

Treatment of Latent Tuberculosis Infection. This project will continue the passive reporting system for SAEs associated with therapy for LTBI. The system will rely on medical chart review and/or onsite investigations by TB control staff.

Potential respondents are any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean).

Data will be collected using the data collection form for SAEs associated with LTBI treatment. Based on previous reporting, CDC anticipates receiving an

average of 10 responses per year from the 60 reporting areas. The data collection form is completed by healthcare providers and health departments for each reported hospitalization or death related to treatment of LTBI and contains demographic, clinical, and laboratory information.

CDC will analyze and periodically publish reports summarizing national LTBI treatment adverse events statistics and also will conduct special analyses for publication in peer-reviewed scientific journals to further describe and interpret these data.

The Food and Drug Administration (FDA) collects data on adverse events related to drugs through the MedWatch: The FDA Medical Products Reporting Program (OMB# 0910-0291, exp. 6/30/2015). CDC is encouraging health departments and healthcare providers to report SAEs to FDA. Reporting will be conducted through telephone, email, or during CDC site visits.

CDC is requesting approval for approximately 60 burden hours annually. The only cost to respondents is time to gather medical records and time to complete the reporting form. There are no costs to respondents other than their time.

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
Physician	NSSAE	10	1	1	10
Nurse	NSSAE	10	1	4	40
Medical Clerk	NSSAE	10	1	1	10
Total	60

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-14-0621]

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

National Youth Tobacco Survey (NYTS) 2015-2017 (OMB No. 0920-0621, expires 01/31/2015)—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 a major preventable cause of morbidity and mortality in the U.S. A limited number of health risk behaviors, including tobacco use, account for the overwhelming majority of immediate and long-term sources of morbidity and mortality. Because the majority of tobacco users begin using tobacco before the age of 18, there is a critical need for public health programs directed towards youth, and for information to support these programs.

Since 2004, the CDC has periodically collected information about tobacco use among adolescents (NYTS 2004, 2006, 2009, 2011, 2012, 2013, 2014 OMB no. 0920-0621, exp. 01/31/2015). This surveillance activity builds on previous surveys funded by the American Legacy Foundation in 1999, 2000, and 2002.

At present, the NYTS is the most comprehensive source of nationally representative tobacco data among students in grades 9–12, moreover, the NYTS is the only source of such data for students in grades 6–8. The NYTS has provided national estimates of tobacco use behaviors, information about exposure to pro- and anti-tobacco influences, information about racial and ethnic disparities in tobacco-related topics, and most recently, estimates of use of emerging products such as water pipes (hookahs) and electronic cigarettes (e-cigarettes). Information collected through the NYTS is used to identify trends over time, to inform the development of tobacco cessation programs for youth, and to evaluate the effectiveness of existing interventions and programs.

CDC plans to request OMB approval to conduct additional cycles of the NYTS in 2015, 2016, and 2017. The survey will be conducted among nationally representative samples of students attending public and private

schools in grades 6–12, and will be administered to students as an optically scannable, eight-page booklet of multiple-choice questions. Information supporting the NYTS also will be collected from state-, district-, and school-level administrators and teachers. During the 2015–2017 timeframe, a number of changes will be incorporated that reflect the collaboration between CDC and the Food and Drug Administration that has been ongoing since 2011 to assist the agency with measuring progress toward meeting strategic goals established by the Family Smoking Prevention and Tobacco Control Act. The 2015 survey will examine the following topics: Use of cigarettes, smokeless tobacco, cigars, pipes, bidis, snus, hookahs, electronic vapor products, and dissolvable tobacco products; knowledge and attitudes; media and advertising; access to tobacco products; secondhand smoke exposure; and cessation. Given the dynamic nature of the tobacco control environment, particularly related to

youth, it may be necessary in the future to make additional requests to OMB for changes in the NYTS instruments to reflect the varying landscape.

Results of the NYTS will continue to be used for public health program planning and evaluation. Information collected through the NYTS is expected to provide measures and data for monitoring progress on one of the 20 tobacco-related objectives for Healthy People 2020 and serve as complementary data for five other tobacco-related objectives.

OMB approval will be requested for three years. Changes described in the Revision request include changes to instrument content, a decrease in the average annualized number of respondents, and a decrease in the average annualized burden hours. There are no changes in the estimated burden per response for any type of respondent. Participation is voluntary and there are no costs to respondents other than their time.

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 Administrators	State-level Recruitment Script for the NYTS.	35	1	30/60	18
District Administrators	District-level Recruitment Script for the NYTS.	150	1	30/60	75
School Administrators	School-level Recruitment Script for the NYTS.	220	1	30/60	110
Teachers	Data Collection Checklist for the NYTS.	973	1	15/60	243
Students	National Youth Tobacco Survey	20,077	1	45/60	15,058
Total	15,504

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2014–0007]

Proposed Revised Vaccine Information Materials for Td, Tdap, Haemophilus influenzae type b, and Rotavirus Vaccines

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa–26), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops

vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. HHS/CDC seeks written comment on proposed updated vaccine information materials for tetanus/diphtheria vaccine (Td), tetanus/diphtheria and acellular pertussis vaccine (Tdap), *Haemophilus influenzae* type b (Hib) vaccine, and rotavirus vaccine.

DATES: Written comments must be received on or before August 25, 2014.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2014–0007, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Written comments should be addressed to Suzanne Johnson-DeLeon (msj1@cdc.gov), National Center for