EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost (millions)	Annualized cost (millions)
Data Collection Activities	86.7	28.9
Data Processing	21.39	7.13
Production of Public Use Data Files	19.53	6.51
Project Management	3.93	1.31
Total	142.8	47.6

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 1, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–16567 Filed 7–13–09; 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 under the project: ''Evaluation of AHRQ's Effective Health Care Program.'' 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 April 24th, 2009 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 August 13, 2009.

ADDRESSES: Written comments should be submitted to: AHRQs 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

''Evaluation of AHRQ's Effective Health Care Program''

AHRQ proposes to perform an evaluation of the Effective Health Care (EHC) programs' governance structure, methods for engaging stakeholders and approaches to setting national research priorities. Pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the EHC program was established by AHRQ to conduct research, demonstrations, and evaluations designed to improve the quality, effectiveness, and efficiency of Medicare, Medicaid, and the State Children's Health Insurance Program. The EHC program was designed to provide effectiveness and comparative effectiveness evidence of medical treatments, therapeutics, devices and drugs to assist policymakers, health care providers, clinicians, consumers, and other stakeholders in making informed decisions. The EHC program has offered a platform for combining explicit reviews of scientific evidence on the clinical effectiveness of pharmaceuticals and other health care interventions, as well as the translation and dissemination of scientific findings into meaningfui messages for a wide variety of audiences. It serves as an interface between the clinical research entities and health policy making entities. This program also provides a critical step in AHRQ's mission to support informed decision making. In addition to its program staff, the EHC program relies on four centers to generate and disseminate evidence: The Evidence-based Practice Centers (EPCs), the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network Centers, the John M. Eisenberg Clinical Decisions and Communications Science Center, and the Centers for Education & Research on Therapeutics (CERTs). Since the process of developing and disseminating this evidence is a complex undertaking, AHRQ has contracted with IMPAQ International, LLC and Abt Associates, Inc. (henceforth referred to as the ''IMPAQ team'') to perform this evaluation.

Information will be collected to identify strengths and weaknesses in the current EHC program's governance structure, methods for engaging stakeholders, and approaches to setting priorities for the research conducted by the EHC program. The second phase of the evaluation will be to contrast the EHC program with international programs of similar purpose. To implement this evaluation, the IMPAQ team will conduct the following information collections:

(1) Key informant interviews about the governance structure of the EHC program;

(2) An online survey of EHC center staff and EHC program users and stakeholders;

(3) An Appreciative Inquiry workshop with EHC program staff and stakeholders;

(4) A document review (will not impose a burden on research participants) and

(5) Interviews with staff at international organizations of similar purpose (will not impose a burden on U.S. citizens).

The latter two activities do not require OMB approval and are not discussed further in this notice. The information collected will ultimately be used to develop a roadmap, including at least three alternative models of governance and operation, to be submitted to AHRQ that could be used to help guide future programmatic development.

Method of Data Collection

Key Informant Interviews

Semi-structured key informant interviews will be used to understand the EHC program's governance components and structure, from the vantage point of individuals governing the program, governed by the program, contributing to the program in various capacities, or impacted by the program's activities. Thirteen EHC Research Centers Staff, two EHC Stakeholder Group Members, and nineteen EHC Program Users and Stakeholders will be interviewed about the governance structure of the EHC program.

Additional key informant interviews with twenty five EHC Program Users and Stakeholders will be used to collect more detailed information on the success or impact of the EHC program product that results from its governance element or approach, or about a specific, important governance element.

All key informant interviews will be tape recorded to improve data capture, with prior permission from the participants.

Online Survey

A structured, web-based online survey of EHC program Research Centers Staff and EHC program Users and Stakeholders will be used to gather information about the EHC program. The survey will provide a robust view of the EHC governance system by providing feedback from a broad group of individuals whose work is related to the program. Specifically, the survey will collect data about these individuals' engagement and involvement with the EHC program; perceptions of the program's governance; experiences with the development, production, dissemination, and use of EHC products; and their beliefs regarding the quality and nature of the collaborative work, including public-private partnerships, being done within centers, across centers, and between centers and stakeholders.

