BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Toxic Substances and Disease Registry

[60Day-15-15TG]

[Docket No. CDC-2015-0009]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC).

ACTION: Notice with comment period

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on Promotion of the National Amyotrophic Lateral Sclerosis (ALS) Registry to Non-

referral Centers.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0009 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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.

Proposed Project

Promotion of the National Amyotrophic Lateral Sclerosis (ALS) Registry to Non-referral Centers – New - Agency for Toxic

Substances and Disease Registry, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a two-year Office of Management and Budget (OMB) information collection clearance for the project entitled "Promotion of the National ALS Registry to Non-referral Centers". ATSDR is authorized by the Public Health Law No: 110-373, ALS Registry Act to (1) develop a system to collect data on amyotrophic lateral sclerosis (ALS) and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, or progress to ALS; and (2) establish a national registry for the collection and storage of such data to develop a population-based registry of cases.

The primary goal of the National ALS surveillance system/registry is to obtain more complete information on the likely prevalence of ALS and to better describe the demographic characteristics (age, race, sex, and geographic location) of those with ALS. The secondary goal of the registry is to collect additional information on potential risk factors for ALS including, but not limited to, family history of ALS, smoking history, and military service. The proposed project is a new

component to be added to the existing Registry and ALS Surveillance Projects to increase self-enrollment rates of those with ALS.

ATSDR implemented the National ALS Registry (Registry) in 2009 using an algorithm applied to national administrative databases. A self-registration component was launched in October 2010. The Registry's case ascertainment methodology required validation; therefore, ATSDR established State and Metropolitan ALS Surveillance Projects (Surveillance Projects). In order to avoid biasing results from the Surveillance Projects' evaluation of the Registry's completeness, staff received instruction to not promote the Registry during the surveillance period.

According to the Morbidity and Mortality Weekly Report (MMWR) published in 2014, the proportion of cases identified via self-registration was lower than those identified in the administrative data for the period October 2010-December 2011. On-going self-registration is critical because not all persons with ALS can be identified through the algorithm, and only self-registering persons with ALS can complete the risk-factor surveys. Therefore, efforts to increase Registry awareness among non-referral center neurology practices/neurologists is needed to increase self-enrollment of persons with ALS.

This new information collection request is a result of the need to promote the Registry among neurologists who do not work at major ALS referral centers. The following objectives are set for this project:

- To implement a pilot project to conduct educational and promotional outreach activities at non-referral center neurology practices in the US, to inform neurologists and their staff about the Registry;

- To encourage neurologists to inform their patients about the Registry, and to increase persons with ALS self-enrollment in the Registry through the web portal via the use of existing Registry brochures, pamphlets, and factsheets; and

- To examine the effectiveness of educational and promotional outreach activities by reviewing persons with ALS self-enrollment rates before, during, and after the project period.

The increase in self-enrollment rates will allow ATSDR to produce more accurate estimates of prevalence of ALS, and collect risk-factor survey data from a more representative

sample of persons with ALS nationwide. Additionally, self-enrollment of people with ALS provides them with opportunities to be informed about the disease risk factors, learn more about beneficial therapies and a cure for the disease. In due course, these activities will also allow ATSDR to fulfill its congressional mandate under the ALS Registry Act.

To achieve the above mentioned objectives, a four group educational and promotional outreach study has been designed. Three groups (Group 1, Group 2 and Group 3), with two states in each group, will receive various educational and promotional components, and a fourth group (Group 4) consisting of the remaining 44 states, will serve as a comparison (will not receive any intervention). This project will implement a methodology similar to that used during previous ALS Surveillance Projects to identify all non-referral center neurologists in Groups 1, 2, and 3. Neurologists who do or would diagnose and/or care for ALS patients in Groups 1 and 2 and all neurologists in Group 3 will receive a mailing about the registry, whereas Group 4 the comparison group will not receive any outreach component. To analyze the change in ALS registry self-enrollment, ATSDR will compare, on a monthly basis, enrollment rates between Groups 1, 2, and 3, and 4, as well as with the 44-state Group 4.

Study activities include, but are not limited to, initial and follow-up phone calls, mailings, train-the-trainer sessions, and key informant interviews. The initial phone call will: (1) determine if the neurologist(s) diagnose/care for patients with ALS; (2) determine how many ALS patients are seen on an annual basis, and (3) confirm contact information for neurologists. Providers who do or would diagnose/care for patients with ALS will receive a targeted mailing about the registry. Follow-up phone calls and faxes, as needed, will confirm the receipt of mailings (including posters, provider guide pamphlet, Persons with ALS Quick Start Guide etc.). Key informant interviews with neurologists will allow for better understanding of their knowledge, attitudes, and beliefs about the Registry, and for gathering additional information about the currently deployed Registry materials. As neurologists may not be familiar with the self-enrollment process of the Registry, the project includes train-the-trainer site visits that will provide neurologists and staff (if requested to attend by the neurologist) with information to educate persons with ALS about the National ALS Registry self-enrollment process. The train-the-trainer module activities do not involve information collections.

Participation is voluntary. For the duration (2 years), the

project staff will conduct 3,800 initial phone calls, 1,900 follow-up #1 calls at one week post-mailing, 1,900 follow-up #2 calls at three months post-mailing, 30 train-the-trainer presentations, and 32 key-informant interviews.

There are no costs to respondents other than their time. The estimated annualized burden hours for this data collection activity are 326.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Neurologist Support Staff	Initial Phone Call Checklist	1,900	1	6/60	190
Neurologist Support Staff	Fax to Determine Provider Status	380	1	1/60	6
Neurologist Support Staff	Follow-up Phone Call #1(One Week Post-Mailing)	950	1	3/60	48
Neurologist Support Staff	Follow-up Phone Call #2(Three Months Post-Mailing)	950	1	3/60	48
Neurologist Support Staff	Fax to Determine if Mailing was Received	190	1	1/60	3
Neurologist	Train-the-	15	1	1	15

	Trainer				
Neurologist	Key Informant Interview	16	1	1	16
	Total				326

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Leroy A. Richardson
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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
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