Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 11, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–00796 Filed 1–17–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–23–0041]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled the ''National Amyotrophic Lateral Sclerosis (ALS) Registry'' to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on September 30, 2022, to obtain comments from the public and affected agencies. ATSDR received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Amyotrophic Lateral Sclerosis (ALS) Registry (OMB Control No. 0923–0041, Exp. 1/31/2023)—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 ''National Amyotrophic Lateral Sclerosis (ALS) Registry'' (OMB Control No. 0923–0041, Exp. Date 01/31/2023).

In 2008, Public Law 110–373 (the ALS Registry Act) amended the Public Health Service Act for ATSDR to: (1) develop a system to collect data 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 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) Demographics; (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 are grouped in the Essential Questionnaire. The remaining questions from one-time survey were 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 0 (baseline), three, and six months. The disease progression survey at 0 (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 new data sources (totaling less than nine), including state ALS registries and non-profit ALS organizations.

There are no costs to the respondents other than their time. 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 time burden per year to 1,757 hours, which is a decrease of 188 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. 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.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Persons with ALS	ALS Case Validation Questions	1,670	1	2/60
	ALS Case Registration Form	1,500	1	10/60
	Essential Questionnaire	750	1	6/60
	Disease Progression Survey	750	3	5/60
	Follow-up Questions—Demography	750	1	2/60
	Follow-up Questions—Lifestyle Information	750	1	32/60
	Follow-up Questions—Environmental Factors	750	1	23/60
	Follow-up Questions—ALS-associated and Clinical Factors.	750	1	7/60
	ALS Biorepository Specimen Processing Form and In-Home Collection.	325	1	30/60
	ALS Biorepository Saliva Collection	350	1	10/60
Researchers	ALS Registry Research Application Form	36	1	30/60
	Annual Update	24	1	15/60
ALS Service Organizations	Chapter/District Outreach Reporting Form	135	12	5/60
	National Office Outreach Reporting Form	2	12	20/60

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