

National Hospital Care Survey (NHCS) (OMB No. 0920–0212); (2) new questions on drug-related ED visits; and (3) new questions on colorectal cancer screening in ambulatory surgery visits.

In 2012, a pretest of 30 hospitals will collect data using methods approved for the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920–0278) data collection. The proposed pretest will test the data collection procedures involved in integrating the NHAMCS into the NHCS. NHAMCS has provided data annually since 1992 concerning the nation’s use of hospital emergency and outpatient departments, and since 2009, on hospital-based ASLs. If the pretest is successful, NHAMCS will be integrated into NHCS in order to increase the wealth of data on health care utilization in hospitals across episodes of care and to allow for linkages to other data sources such as the National Death Index and data from Centers for Medicare and Medicaid Services (CMS).

The data items to be collected from the recruited hospitals in the pretest will include facility level data items such as visit volume, number of treatment areas, and information on electronic health record systems. Facility level data will be collected through in-person interviews and recorded on computerized survey

instruments, at the hospital-level and at the ambulatory unit level. It is anticipated that each hospital will have approximately four ambulatory units.

Patient level data items will include basic demographic information, name, address, social security number (if available), and medical record number (if available), and characteristics of the patients including admission and discharge dates, reason for visit, diagnoses, diagnostic services, procedures, medications, providers seen, and disposition. Patient visit data will be abstracted by field representatives of the data collection agent. A targeted number of patient visits will be sampled from each department depending on the type of department—approximately 100 across ambulatory units in the ED, 200 across ambulatory units in the OPD, and 100 across ambulatory units in ASLs.

Secondly, the pretest will collect specific information on drug-related visits to the ED. This endeavor, funded by the Center for Behavioral Health Statistics & Quality (CBHSQ) of the Substance Abuse & Mental Health Administration (SAMHSA), will assess the feasibility of integrating the Drug Abuse Warning Network (DAWN) (OMB No. 0930–0078) into the emergency department component of the NHCS. In each of the 30 pretest hospitals with an

emergency department, a sample of all patient visits will be abstracted; for each drug-related visit within this sample, additional drug-related data will be abstracted. The only burden to the respondent at the patient visit level will be due to pulling and refiling of approximately 133 medical records at each ambulatory unit.

Finally, the pretest will assess the feasibility of obtaining information on colorectal cancer screening during ambulatory surgery visits where a colonoscopy is performed. The endeavor is sponsored jointly by the National Center for Chronic Disease Prevention and Promotion (NCCDPHP) and the National Cancer Institute (NCI). The questions will be added to the Ambulatory Surgery Patient Record form and will be completed for patients that have a colonoscopy performed at the sampled visit.

Potential users of the NHCS ambulatory data include, but are not limited to CDC, Congressional Research Office, Office of the Assistant Secretary for Planning and Evaluation (ASPE), American Health Care Association, Centers for Medicare & Medicaid Services (CMS), Bureau of the Census, state and local governments, and nonprofit organizations. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden hours
Hospital Chief Executive Officer .....	Hospital Induction Interview .....	30	1	1	30
Ancillary Service Executive .....	Ambulatory Unit Induction .....	120	1	15/60	30
Medical Record Clerk .....	Pulling and Refiling Records .....	120	133	1/60	266
<b>Total .....</b>					<b>326</b>

Dated: October 26, 2011.

**Daniel Holcomb,**

*Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review**

The meeting announced below concerns Emerging Infections Programs, Funding Opportunity Announcement (FOA) CK12–1202, initial review.

*Correction:* The notice was published in the **Federal Register** on September 13, 2011, Volume 76, Number 177, Page 56461. The place should read as follows:

*Place:* Sheraton Gateway Hotel Atlanta Airport, 1900 Sullivan Road, Atlanta, Georgia 30337, *Telephone:* (770) 997–1100.

*Contact Person For More Information:* Amy Yang, Ph.D., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, *Telephone:* (404) 498–2733.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 25, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Council for the Elimination of Tuberculosis (ACET)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

##### *Times and Dates:*

8:30 a.m.–5:30 p.m., December 6, 2011.

8:30 a.m.–2:30 p.m., December 7, 2011.

*Place:* Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333, telephone (404) 639-8317.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

*Purpose:* This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

*Matters to be Discussed:* Agenda items include issues pertaining to the future directions of tuberculosis control and elimination in the United States: (1) STOP TB USA; (2) Institute of Medicine Report; and (3) The Restructuring of United States Tuberculosis Program (TRUST); Update on ACET Workgroups; and other related tuberculosis issues.

Agenda items are subject to change as priorities dictate.

*Contact Person For More Information:* Margie Scott-Cseh, Centers for Disease Control and Prevention, 1600 Clifton Road NE., M/S E-07, Atlanta, Georgia 30333, telephone (404) 639-8317.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 25, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0766]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of “Health Care Providers’ Responses to Medical Device Labeling”

**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 this proposed information collection “Health Care Providers’ Responses to Medical Device Labeling.”

**DATES:** Submit either electronic or written comments on the collection of information by January 3, 2012.

**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:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@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.

#### Survey of “Health Care Providers’ Responses to Medical Device Labeling”—21 CFR Part 801 (OMB Control Number 0910–New)

The purpose of this study is to determine the most effective device labeling format and inform an FDA’s regulatory approach on standardized device labeling. Building upon the research methodology and success of the approach FDA used to evaluate drug labeling, we propose to ask health care providers (HCPs) to evaluate the quality of labeling (e.g. instructions for use, directions) for a medical device and to report the degree to which they could follow those instructions, how useful the information is, and how well organized the information is. This work will allow FDA to assess whether HCPs find the format and content of device labeling clear, understandable, useful, and user-friendly. Findings will provide evidence to inform FDA’s regulatory approach to standardizing medical device labeling across the United States.

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