Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ1s 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: January 3, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–1172 Filed 1–24–11; 8:45 am]

BILLING CODE 4160–90–M

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: "Synthesis Reports for Grants and Cooperative Agreements for Transforming Healthcare Quality through Information Technology (THQIT)." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on November 2, 2010 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 February 24, 2011.

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 e-mail 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 e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Synthesis Reports for Grants and Cooperative Agreements for Transforming Healthcare Quality Through Information Technology (THQIT)

AHRQ's health information technology initiative is part of the Nation's strategy to put information technology to work in health care. By developing secure and private electronic health records and making health information available electronically when and where it is needed, health IT can improve the quality of care, even as it makes health care more cost-effective. This proposed information collection will help AHRQ enhance the evidence base to support effective information technology (IT) implementation and add to knowledge about health IT by synthesizing and drawing lessons from its Transforming Healthcare Quality through Information Technology (THQIT) program.

From 2004–2010, the THQIT program has supported the adoption of health IT through 118 grants and cooperative agreements. These grants fall into three main categories: planning grants, implementation grants and value demonstration grants. Planning grants are intended to develop health IT infrastructure and data-sharing capacity among clinical provider organizations in their communities by (1) Creating multidisciplinary collaboratives and coalitions of health care providers, (2) conducting needs assessments and feasibility studies, and (3) developing plans to implement electronic health records. Implementation grants support community-wide and regional health IT systems by (1) Developing shared registries, electronic health record systems, and telemedicine networks, (2) integrating clinical data from a variety of health IT systems, including pharmacy, laboratory, and public health organizations, (3) redesigning clinical workflow to improve patient care and provider access to information and (4) creating novel methods for delivering information to providers. Value demonstration grants evaluate how the adoption of health IT will (1) Impact quality, safety, and resource use in large, integrated delivery systems, (2) advance the effectiveness of Web-based, patient education tools and (3) improve patient transitions between health care facilities and their homes. The program places an emphasis on grants to rural health organizations.

AHRQ does not currently have a system in place for assessing the overall outcomes and lessons learned from these health IT grants. This project seeks to create such a system and has the following goals:

(1) Further the state of knowledge of health IT planning, implementation, and effects by synthesizing the experiences of THQIT grantees and the reported effects of the grants;

(2) Translate this knowledge into a practical tool to assist rural hospitals with electronic health record implementations; and

(3) Translate this knowledge into recommendations for AHRQ activities.

This study is being conducted by AHRQ through its contractor, Mathematica Policy Research, Inc. (Mathematica), pursuant to AHRQ's statutory authority to conduct and support research (1) on healthcare and on systems for the delivery of such care, 42 U.S.C. 299a, and (2) on information systems for health care improvement. 42 U.S.C. 299b–3.

Method of Collection

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

(1) Planning Grant Survey for all grantees that received a planning grant;

(2) Implementation Grant Survey for all grantees that received an implementation grant;

(3) Value Grant Survey for all grantees that received a value grant; and

(4) In-Depth Interviews will be conducted via telephone with a sample of grantees from each of the three types of grants. Given the complex nature of many of the projects conducted under these grants, from each selected grantee organization 1 to 3 persons with different areas of expertise will participate in the interview with the

most knowledgeable person responding to a given question. Questions vary by grant type.

These proposed data collections will gather information from grantee principal investigators on topics including: (1) Partnerships, which were required of all the grantees—what types are most effective and long-lasting and how partnerships can be made more effective; (2) planning for health IT—information that can help identify successful pathways; (3) implementation of health IT—including common and unique barriers and facilitators to implementation across types of health IT and care settings; (4) the outcomes, benefits, and drawbacks of the grant projects; and (5) the sustainability and expansion of implemented health IT.

Collecting this information will assist AHRQ in its mission of supporting the synthesis and dissemination of available evidence for the planning, implementation, and use of health IT by patients, practitioners, providers, purchasers, policymakers, and educators.

The proposed data collection is also designed to assist AHRQ in improving the effectiveness with which it supports future research, synthesis, and initiatives on health IT topics. The grantees' experiences with the THQIT grant process and features is an important topic covered including feedback on whether the funding and time period were sufficient, how effective the grant was in furthering health IT in grantee organizations, and whether planning grants are a useful mechanism to prepare health care organizations and researchers to participate in future large-scale research.

