

Attachment 2 – Published 60-Day Federal Register Notice

(2) determine whether the exposure control plan or other resource is actively used to prevent occupational exposures;

(3) determine available resources and barriers to use such as relevant educational materials, knowledge, costs, availability; and

(4) develop strategies to overcome key barriers to compliance.

The Organization for Safety, Asepsis and Prevention (OSAP) is a unique group of dental educators and consultants, researchers, clinicians, industry representatives, and other interested persons with a collective mission to be the world's leading advocate for the safe and infection-free delivery of oral healthcare. OSAP supports this commitment to dental

workers and the public through quality education and information dissemination. OSAP's unique membership includes the variety of partners critical to gather the data on compliance with the OSHA bloodborne pathogens standard, identify barriers and develop strategies to overcome barriers to compliance.

OSAP will be conducting a web survey of private dental practices in the United States. Information collected will include an inventory of existing exposure control plans; whether the plan or other resource is actively used to prevent occupational exposure to bloodborne pathogens; available resources and barriers to use such as relevant education materials,

knowledge, costs, and availability. There are no costs to the respondents other than their time. OSAP is working with a publishing partner that has an email distribution list of 45,419 dentists, representing every state in the country. The list represents nearly one-third (32%) of the total population of working dentists in the United States.

The targeted number of completed questionnaires is estimated at about 22,700 (50% participation rate). The survey is estimated to take about 15 minutes for respondents to complete. This survey completion scenario yields an annualized hour burden estimate of 5,675 hours.

There are no costs to 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)
Private Dental Practices	BBP Exposure Control Plan Survey	22,700	1	15/60	5,675
Total	5,675

Kimberly S. Lane,
Deputy Director, 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-13-0041]

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 Kimberly S. Lane, 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

Registration of individuals with Amyotrophic Lateral Sclerosis (ALS) in the National ALS Registry—Revision—(0923-0041, Expiration 7/31/2013)—Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

On October 10, 2008, President Bush signed S. 1382: ALS Registry Act which amended the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis (ALS) Registry. The activities described are part of the effort to create the National ALS Registry. The purpose of the registry is to: (1) Better describe the incidence and prevalence of ALS in the United States; (2) examine appropriate factors, such as environmental and occupational, that might be associated

with the disease; (3) better outline key demographic factors (such as age, race or ethnicity, gender, and family history) associated with the disease; and (4) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS. The registry will collect personal health information that may provide a basis for further scientific studies of potential risks for developing ALS.

After piloting methodology, on October 18, 2010, the Agency for Toxic Substances and Disease Registry (ATSDR) launched the registration component of the National ALS Registry www.cdc.gov/als.

The registration portion of the data collection is limited to information that can be used to identify an individual to assure that there are not duplicate records for an individual. Avoiding duplication of registrants due to obtaining records from multiple sources is imperative to get accurate estimates of incidence and prevalence, as well as accurate information on demographic characteristics of the cases of ALS.

In addition to questions required for registration, there are a series of short surveys to collect information on such things as military history, occupations, residential history, and family history that would not likely be available from other sources.

This project proposes to continue collecting information on individuals with ALS which can be combined with information obtained from existing sources of information and add additional optional risk factor surveys. This combined data will become the National ALS Registry and will be used to provide more accurate estimates of the incidence and prevalence of disease as well as the demographic characteristics of the cases. Information

obtained from the surveys will be used to better characterize potential risk factors for ALS which will lead to further in-depth studies.

The existence of the Web site has been advertised by ATSDR and advocacy groups such as the Amyotrophic Lateral Sclerosis Association (ALSA) and the Muscular Dystrophy Association (MDA).

There are between 15,000 and 30,000 individuals living with ALS at any

given time. In addition, approximately 6,000 people are diagnosed with ALS each year and we expect about one-quarter of them will participate in the registry. Because an advantage to registration is participating in the surveys, we expect the one time surveys, and the twice yearly survey participation rate will be 50%.

There are no costs to the 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 (in hours)
Person with ALS	Validation questions (Screener) for suspected ALS cases.	1670	1	2/60	56
	Registration Form of ALS cases	1500	1	7/60	175
	Cases of ALS completing 1-time surveys	750	16	5/60	1000
	Cases of ALS completing twice yearly surveys*.	750	2.7	5/60	169
Total					1400

* The disease progression survey is taken initial and then 3 times the first year (3, 6, 12 months after the initial survey). Because some people's disease progresses more rapidly, clinicians recommended adding the survey at 3 months to make sure everyone had the opportunity to take the survey a second time. In years 2 and 3, the survey would be taken at 6 and 12 months.

Kimberly S. Lane,
*Deputy Director, 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-13-13GX]

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Proposed Project

Assessment of a Comprehensive Human immunodeficiency virus (HIV) Clinic-Based Intervention to Promote Patients' Health and Reduce Transmission Risk—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting Office of Management and Budget (OMB) approval to collect data that will be used to evaluate an HIV clinic-based intervention to increase the number of HIV patients who (1) have undetectable levels of HIV in their blood, (2) adhere optimally to antiretroviral therapy (ART), (3) attend clinic regularly for primary care, and (4) practice safer sex. These are objectives of the National

HIV/AIDS Strategy and goals of the strategic plan of the Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention.

The project will be conducted at six HIV clinics in the United States. This proposed data collection will occur over 3 years.

The intervention that is part of this project focuses primarily on HIV patients who have a detectable viral load, i.e., their viral load is not as low as it can be and is not fully controlled. The intervention components include: (1) Brief counseling from medical providers during primary care visits informed by a behavioral screener completed by patients; (2) a computer-based intervention (CBI) in which patients see short videos of HIV medical providers (not their own providers) talking about the importance of regular clinic attendance, adherence to ART, and safer sex; and (3) one-on-one counseling from a prevention specialist if needed.

The following data will be collected in this project:

- A data manager at each clinic will electronically transmit patient clinical data to CDC using a unique study identification code as the only means of identifying a patient's data. The data files sent to CDC will not contain any medical record numbers, names, or social security numbers. The information will be encrypted and stored in a secure CDC server. The data