

activities are requested. Potential users must request and receive permission to view the BioSense Application. Federal rules mandate that this permission be

renewed each year. We estimate about 800 users per year will need to request new or continued access to the BioSense Application.

There is no cost to respondents other than their time. The total estimated annual burden hours are 147 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Recruitment of Prospective Data Source Entities			
Federal, State & Local Governments, Private Sector	20	1	4
Access to BioSense Application			
Federal, State & Local Governments, Private Sector	800	1	5/60

Dated: August 14, 2009.
Maryam I. Daneshvar,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
 [FR Doc. E9-20000 Filed 8-19-09; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2008-N-0077]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; MedWatch: Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "MedWatch: Food and Drug Administration Medical Products Reporting Program" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, *Elizabeth.Berbakos@fda.hhs.gov*, 301-796-3792.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 24, 2008 (73 FR 55111), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it

displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0291. The approval expires on December 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: August 13, 2009.
Jeffrey Shuren,
Associate Commissioner for Policy and Planning.
 [FR Doc. E9-19980 Filed 8-19-09; 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: "2010-2011 Medical Expenditure Panel Survey Insurance Component." In accordance with the Paperwork Reduction Act of 1995, 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 June 16th, 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 September 21, 2009.

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

2010-2011 Medical Expenditure Panel Survey Insurance Component

AHRQ seeks to renew the Medical Expenditure Panel Survey Insurance Component (MEPS-IC) for calendar years 2010 and 2011. The MEPS-IC, an annual survey of the characteristics of employer-sponsored health insurance, was first conducted by AHRQ in 1997 for the calendar year 1996. The survey has since been conducted annually for calendar years 1996 through 2009, except for 2007. A change from prior year collection to calendar year collection in 2008 meant that no data were collected for the 2007 calendar year, but the change has allowed for much earlier release of the survey results for the 2008 calendar year forward. AHRQ is authorized to conduct the MEPS-IC pursuant to 42 U.S.C. 299b-2.

Employment-based health insurance is the source of coverage for over 90 million workers and their family members, and is a cornerstone of the current U.S. health care system. The MEPS-IC measures the extent, cost, and coverage of employment-based health

insurance. Statistics are produced at the National, State, and sub-State (metropolitan area) level.

The MEPS-IC is designed to provide data for Federal policymakers evaluating the effects of National and State health care reforms. It also provides descriptive data on the current employment-based health insurance system and data for modeling the differential impacts of proposed health policy initiatives. The MEPS-IC also supplies critical State and National estimates of health insurance spending for the National Health Accounts and Gross Domestic Product. Data to be collected from each employer will include a description of the organization (e.g., size, industry) and descriptions of health insurance plans available, plan enrollments, total plan costs and costs to employees. This survey will be conducted for AHRQ by the Bureau of the Census using an annual sample of employers selected from Census Bureau lists of private sector employers and governments.

The MEPS-IC is one of three components of the MEPS. The others are the Household and Medical Provider Components:

MEPS Household Component is a sample of households participating in the National Health Interview Survey in the prior calendar year. These households are interviewed 5 times over a 2½ year period for MEPS. The 5 interviews yield two years of information on use of and expenditures for health care, sources of payment for

that health care, insurance status, employment, health status and health care quality.

MEPS Medical Provider Component collects information from medical and financial records maintained by hospitals, physicians, pharmacies, health care institutions, and home health agencies named as sources of care by household respondents.

This clearance request is for the MEPS-IC only.

Method of Collection

Data collection for the MEPS-IC takes place in three phases at each sample establishment: prescreening interview, questionnaire mailout, and nonresponse follow-up. An establishment is a single location of a private sector or State and local government employer.

First, a prescreening interview is conducted by telephone. For those establishments that offer health insurance, its goal is to obtain the name and title of an appropriate person in each establishment to whom a MEPS-IC questionnaire will be mailed. For establishments which do not offer health insurance, a brief set of questions about establishment characteristics is administered at the end of the prescreening interview to close out the case. This step minimizes burden for many small establishments that do not offer health insurance.

The next phase, questionnaire mailout, makes use of two forms—one requests establishment-level information (e.g., total number of employees) and the other requests plan-

level information (e.g., the plan premium for single coverage) for each plan (up to four) offered by the establishment.