This research also supports AHRQ's mission, 42 U.S.C. 299(c), to specifically focus on rural populations and priority populations by collecting information on special factors affecting rural health care grantees, and the outcomes of the grant projects for AHRQ priority populations.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours associated with the respondents' time to participate in this research. The Value Grant Survey will be completed by the 24 grantees that received a value grant and takes 30 minutes to complete. The Planning Grant Survey will be completed by all 38 recipients of a planning grant and requires 30 minutes to complete. The Implementation Grant Survey will be completed by the 56 grantees that received an implementation grant and takes 45 minutes to complete. In-depth interviews will be conducted with 1 to 3 persons (2 on average) from each of 30 different grantee organizations and is estimated to average 1.8 hours; actual burden will vary since some sections apply to specific grant types. The total annualized burden is estimated to be 181 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annualized cost burden is estimated to be $7,917.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of response per respondent	Hours per response	Total burden hours
Value Grant Survey	24	1	30/60	12
Planning Grant Survey	38	1	30/60	19
Implementation Grant Survey	56	1	45/60	42
In-Depth Interviews	30	2	1.8	108
Total	148	n/a	n/a	181

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total Cost burden
Value Grant Survey	24	12	43.74	$525
Planning Grant Survey	38	19	43.74	831
Implementation Grant Survey	56	42	43.74	1,837
In-Depth Interviews	30	108	43.74	4,724
Total	148	181	na	7,917

*Based upon the mean of the average wages for medical and health services managers, Department of Labor, Bureau of Labor Statistics, Occupational and Employment Wages. May 2009. Accessed at: *http://www.bls.gov/news.release/pdf/ocwage.pdf.*

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost for this project. Although data collection activities will last for one year, the entire project will span 2.25 years; therefore, the annualized costs cover two and a quarter years. The total project cost is estimated to be $600,055.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$80,584	$35,815
Data Collection Activities	72,198	32,088
Data Processing and Analysis	52,389	23,284

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost	Annualized cost
Publication of Results	149,476	66,434
Project Management	70,313	31,250
Overhead	175,095	77,820
Total	600,055	266,691

Request for Comments

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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: January 3, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–1169 Filed 1–24–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0370]

Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance entitled "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010" dated August 2010, that was announced in the **Federal Register** of August 25, 2010. FDA now intends to complete the notice and comment rulemaking process for the Patient Protection and Affordable Care Act of 2010 (hereinafter "section 4205") before initiating enforcement activities based, in part, on extensive comments on the draft guidance submitted to the Agency. FDA believes that this approach to implementing section 4205 will minimize uncertainty and confusion among all interested persons.

DATES: The withdrawal is effective January 25, 2011.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Foods Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 25, 2010 (75 FR 52426), FDA announced the availability of a draft guidance entitled "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010." As stated in the draft guidance, certain provisions of section 4205 became requirements immediately upon enactment of the law. FDA recognized that industry may need additional guidance from the Agency and time to comply with these provisions. As a result, FDA stated that it expected to refrain from initiating enforcement action against establishments that are subject to, but not in compliance with, the provisions of section 4205 that became requirements immediately upon enactment of the law until a time period established in the draft guidance. FDA also stated that it anticipated issuing the guidance in December 2010.

Based, in part, on extensive comments on the draft guidance submitted to the Agency, FDA now intends to complete the notice-and-comment rulemaking process for section 4205 before initiating enforcement activities. As noted in the draft guidance, FDA is required to issue proposed regulations to carry out provisions of section 4205 no later than March 23, 2011. FDA intends to meet this statutory deadline. In the course of developing the proposed rule, the Agency has considered the comments received on the draft guidance. FDA will then review the comments it receives on the proposed rule and issue a final rule expeditiously.

FDA believes that this approach to implementing section 4205 will minimize uncertainty and confusion among all interested persons. The Agency also believes that expeditious completion of the rulemaking process will most rapidly lead to full and consistent availability of the newly required nutrition information for consumers.

For these reasons, FDA is at this time withdrawing the draft guidance entitled "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010."

Dated: January 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1530 Filed 1–21–11; 12:00 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0559]

Guidance for Industry on Process Validation: General Principles and Practices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the