

6 MONTHS ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Number of respondents	Number of responses/respondent	Average burden hours per response	Total burden hours
Hospital staff (data collection) .....	6000	96	1	576,000
State/Territory Preparedness staff (training) .....	62	1	1	62
State/Territory Preparedness staff (data collection) .....	62	288	3	53,568
Total .....		386		635,630

The burden was determined by asking the States that participated in a pilot study to report who collected the data and how long it took them to gather the information.

**Terry Nicolosi,**  
*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*  
 [FR Doc. E9-20073 Filed 8-19-09; 8:45 am]  
**BILLING CODE 4150-37-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-N-0030]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Investigational New Drug Regulations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Investigational New Drug Regulations" 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 May 8, 2009 (74 FR 21690), 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 0910-0014. The approval expires on August 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. E9-19972 Filed 8-19-09; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-09-09AA]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

BioSense—Recruitment of Data Sources—Existing Data Collection Without an OMB Number—National Center for Public Health Informatics (NCPHI), *Coordinating Center for Health Information and Service (CCHIS)*, Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which requires specific activities related to bioterrorism preparedness and response. This congressional mandate outlines the need for improving the overall public's health through electronic surveillance.

The Department of Health and Human Services outlined strategies aimed at achieving this goal via the Public Health IT Initiative thereby creating the BioSense program.

BioSense is a national, human health surveillance system designed to improve the nation's capabilities for disease detection, monitoring, and real-time health situational awareness. This work is enhanced by providing public health real-time access to existing data from healthcare organizations, state syndromic surveillance systems, national laboratories, and others for just in time public health decisionmaking; this information is made available to users in the BioSense Application. The application provides data, charts, graphs, and maps through a secure Web-based interface which can be accessed by CDC and authorized users from state and local public health departments and healthcare organizations.

In order to meet the congressional mandate, the BioSense program must have access to electronic health data. Recruitment of data sources includes collecting information on the types of data available, the types of computer systems used, and the approximate record volume. This information is used by BioSense personnel and contractors to determine technical requirements for linking a data source into the BioSense program. To collect this information, a series of questionnaires in an Excel spreadsheet have been designed. Information collection will take place during and after on-site visits by BioSense personnel and contractors. We estimate that such information will be collected from 20 new entities (each representing many facilities or clinics) each year.

Since the publication of the 60-day **Federal Register** Notice, the information collection instrument for the provision of access to the BioSense Application has been included in this information collection request. Access to the BioSense Application is obtained using an automated data collection form. This form is completed on the Internet via the CDC Secure Data Network (SDN) in which a prospective user identifies what

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)
<b>Recruitment of Prospective Data Source Entities</b>			
Federal, State & Local Governments, Private Sector .....	20	1	4
<b>Access to BioSense Application</b>			
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]  
**BILLING CODE 4163-18-P**

**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]  
**BILLING CODE 4160-01-S**

**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