

and Value Research (HSVR) will take place at: Hyatt Regency Hotel Bethesda, One Metro Center, Bethesda, MD 20814.

Conference Call of Health Care Research and Training (HCRT) meeting will take place at: AHRQ, (Conference Room TBD), 540 Gaither Road, Rockville, MD 20850.

**FOR FURTHER INFORMATION CONTACT:** (to obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research Education and Priority Populations, AHRQ, 540 Gaither Road, Suite 2000, Rockville, Maryland 20850, Telephone (301) 427-1554.

**SUPPLEMENTARY INFORMATION:** In accordance with section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), AHRQ announces meetings of the scientific peer review groups listed above, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committee. Each subcommittee meeting will commence in open session before closing to the public for the duration of the meeting. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6) The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: October 24, 2013.

**Richard Kronick,**  
AHRQ Director.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-14-0892]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

*Clostridium difficile* Infection (CDI) Surveillance (0920-0892, Expiration 07/31/2014)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Steady increases in the rate and severity of *Clostridium difficile* infection (CDI) indicate a clear need to conduct longitudinal assessments to continue to monitor changes in CDI epidemiology, including changes in risk factors for disease, as well as increases. The surveillance population will consist of persons residing in the catchment area of the participating Emerging Infections Program (EIP) sites who are 1 year of age or older. This surveillance poses no more than minimal risk to the study participants as there will be no interventions or modifications to the care study participants receive. EIP surveillance personnel will perform active case finding from laboratory reports of stool specimens testing positive for *C. difficile* toxin and abstract data on cases using a standardized case report form. For a subset of cases (e.g., community-associated *C. difficile* cases) sites will administer a health interview.

CDC requests Office of Management and Budget (OMB) extension of standardized data collection for an additional three years. The epidemiology of *C. difficile* continues to evolve and incidence of disease is still high with no significant declines being observed. Continuing to understand what put persons at risk for *C. difficile* in the community is critical to inform prevention strategies. There are no changes in the burden estimates or data collection instruments from what is shown in the current inventory.

A total of 600 individuals who develop CDI will be contacted for a telephone interview annually and of those it is estimated that 500 will meet study inclusion criteria. The interview screening is estimated to take 5 minutes and the full telephone interview is estimated to take 40 minutes. Therefore, the total estimated annualized burden for this data collection is estimated to be 383 hours.

There are no costs to the respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

| Type of respondents                                          | Form name                 | Number of respondents | Number of responses per respondent | Avg. burden per response (in hrs.) | Total burden (in hrs.) |
|--------------------------------------------------------------|---------------------------|-----------------------|------------------------------------|------------------------------------|------------------------|
| Persons in the community infected with <i>C. difficile</i> . | Screening Form .....      | 600                   | 1                                  | 5/60                               | 50                     |
|                                                              | Telephone Interview ..... | 500                   | 1                                  | 40/60                              | 333                    |
| <b>Total .....</b>                                           | .....                     | .....                 | .....                              | .....                              | <b>383</b>             |

**Leroy A. Richardson,**

Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-14-0338]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to CDC, LeRoy Richardson, 1600 Clifton Road, MS D-74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

#### Proposed Project

Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S. (OMB No. 0920-0338, exp. 02/28/2014)—Extension—Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

The oral use of smokeless tobacco (SLT) products represents a significant health risk. Smokeless tobacco products contain carcinogens which can cause cancer and a number of non-cancerous oral conditions, as well as leading to nicotine addiction and dependence. Furthermore, SLT use is not a safe substitute for cigarette smoking. Adolescents who use smokeless tobacco are more likely to become cigarette smokers.

The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH), has primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. HHS's overall goal is to reduce death and disability resulting from the use of smokeless tobacco products and other forms of tobacco through programs of information, education and research.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 et seq., Pub. L. 99-252) requires each person who manufactures, packages, or imports smokeless tobacco products to provide the Secretary of HHS with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products. CSTHEA further requires submission of the quantity of nicotine contained in each smokeless tobacco product. Finally, the legislation authorizes HHS to undertake research, and to report to Congress (as deemed

appropriate) discussing the health effects of these ingredients.

HHS has delegated responsibility for implementing the required information collection to CDC's Office on Smoking and Health. Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies that are required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report. Respondents may submit the required information to CDC through a designated representative. The information collection is subject to strict confidentiality provisions.

Ingredient reports for new SLT products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, which may be accompanied by a Compact Disc (CD), three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted. Annual submission reports are mailed to: Office on Smoking and Health, Attention: FCLAA Program Manager, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE., MS F-79, Atlanta, GA 30341-3717. Upon receipt and verification of the annual nicotine and ingredient report, OSH issues a Certificate of Compliance to the respondent.

There are no costs to respondents other than their time. Office of Management and Budget (OMB) approval is requested for three years.

#### ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents                                        | Form name                          | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|------------------------------------------------------------|------------------------------------|-----------------------|------------------------------------|----------------------------------------|-------------------------|
| Smokeless Tobacco Manufacturers, Packagers, and Importers. | SLT Nicotine and Ingredient Report | 13                    | 1                                  | 1,713                                  | 22,269                  |