

Attachment 2
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-0923-09BR]

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 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail 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--New--Agency for Toxic Substances and Disease Registry (ATSDR), Coordinating

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Center for Environmental Health and Injury Prevention (CCEHIP), 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.

During a workshop held by The Agency for Toxic Substances and Disease Registry (ATSDR) in March 2006 to discuss surveillance of selected autoimmune and neurological diseases, it was decided to develop a proposal to build on work that had already been done and coordinate existing datasets to create a larger database, rather than to start from scratch with medical records review and physician reporting. Four pilot projects were funded to evaluate the accuracy and reliability of existing data from the Center for Medicare and Medicaid Services (CMS) and various datasets from the Veterans Administration. Preliminary results indicate that additional ways to identify cases of ALS will be necessary to increase completeness of the registry. Therefore, ATSDR developed a Web site where individuals will register and will also have the opportunity to provide additional information on such things as occupation, military service, and family history of ALS, which is not available in existing records.

The registration portion of the data collection will be 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 will be a series of short surveys to collect information on such things as military history, occupations, and family history that would not likely be available from other sources.

This project proposes to collect information on individuals with ALS which can be combined with information obtained from existing sources of information. 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 will be advertised by ATSDR and advocacy groups such as the Amyotrophic Lateral Sclerosis Association (ALSA) and the Muscular Dystrophy Association (MDA).

There will be approximately 30,000 individuals living with ALS when the National ALS Registry is initiated, and it is estimated that approximately 25% of those individuals will also participate. In addition, approximately 6,000 people are diagnosed with ALS each year and we expect about one-third 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

Data collection instruments/respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Validation questions (Screener) for suspected ALS cases.....	6,000	1	2/60	200
Registration Form of ALS cases.....	4,667	1	7/60	544
Cases of ALS completing 1-time surveys.	2,334	6	5/60	1167
Cases of ALS completing twice yearly surveys.	2,334	2	5/60	389
Total.....				2300

 Dated: May 20, 2009.
 Maryam I. Daneshvar,
 Acting Reports Clearance Officer, Centers for Disease Control and
 Prevention.
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