and are in use at a number of hospitals throughout the country. The QIs and supportive documentation on how to work with them are posted on AHRQ's Web site at www.qualityindicators.ahrq.gov.

Despite the availability of the QIs as tools to help hospitals assess their performance, many U.S. hospitals have limited experience with the use of such measurement tools, or in using quality improvement methods to improve their performance as assessed by these measures. To this end, RAND has previously contracted with AHRQ to develop an AHRQ Quality Indicators Toolkit for Hospitals (Toolkit). This Toolkit is publicly available and is posted on AHRQ's Web site at <http://www.ahrq.gov/professionals/systems/hospital/qitoolkit/index.html>. The Toolkit assists hospitals in both using the QIs and improving the quality and safety of the care they provide, as measured by those indicators. As such, the Toolkit includes: (1) Instruction on how a hospital can apply the QIs to its inpatient data to estimate rates for each indicator; (2) methods the hospital can use to evaluate these QI rates for identifying opportunities for improvement; (3) strategies for implementing interventions (or evidence-based best practices); (4) methods to measure progress and performance on the QIs; (5) tools for evaluating the cost-effectiveness of these changes; and (6) discussion of the value of using the QIs for quality improvement as well as potential challenges and barriers to quality improvement efforts that incorporate the QIs and how to help overcome them.

OMB approval was obtained for the development and evaluation of the original Toolkit in 2012, Development and Evaluation of AHRQ's Quality Indicators Improvement Toolkit (OMB #0935-0164), which consisted of a protocol very similar to the one described in this statement.

Since the release of the Toolkit in 2012, the QIs have been updated and expanded, best practices have advanced, and many hospitals have improved their understanding of their quality improvement needs as well as increased their familiarity with the use of the Toolkit. These factors all point to the critical need to update the Toolkit. AHRQ has funded RAND which partners with the University HealthSystem Consortium (UHC) to update and expand the Toolkit, and field test the updated Toolkit with hospitals as they carry out initiatives designed to improve performance on the QIs.

This research has the following goals:

(1) To assess the usability of the updated Toolkit for hospitals—with an emphasis on the Pediatric Quality Indicators (PDI)—in order to improve the Toolkit, and

(2) To examine hospitals' experiences in implementing interventions to improve their performance on the AHRQ QIs, the results of which will be used to guide successful future applications of the Toolkit.

This study is being conducted by AHRQ through its contractor, the RAND Corporation, under contract number HHS2902010000171, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care 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 data collections will be implemented:

(1) Pre/post-test interview protocol—consisting of both open and closed ended questions will be administered prior to implementation of the Toolkit and again post implementation. The purpose of this data collection is to obtain data on the steps the hospitals took to implement actions to improve performance on the QIs; their plans for making process changes; and their experiences in achieving changes and perceptions regarding lessons learned that could be shared with other hospitals.

(2) Update protocol—consisting of both open and closed ended questions will be administered three times during the study (quarterly during the implementation year). The purpose of this data collection is to capture longitudinal data regarding hospitals' progress in implementing changes, successes and challenges, and plans for subsequent actions. These data will include descriptive information on changes over time in the hospitals' implementation actions and how they are using the Toolkit, as well as experiential information on the perceptions of participants regarding the improvement implementation process and its effects. It also ensures the collection of information close to pertinent events, which avoids the recall bias associated with retrospective reporting of experiences.

(3) Usability testing protocol—also consisting of both open and closed ended questions will be administered once at the end of the evaluation period. The purpose of this data collection is to gather information from the hospitals on how they used each tool in the updated Toolkit, the ease of use of each tool, which tools were most helpful, suggested changes to improve each tool, and suggestions for other tools to add to the updated Toolkit. This information will be used in the revisions of the updated Toolkit following the end of the field test.

All the information obtained from the proposed data collection will be used to strengthen the updated Toolkit before finalizing and disseminating it to hospitals for their use. First, information will be collected from the six hospitals participating in the Toolkit field test about their experiences in implementing performance improvements related to the AHRQ QIs, which will be used to prepare experiential case examples for inclusion in the Toolkit as a resource for other hospitals. Second, feedback will be elicited from them about the usability of the Toolkit, which will be applied to modify and refine the Toolkit so that it is as responsive as possible to the needs and priorities of the hospitals for which it is intended.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this information collection. Three protocols will be used to collect data from respondents in interviews that will take one hour each. The pre/post-test interview protocol will be administered twice—at the beginning and end of the field-test year. The pre-test interviews will be performed as one-hour group interviews with the six hospitals' implementation teams at the start of the year. Each hospital's implementation team is expected to consist of about five people. At the end of the year, post-test interviews that last one hour each and

use the same protocol as the pre-test interviews will be conducted during site visits at the six hospitals with the implementation team. The five people of the implementation team at each hospital will be interviewed twice, both pre- and post-field test. At the post-test site visits, data will also be collected through one-hour interviews performed separately with four key stakeholder groups—physicians, nurses, clerks, and others—that are not on the implementation team. Each stakeholder group is expected to consist of about five people. These 20 people from the four stakeholder groups at each hospital will be interviewed once in a one hour post-field test. Interviewing these additional stakeholder groups will ensure that information is gathered on stakeholder variations in perceptions and experiences, of which the implementation teams might not be aware.

The quarterly update protocol will be administered quarterly to two hospital staff members from each hospital during the year (in months 3, 6, and 9). The usability testing protocol will be administered to four staff members once at the end of the evaluation period. The total burden is estimated to be 240 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in the evaluation. The total cost burden is estimated to be \$7,179.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Pre/Post-Test Interview Protocol with Implementation Team	30	2	1	60
Pre/Post-Test Interview Protocol with Stakeholder Groups	120	1	1	120
Quarterly Update Protocol	12	3	1	36
Usability Testing Protocol	24	1	1	24
Total	186	NA	NA	240

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Pre/Post-Test Interview Protocol (Implementation Team and Stakeholder Groups)	150	180	29.91	5,384
Quarterly Update Protocol	12	36	29.91	1,077
Usability Testing Protocol	24	24	29.91	718
Total	186	240	NA	\$7,179

*Based upon the mean of the average wages taken from an average of hourly rates for occupations likely to be involved in the QI process (registered nurses, nurse practitioners, medical records and health information technicians, statisticians, and health technologists and technicians). Statistics are taken from the General Medical and Surgical Hospitals industry category in the May 2012 National Industry-Specific Occupational Employment and Wage Estimates from the Bureau of Labor Statistics, U.S. Department of Labor, accessed on January 22, 2014 [www.bls.gov/oes/].

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 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 24, 2014.

Richard Kronick,
AHRQ Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2014-N-1072]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Food and Drug Administration Commissioner's Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the application for participation in the FDA Commissioner's Fellowship Program (CFP).

DATES: Submit either electronic or written comments on the collection of information by October 3, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each

proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for Participation in the FDA Commissioner's Fellowship Program; (OMB Control Number 0910—New)

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the CFP will allow FDA's Office of the Commissioner to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity/5 U.S.C. Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1104,1302, 3301, 3304, 3320, 3361, 3393, and 3394	600	1	600	1.33	798
Total	798

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.