Appreciative Inquiry Workshop

Small- and large-group discussions as part of an Appreciative Inquiry workshop will be designed to encourage EHC decision-makers (AHRQ staff, EHC program staff, AHRQ project officers for each of the Research Center networks, principal investigators or other representatives from each of the Research Center network) and key program stakeholders or uers to consider anddecide which are the preferred alternative governance models or elements for which roadmaps should be developed. Appreciative Inquiry (AI) approach is an organizational development process that engages individuals within an organization in renewal, change, and focused performance. The AI approach focuses on successes and opportunities to improve things by looking forward, rather than looking back on the problems or issues. The AI workshop is expected to facilitate consensus among decision-makers to contribute to the endorsement of the roadmap(s), and to encourage utilization of the evaluation findings. The workshop will involve a creative thinking process that will build on existing successes, identify and rank preferred alternatives, and ultimately develop a plan to strengthen the EHC program's governance system.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents to participate in this evaluation. Key informant interviews will be conducted about the governance structure of the EHC program and will last about one hour. The online survey will be completed by 95 EHC program Research Centers Staff and 170 EHC Program Users and Stakeholders and will require about 15 minutes to complete. The Appreciative Inquiry workshop will be conducted with 20 participants and will last about 6 hours. The total burden hours are estimated to be 246 hours. Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to participate in the evaluation. The total cost burden is estimated to be $12,297.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Activity name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Key Informant Interviews with EHC Research Centers Staff	13	1	1	13
Online Survey with EHC Research Centers Staff	95	1	15/60	24
Key Informant Interviews with EHC Stakeholder Group Members	2	1	1	2
Key Informant Interviews with EHC Program Users and Stakeholders	19	1	1	19
Online Survey with EHC Program Users and Stakeholders	170	1	15/60	43
Key Informant Interviews with EHC Program Users and Stakeholders to Develop Cases	25	1	1	25
Appreciative Inquiry Workshop	20	1	6	120
Total	344	na	na	246

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Activity name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Key Informant Interviews with EHC Research Centers Staff	13	13	$54.27	$706
Online Survey with EHC Research Centers Staff	95	24	54.27	1,302

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Activity name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Key Informant Interviews with EHC Stakeholder Group Members	2	2	43.52	87
Key Informant Interviews with EHC Program Users and Stakeholders	19	19	46.73	888
Online Survey with EHC Program Users and Stakeholders	170	43	46.73	2,009
Key Informant Interviews with EHC Program Users and Stakeholders to Develop Cases	25	25	46.73	1,168
Appreciative Inquiry Workshop	20	120	51.14	6,137
Total	344	246	na	12,297

*Wage rates were calculated using the following data: (1) For the Governance Interviews and the Online Survey with EHC Research Centers Staff the hourly rate is a weighted average for physicians ($58.76 per hour) and medical and health services managers ($37.82); (2) for the Governance Interviews with EHC Stakeholder Group Members the hourly rate is the rate for average for medical and health services managers ($37.82); (3) for the Governance Interviews and the Online Survey with EHC Program Users and Stakeholders the hourly rate is a weighted average for physicians ($58.76 per hour), general and operations managers ($43.52 per hour), medical and health services managers ($37.82 per hour), and social and community service managers ($24.73 per hour); (4) for the Workshop the hourly rate is a weighted average for physicians ($58.76 per hour) and general and operations managers ($43.52 per hour) from the mean of the average wages, National Compensation Survey: Occupational Wages in the United States 2006, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated cost of this one year data collection for the evaluation of the EHC program, including the cost of developing the methodology and data collection instruments, collecting and analyzing the data, publishing the results, etc. The work will be carried out by IMPAQ International and Abt Associates under contract to the Agency for Healthcare Research and Quality.

EXHIBIT 3—ESTIMATED ANNUAL COST TO THE FEDERAL GOVERNMENT

Cost component	Total cost
Project Development	$137,901
Data Collection Activities	179,172
Data Processing and Analysis	170,577
Publication of Results	63,686
Project Management	97,236
Total	648,572

*Please note the costs include fully loaded costs (overhead, G&A).

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 2, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–16568 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0212]

Draft Guidance for Industry on ''Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting,'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting.'' This draft guidance provides recommendations to pharmaceutical manufacturers on design considerations for incorporating physical-chemical identifiers (PCIDs) into solid oral dosage forms (SODFs), supporting documentation to be submitted in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) to address the proposed incorporation of PCIDs in SODFs, supporting documentation to be submitted in postapproval submissions to report or request approval to incorporate PCIDs into SODFs, and procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a postapproval change. This draft guidance also provides our recommendations regarding evaluation of toxicological and other concerns for PCIDs that are incorporated into packaging and labeling and procedures for reporting or requesting approval to add PCIDs to packaging and containers as a postapproval change.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 13, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.