

information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-26-0041]

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 December 22, 2025, to obtain comments from the public and affected agencies. ATSDR received 14 comments during the comment period. 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. Date 05/31/2026)—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 05/31/2026).

In 2008, Public Law 110-373 (the ALS Registry Act) amended the Public Health Service Act for the Agency for Toxic Substances and Disease Registry (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. 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). ATSDR aims to achieve more complete ALS case ascertainment by adding new data sources, including state ALS registries and non-profit ALS organizations.

Since the last continuation, there have been only minor updates to documents. All changes have been approved by the organization's IRB. These changes have no impact on the burden hours. This is a Revision request for PRA clearance. The revisions requested are designed to strengthen the usefulness of the National ALS Registry for researchers. The revisions include:

1. Updating the Consent Form to include the addition of an interagency data exchange between Unite Genomics

and the National ALS Registry. Participants will have the opportunity to share personal information relating to their health history with ATSDR through an integration between the Registry portal and a third-party online platform called Unite Genomics. This update will not impact burden hours.

2. As required by the E.O. in February 2025, all use of the term "gender" has been replaced with "sex." All changes made are minor changes to terminology as the current protocol only collects data on the registrant's sex (male/female). Changes have been made throughout the documents.

3. The OMB package being submitted reflects changes recently approved by IRB to the ALS Biorepository pre-mortem patient consent forms for the biospecimen and saliva collection. The changes include the addition of the language describing genomic data sharing and associated risk, clarification on the limited use of established cell line for commercial gain, and absence of

cell line establishment for commercial gain. Furthermore, update has been made for the ALS research application forms in Part B to include a biospecimen sample and aliquot sizes that were not previously listed, in Part C to add a postmortem sample and price that was not previously listed, and to include a new form Part E which is only applicable to the researchers making changes to their formerly approved application such as their affiliation status or additional sample request for the same study.

CDC requests OMB approval for an estimated 1,757 annual burden hours. There are no costs to the respondents other than their time. 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. ATSDR-2026-0034]

Agency for Toxic Substances and Disease Registry; Availability of Draft Toxicological Profile for Xylene

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), within the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comments on a draft of the updated Toxicological Profile for Xylene. This action is necessary as this is an opportunity for members of the public and organizations to submit comments on drafts of the profiles. The intended effect of this action is to ensure that the public can note any pertinent additional information or reports on studies about the health

effects caused by exposure to the substances covered in the profile for review.

DATES: Written comments must be received on or before August 3, 2026.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2026-0034 by either of the methods listed below. Do not submit comments by email. ATSDR does not accept comments by email.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Agency for Toxic Substances and Disease Registry, Office of Innovation and Analytics, 4770 Buford Highway, Mail Stop S106-5, Atlanta,