DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-22-0041; Docket No. ATSDR-2022-0004]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "National Amyotrophic Lateral Sclerosis (ALS) Registry." The National ALS Registry collects information from persons with ALS to better describe the prevalence and potential risk factors for ALS.

DATES: ATSDR must receive written comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2022-0004 by any of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; 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 a previously approved information

collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

National Amyotrophic Lateral Sclerosis (ALS) Registry (OMB Control No. 0923-0041, Exp. 01/31/2023) – Revision - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) clearance for a Revision information collection request (ICR) titled the "The National Amyotrophic Lateral Sclerosis (ALS) Registry" (OMB Control No. 0923-0041, Exp. 01/31/2023).

In 2008, Public Law No. 110-373 (the ALS Registry Act) amended the Public Health Service Act for ATSDR 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. Under these two mandates, ATSDR established the National Amyotrophic Lateral Sclerosis (ALS) Registry.

The primary operational goal of the Registry is to obtain reliable information on the incidence and prevalence of ALS, and to better describe the demographic characteristics (age, race, sex, and geographic location) of persons with ALS. The secondary operational goal of the surveillance system/Registry is to collect additional information on potential risk factors for ALS, including, but not limited to, family history of ALS, smoking history, military service, residential history, lifetime occupational exposure, home pesticide use, hobbies, participation in sports, hormonal and reproductive history

(women only), caffeine use, trauma, health insurance, open-ended supplemental questions, and clinical signs and symptoms.

With those goals in mind, persons with ALS first joined the Registry in 2010. Those interested in taking part answered a series of validation questions. If determined to be eligible, they created an online account to enroll in the Registry. Next, they were asked to complete up to 17 one-time voluntary survey modules, each taking up to five minutes. New registrants were also asked to complete a longitudinal disease progression survey (modified from the ALS Functional Rating Scale - Revised [ALSFRS-R]) at regular intervals over their first three years in the Registry.

A biorepository component was added in 2016. At the time of enrollment, interested registrants can request additional information about the biorepository and provide additional contact information. ATSDR selects a geographically representative sample from among the interested registrants to collect specimens. There are two types of specimen collections, in-home and postmortem. The in-home collection includes blood, urine, hair, nails, and saliva. The postmortem collection includes the brain, spinal cord, cerebral spinal fluid (CSF), bone, muscle, and skin.

Researchers can now request access to registrants' specimens, data, or both through an ATSDR research application process. Once approved for scientific merit, validity, and human

subjects protections, ATSDR makes the requested data and/or specimens available to the requester.

ATSDR also collaborates with ALS service organizations to conduct outreach activities through their local chapters and districts as well as on a national level. The service organizations provide ATSDR with monthly reports on their outreach efforts in support of the Registry.

Under this Revision ICR, the respondent types still include persons with ALS, researchers, and ALS service organizations. In summary, three main revisions to the ICR are proposed.

First, based on feedback from patients, caregivers, researchers as well as the National Center for Health Statistics (NCHS) Collaborating Center for Questionnaire Design and Evaluation Research, ATSDR proposes to restructure the original five-minute survey modules to make them more user-friendly and easier to navigate for patients. These changes are designed to increase completion rates for all surveys. Therefore, ATSDR requests to restructure the layouts of the 17 one-time ALS survey modules. The previously approved questions in the 17 modules are reorganized into the Essential Questionnaire and one of the four Follow-up Question modules: 1) Demography; 2) Lifestyle Information; 3) Environmental Factors; and 4) ALS-associated Clinical Factors. Questions determined to be critical in capturing the information about Registry participant at the time of enrollment is grouped as Essential Questionnaire. The

remaining questions from one-time survey are evaluated for proper classification in the new format.

The five-minute disease progression survey requirements remain unchanged. In Year 1, new registrants are asked to complete the disease progression survey at zero (baseline), three, and six months. The disease progression survey at zero (baseline) months will be administered after completion of the Essential Questionnaire. In Year 2 and Year 3, they are asked to repeat the disease progression survey on their anniversary date and at six months. Therefore over three years, new registrants are requested to complete the survey seven times. For time burden estimation, the number of responses is rounded up to three times per year.

As a second revision, ATSDR proposes to release state level data as four-year rolling averages for ALS incidence, prevalence, and mortality. Case counts for the four-year moving average will only be released for states with more than 16 ALS cases and is consistent with United States Cancer Statistics practices where cases or deaths are small and tend to have poor reliability.

In addition to identifying cases through Registry enrollment, ATSDR currently identifies additional cases from three large national administrative databases (Medicare, Veterans Health Administration, and Veterans Benefits Administration). As a third revision, ATSDR aims to achieve more complete ALS case ascertainment by adding several new data

sources, including state ALS registries, non-profit ALS organizations, national ALS multidisciplinary clinics affiliated with academic research institutions and hospital systems, and health insurance companies and neurologists.

There is a change to the total time burden requested for persons with ALS due to reformatting and restructuring the one-time survey questions. This reformatting has reduced the overall time burden per year by 188 hours from the previously approved 1,945 hours. The annual number of responses requested is 11,549, which is an increase of 3,000 over the previously approved 8,549 responses. This increase is due to the more accurate presentation of each online survey module in a separate row in the burden table. Previously, the 17 online survey modules were aggregated in a single row in the burden table. CDC requests OMB approval for an estimated 1,757 burden hours annually. Participation in this information collection is completely voluntary for persons with ALS and for researchers. ALS service organizations report their outreach information under contract with ATSDR. There are no costs to the respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Persons with ALS	ALS Case Validation Questions	1,670	1	2/60	56

	ALS Case Registration Form	1,500	1	10/60	250
	Essential Questionnaire	750	1	6/60	75
	Disease Progression Survey	750	3	5/60	188
	Follow-up Questions - Demography	750	1	2/60	25
	Follow-up Questions - Lifestyle Information	750	1	32/60	400
	Follow-up Questions - Environmental Factors	750	1	23/60	288
	Follow-up Questions - ALS-associated and Clinical Factors	750	1	7/60	88
	ALS Biorepository Specimen Processing Form and In-Home Collection	325	1	30/60	162
	ALS Biorepository Saliva Collection	350	1	10/60	58
Researchers	ALS Registry Research Application Form	36	1	30/60	18
	Annual Update	24	1	15/60	6
ALS Service Organizations	Chapter/District Outreach Reporting Form	135	12	5/60	135
	National Office Outreach Reporting Form	2	12	20/60	8
Total					1,757

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2022-21219 Filed: 9/29/2022 8:45 am; Publication Date: 9/30/2022]