DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60 Day–17–17KN; Docket No. ATSDR–2017–0001]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

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 ''Cognition, Behavior, and Caregiver Burden in Amyotrophic Lateral Sclerosis (ALS).'' Measures of ALS severity, cognition, mood and behavior, and caregiver burden will be completed by telephone and by mail.

DATES: Written comments must be received on or before March 27, 2017.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2017–0001 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., 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 NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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

Cognition, Behavior, and Caregiver Burden in Amyotrophic Lateral Sclerosis (ALS)—New—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a two-year clearance for a new information collection request (ICR) titled ''Cognition, Behavior, and Caregiver Burden in Amyotrophic Lateral Sclerosis (ALS).'' ATSDR awarded funds to Boston Veterans Affairs Research Institute (BVARI) through a contract (200–2014–59030) to conduct this study. This new information collection will enhance the scientific value of the ATSDR's National ALS Registry (OMB Control No. 0923–0041; expiration 11/30/2019) and focus on two topic areas: (a) Risk factors for ALS and (b) the burden that ALS places on persons with ALS (PALS), their family and caregivers, and whether these relationships affect ALS disease progression over a 1-year interval.

ALS is an adult-onset, rapidly fatal, neurodegenerative disease of unknown etiology that has been linked to genetic and environmental risk factors. Although ALS is primarily a motor neuron disease, there is a growing consensus about impaired cognitive function and behavioral disturbance in the disease, with prevalence estimates ranging from 10–75 percent for cognitive and behavioral disturbance and 15–41 percent for dementia. Cognitive and behavioral dysfunction in PALS is associated with shorter survival, and, perhaps, ALS disease progression. Research reported demonstrates that there is scarce information on risk factors for developing specific cognitive and behavioral ALS subtypes and whether these subtypes represent a continuum of cognitive and behavioral impairment associated with ALS disease progression. Better understanding of ALS subtypes and caregiver burden will provide crucial insights into the risk factors for and pathophysiology of the disease and caregiver burden.

This is a prospective study. A national sample of PALS and their caregivers (dyads) will be recruited from the ATSDR National ALS Registry to study the following aims:

1. Characterize the cognitive/behavioral subtypes in a large national cohort of PALS and identify risk factors for these subtypes;

2. Study cross-sectional and longitudinal relationships among cognitive/behavioral subtypes in PALS and caregiver giver burden, and whether these relationships affect ALS disease progression over a one year interval.

The study sample will be composed of men and women with ALS and their caregivers (*i.e.,* patient/caregiver dyads) from across the U.S. All patient enrollees will have a diagnosis of possible, probable or definite ALS according to the El Escorial World Federation of Neurology criteria for the diagnosis of ALS. Examining the effects of cognitive and mood changes in PALS on disease progression and caregiver burden may illustrate new ways to slow the rapid progression of the disease and develop better coping strategies to help caregivers provide effective care for longer periods.

Data will be collected on ALS severity, cognition, mood and behavior, and caregiver burden measures will be completed by telephone or by mail. In PALS, measures of ALS severity, cognition, and mood and behavior will be collected at baseline and at follow-up one year thereafter. In caregivers, measures related to caregiver burden will be collected at baseline and every 6 months thereafter. Furthermore, caregivers may be asked to complete additional measures if PALS are unable, including cognition of PALS and ALS severity in PALS at baseline and annual follow-up.

We estimate that 1,500 PALS/caregiver dyads will be screened for recruitment and 300 dyads will be enrolled. In addition, the 300 caregivers will respond for themselves. Participation in the study is voluntary and 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	Average burden of response (in hours)	Total burden hours
Persons with ALS (PALS) and caregiver dyads.	Recruitment and Enrollment Telephone Script.	1,500	1	30/60	750
Person with ALS	ALS Functional Rating Score—Extended Edition (ALSFRS–EX).	150	2	30/60	150
	Telephone Interview for Cognitive Status-modified (TICSm).	150	2	20/60	100
	ALS Cognitive Behavioral Screen (ALS–CBS).	150	2	15/60	75
	Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME–MD PHQ).	150	2	10/60	50
	Beck Depression Inventory-II (BDI–II)	150	2	10/60	50
	Beck Hopelessness Scale (BHS)	150	2	5/60	25
	Dysexecutive Questionnaire (DEX)	150	2	10/60	50
Caregiver proxy for person with ALS (PALS).	ALS Functional Rating Score—Extended Edition (ALSFRS–EX).	150	2	30/60	150
	Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME–MD PHQ).	150	2	10/60	50
	Beck Depression Inventory-II (BDI–II)	150	2	10/60	50
	Beck Hopelessness Scale (BHS)	150	2	5/60	25
	Dysexecutive Questionnaire (DEX)	150	2	10/60	50
	Cambridge Behavioural Inventory Revised (CBI–R).	150	2	10/60	50
Caregiver of person with ALS (PALS).	Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME–MD PHQ).	300	2	10/60	100
	Beck Depression Inventory-II (BDI–II)	300	3	10/60	150
	Beck Hopelessness Scale (BHS)	300	3	5/60	75
	Dysexecutive Questionnaire (DEX)	300	2	10/60	100
	Zarit Burden Interview (ZBI)	300	3	10/60	150
	Social Support Questionnaire Short Form (SSQSF).	300	3	10/60	150
	Kosberg Cost of Care Index	300	3	5/60	75
	ALS Cognitive Behavioral Screen (ALS–CBS)—Caregiver portion.	300	3	5/60	75
	Brief COPE	300	3	10/60	150
	Perceived Stress Scale (PSS)	300	3	5/60	75
Total					2,725

Leroy A. 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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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–0006; Docket No. CDC–2017–0004]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), 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 an extension request for the information collection titled ''Statements in Support of Application of Waiver of Inadmissibility.'' Approved under Office of Management and Budget (OMB) Control Number 0920–0006, this information collection allows CDC to review Class A medical waiver applications for prospective immigrants to the United States. CDC assists DHS/USCIS in determining whether or not a prospective immigrant with a Class A mental health designation may be admitted into the United States.

DATES: Written comments must be received on or before March 27, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0004 by any of the following methods:

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

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SUPPLEMENTARY INFORMATION:

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Proposed Project

Statements in Support of Application of Waiver of Inadmissibility (OMB Control No. 0920–0006; Expires 8/31/2017)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 212(a)(1) of the Immigration and Nationality Act states that aliens with specific health related conditions are ineligible for admission into the United States. The Attorney General may waive application of this inadmissibility on health-related grounds if an application for waiver is filed and approved by the consular office considering the application for visa. CDC uses this application primarily to collect information to establish and maintain records of waiver applicants in order to notify the U.S. Citizenship and Immigration Services when terms, conditions and controls imposed by waiver are not met.

CDC is requesting approval from OMB to collect this data for another three years. Based on a review of the number of waivers processed by CDC over the last three years, CDC does not request a change in the amount of burden.

Respondents must mail these documents to CDC, and this entails an additional cost. CDC estimates that respondents will spend approximately $15 per year on postal fees, for a total of $3,000 annually.