

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	Focus Group Discussion Guide	400	1	2	800
Total	1,680

Leroy 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

[60 Day-14-0870]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan 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 submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. 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; (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; and (e) estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Monitoring and Reporting System for Chronic Disease Prevention and Control Programs (OMB No. 0920-0870, exp. 11/30/2014)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Tobacco use is the single most preventable cause of death and disease in the United States. Tobacco use causes heart disease and strokes, lung cancer and many other types of cancer, chronic obstructive pulmonary disease, lung disorders, pregnancy problems, sudden infant death syndrome, gum disease, and vision problems. Approximately 480,000 Americans die from tobacco-related illnesses annually, a higher number of deaths than the combined total deaths from HIV/AIDS, alcohol use, cocaine use, heroin use, homicides, suicides, motor vehicle crashes, and fires. For every person who dies from tobacco use, 20 more people suffer with at least one serious tobacco-related illness. There are also severe economic consequences of tobacco use as the U.S. spends approximately \$280 billion annually in direct medical expenses and

lost productivity attributable to the effects of tobacco use.

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) provides funding to health departments in States, territories, and the District of Columbia to implement and evaluate chronic disease prevention and control programs, including tobacco control programs. Currently, CDC has cooperative agreements to support tobacco control programs in all 50 states and the District of Columbia under FOA DP14-1415, an extension of FOA DP09-901. These cooperative agreements technically ended on March 28, 2014, however a one-year cost extension (DP14-1415) was granted. Due to the cost extension, final reports on awardee activities are due to CDC approximately 90 days after the end of the funding period (June 26, 2015).

In order to maintain continuity in progress reporting through the end of the cost extension, CDC requests OMB approval to continue the collection of information from tobacco control program awardees for one year. Awardees will continue to submit semi-annual progress reports through a Web-based management information system (MIS).

CDC will continue to collect information about each awardee's tobacco control objectives, planning, activities, resources, partnerships, strategies, and progress toward meeting objectives. Awardees will use the information reported through the electronic MIS to manage and coordinate their activities and to improve their efforts. CDC will use the information reported through the MIS to document and monitor each awardee's progress and to make adjustments, as needed, in the type and level of technical assistance provided to them. The information collection allows CDC to oversee the use of federal funds, and identify and disseminate information about successful tobacco control strategies implemented by awardees. CDC also uses the information to respond to Congressional and stakeholder inquiries about awardee

activities, program implementation, and program impact.

Progress reporting through the MIS is required for CDC funded awardees. There are no costs to respondents other than their time. There are no changes to the content of the information

collection, the frequency of information collection, or the estimated burden per response. The only change is a decrease in the number of tobacco control program respondents from 53 to 51. Puerto Rico and the Virgin Islands were

originally funded under DP09-901 but discontinued their participation under the DP14-1415 cost extension. As a result, the total estimated annualized burden hours will decrease from 636 to 612.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
State Tobacco Control Program	Management Information System	51	2	6	612
Total	612

Leroy 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-14-0773]

Proposed Data Collections Submitted for Public Comment and Recommendations

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quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection (OMB No. 0920-0773, expires 11/30/2014)—Extension—Division of Tuberculosis Elimination (DTBE), National Center for HIV, Viral Hepatitis, STD, and TB Prevention NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the national tuberculosis (TB) elimination strategy, the American Thoracic Society and CDC have published recommendations for targeted testing for TB and treatment for latent TB infection (LTBI) (Morbidity and

Mortality Weekly Report (MMWR) 2000;49[RR06];1-54). However, between October 2000 and September 2004, the CDC received reports of 50 patients with severe adverse events (SAEs) associated with the use of the two or three-month regimen of rifampin and pyrazinamide (RZ) for the treatment of LTBI; 12 (24%) patients died (MMWR 2003;52[31]:735-9).

In 2004, CDC began collecting reports of SAEs associated with any treatment regimen for LTBI. For surveillance purposes, an SAE was defined as any drug-associated reaction resulting in a patient's hospitalization or death after at least one treatment dose for LTBI. During 2004-2008, CDC received 17 reports of SAEs in 15 adults and two children; all patients had received isoniazid (INH) and had experienced severe liver injury MMWR 2010; 59:224-9).

Reports of SAEs related to RZ and INH have prompted a need for this project (a national surveillance system of such events). The objective of the project is to determine the annual number and temporal trends of SAEs associated with any treatment for LTBI in the United States. Surveillance of such events will provide data to support periodic evaluation or potential revision of guidelines for treatment of persons with LTBI.

On December 9, 2011, CDC published the *Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent Mycobacterium tuberculosis Infection* in MMWR 2011;60(48):1650-1653. Isoniazid-Rifapentin (3HP) is a new biweekly 3-month treatment regimen for LTBI. Since 2011, there have been 28 reports of SAE; 26 of these were associated with 3HP.

The CDC requests approval for a 3-year extension of the previously approved National Surveillance for Severe Adverse Events Associated with