

## 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](mailto: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 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 (ALSFERS—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
Caregiver proxy for person with ALS (PALS).	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
	ALS Functional Rating Score—Extended Edition (ALSFERS—EX).	150	2	30/60	150
	Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME—MD PHQ).	150	2	10/60	50
Caregiver of person with ALS (PALS).	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
	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
Total .....	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
	.....	.....	.....	.....	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.

[FR Doc. 2017-01741 Filed 1-25-17; 8:45 am]

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.

*Instructions:* All submissions received  
must include the agency name and  
Docket Number. All relevant comments  
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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

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.