In the final phase, establishments which do not respond to the initial MEPS-IC mail questionnaire are mailed a nonresponse follow-up package. Those establishments which fail to respond to the second mailing are contacted for a telephone follow-up using computer-assisted interviewing.

Data collection for the largest private sector and government units, which have high survey response burdens, may differ somewhat from the above pattern.

Estimated Annual Respondent Burden

Exhibit I shows the estimated annualized burden hours for the respondents' time to provide the requested data. The Prescreener questionnaire will be completed by 32,006 respondents and takes about 5½ minutes to complete. The Establishment questionnaire will be completed by 24,965 respondents and takes about 23 minutes to complete. The Plan questionnaire will be completed by 21,437 respondents and will require an average of 2.1 responses per respondent. Each Plan questionnaire takes about 11 minutes to complete. The total annualized burden hours are estimated to be 20,471 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this data collection. The annualized cost burden is estimated to be \$546,576.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per response	Hours per response	Total burden hours
Prescreener Questionnaire	32,006	1	0.09	2,881
Establishment Questionnaire	24,965	1	0.38	9,487
Plan Questionnaire	21,437	2.1	0.18	8,103
Total	78,408	na	na	20,471

Note: The total number of respondents increased from previous clearances not due to any increase in sample size, but due to a

change in the way the number of respondents is reported. While now total respondents are the sum of respondents per form, previously

they were reported as the number of unique establishments completing at least one form.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Prescreener Questionnaire	32,006	2,881	26.70	\$76,923
Establishment Questionnaire	24,965	9,487	26.70	253,303
Plan Questionnaire	21,437	8,103	26.70	216,350
Total	78,408	20,471	na	546,576

*Based upon the mean wage for Compensation, benefits, and job analysis specialists, civilian workers, National Compensation Survey: Occupational Earnings in the United States, 2007, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost for this two year

project. The annual cost to the Federal Government is estimated to be \$10.3 million.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST
[\$ thousands]

Cost component	Total cost	Annualized cost
Project Development	\$3,099	\$1,550
Data Collection Activities	7,230	3,615
Data Processing and Analysis	7,230	3,615
Project Management	2,066	1,033
Overhead	1,033	517
Total	\$20,658	\$10,329

Note: Components may not sum to Total due to rounding.

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, quality improvement and 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: August 13, 2009.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the AHRQ National Advisory Council for Healthcare Research and Quality Subcommittee on Quality Measures for Children's Healthcare in Medicaid and Children's Health Insurance Programs

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality Subcommittee on Quality Measures for Children's Healthcare in Medicaid and Children's Health Insurance Programs (CHIP).

DATES: The meeting will be held on Thursday, September 17, 2009, from 8 a.m. to 5 p.m. and Friday, September 18, 2009 from 8 a.m. to 12 p.m.

ADDRESSES: Holiday Inn Capitol, 550 C Street, SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Padmini Jagadish, Public Health Analyst at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, (301) 427-1927. For press-related information, please contact Karen Migdail at (301) 427-1855.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Mr. Michael Chew, Director, Office of Equal Employment Opportunity Program, Program Support Center, on (301) 443-1144, no later than August 31, 2009.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality was established in accordance with Section 921 (now Section 931) of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to actions of AHRQ to enhance the quality, and improve the outcomes, of health care services; improve access to such services through scientific research; and promote improvements in clinical practice and in the organization, financing, and delivery of health care services.

The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members.

AHRQ's National Advisory Council on Healthcare Research and Quality (NAC) has established a Subcommittee on Quality Measures for Children's Healthcare in Medicaid and Children's Health Insurance Programs (CHIP). The Subcommittee was created to provide advice to the NAC for consideration and transmission to AHRQ as AHRQ undertakes responsibilities in the identification of an initial core quality measure set for use by Medicaid and CHIP programs for children's healthcare. A roster of the Subcommittee members is available at <http://www.ahrq.gov/chip/chipraact.htm>. The first meeting of the subcommittee took place on July 22 and 23, 2009. The September meeting is the second working meeting that will be held as a part of this effort.

The identification of an initial core measure set for public comment is required under Public Law 111-3, the Child Health Insurance Program