

3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO had 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that was currently in the PSOs' possession.

More information on PSOs can be obtained through AHRQ's PSO website at <http://www.pso.ahrq.gov>.

**Virginia L. Mackay-Smith,**  
Associate Director.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Common Formats for Patient Safety Data Collection

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability—new common formats.

**SUMMARY:** As authorized by the Secretary of HHS, AHRQ coordinates the development of sets of common definitions and reporting formats (Common Formats or formats) for reporting on health care quality and patient safety. The purpose of this notice is to announce the availability of the Common Formats for Nursing Home Version 1.0

**DATES:** Ongoing public input.

**ADDRESSES:** The *Common Formats for Nursing Home Version 1.0* can be accessed electronically at the following website: [https://www.psoppc.org/psoppc\\_web/publicpages/commonFormatsOverview](https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview).

**FOR FURTHER INFORMATION CONTACT:** Dr. Hamid Jalal, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: [psa@ahrq.hhs.gov](mailto:psa@ahrq.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### Background on Common Formats Development

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to 299b-26, (Patient Safety Act)

and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70731-70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, and analyze confidential and privileged information regarding the quality and safety of health care delivery. The collection of patient safety work product allows the aggregation of data that help to identify and address underlying causal factors of patient safety and quality issues.

Aggregation of these data enables PSOs and others to identify and address underlying causal factors of patient safety and quality issues. The Patient Safety Act provides for the development of standardized reporting formats using common language and definitions to ensure that health care quality and patient safety data collected by PSOs and other entities are comparable. The Common Formats facilitate aggregation of comparable data at local, PSO, regional and national levels. In addition, the formats are intended to enhance the reporting of information that is standardized both clinically and electronically.

AHRQ has developed Common Formats for three settings of care—acute care hospitals, nursing homes, and community pharmacies—for use by health care providers and PSOs. AHRQ-listed PSOs are required to collect patient safety work product in a standardized manner to the extent practical and appropriate; this is a requirement the PSO can meet by collecting such information using Common Formats. Additionally, providers and other organizations not working with an AHRQ-listed PSO can use the Common Formats in their work to improve quality and safety; however, they cannot benefit from the federal confidentiality and privilege protections of the Patient Safety Act.

Since February 2005, AHRQ has convened the Federal Patient Safety Work Group (PSWG) to assist AHRQ in developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS as well as the Departments of Defense and Veterans Affairs. The PSWG helps assure the consistency of definitions/formats with those of relevant government agencies. In addition, AHRQ has solicited comments from the private and public sectors regarding proposed versions of the Common Formats through a contract, since 2008, with the National Quality Forum (NQF), which is a non-profit organization focused on health care quality. After

receiving comments, the NQF solicits review of the formats by its Common Formats Expert Panel. Subsequently, NQF provides this input to AHRQ who then uses it to refine the Common Formats.

The *Common Formats Nursing Home Version 1.0* include five modules: Generic, falls, medication, pressure injury and device. AHRQ developed other elements of the Common Formats for Event Reporting—Nursing Homes including aggregate reports, data elements and algorithms, and technical specifications. All elements of the Common Formats for Event Reporting—Nursing Home will be posted at the PSOPPC website: [https://www.psoppc.org/psoppc\\_web](https://www.psoppc.org/psoppc_web).

AHRQ is specifically interested in receiving feedback in order to guide the improvement of the formats. Information on how to comment on the *Common Formats for Nursing Home Version 1.0* is available at: [http://www.qualityforum.org/Project\\_Pages/Common\\_Formats\\_for\\_Patient\\_Safety\\_Data.aspx](http://www.qualityforum.org/Project_Pages/Common_Formats_for_Patient_Safety_Data.aspx).

Additional information about the Common Formats can be obtained through AHRQ's PSO website: <https://pso.ahrq.gov/>.

**Virginia L. Mackay-Smith,**  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[30Day-19-0041]

#### 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 "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 May 24, 2019 to obtain comments from the public and affected agencies. ATSDR did not receive comments 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 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). 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. 11/30/2019)—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) entitled “The National Amyotrophic

Lateral Sclerosis (ALS) Registry.” (OMB Control No. 0923-0041, Expiration Date 11/30/2019). The current request is a revision designed to strengthen the usefulness of the National ALS Registry for researchers. The changes to the ICR include:

(1) Addition of an organized sports participation survey to capture history and current participation in physical activities. This additional survey will take approximately five minutes to complete and will add an additional 63 total burden hours for respondents;

(2) Two additional questions to capture race and ethnicity upon registration with other basic demographic information will be added to ALS Case Registration Form prior to Persons with ALS (PALS) completing more detailed surveys.

On October 10, 2008, President Bush signed S.1382: ALS Registry Act which amended the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis (ALS) Registry. The activities described are part of the ongoing effort to maintain the National ALS Registry.

First approved in 2010 for self-registration, the primary goal of the surveillance system/registry remains 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. Those interested in participating in the National ALS Registry must answer a series of validation questions and if determined to be eligible, they can register.

The secondary 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. After registration, participants complete as many as 17

voluntary survey modules, each taking up to five minutes. In addition, in Year 1, a disease progression survey for new registrants is completed at zero, three, and six months. In Year 2 and Year 3, the disease progression survey is repeated at the yearly anniversary, and at six months. For burden estimation, the number of disease progression survey responses per year has been rounded up to three times.

A biorepository component was added in 2016 to increase the value of the National ALS Registry to researchers. As part of registration the participant can request additional information about the biorepository and provide additional contact information. A geographically representative sample is selected to provide specimens. There are two types of specimen collections, in-home and postmortem. The in-home collection includes blood, urine, and saliva. The postmortem collection includes the brain, spinal cord, cerebral spinal fluid (CSF), bone, muscle, and skin.

In addition to fulfilling the two-part Congressional mandate, the Registry is designed to be a tool for ALS researchers. Now that the Registry has matured, ATSDR has made data and specimens available to approved researchers and has added a respondent type. Researchers can request access to specimens, data, or both collected by the National ALS Registry for their research projects. ATSDR will review applications for scientific validity and human subjects' protection and make data/specimens available to approved researchers. ATSDR is collaborating with ALS service organizations to conduct outreach activities through their local chapters and districts as well as on a national level. They provide ATSDR with information on their outreach efforts in support of the Registry on a monthly basis.

There are no costs to the respondents other than their time. Participation in this proposed information collection is completely voluntary. The total number of burden hours requested is 1,946 hours.

### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Person with ALS .....	ALS Case Validation Questions .....	1,670	1	2/60
	ALS Case Registration Form .....	1,500	1	10/60
	Voluntary Survey Modules .....	750	1	85/60
	Disease Progression Survey * .....	750	3	5/60
	ALS Biorepository Specimen Processing Form and In-Home Collection.	325	1	30/60

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Researchers .....	ALS Biorepository Saliva Collection .....	350	1	10/60
	ALS Registry Research Application Form .....	36	1	30/60
	Annual Update .....	24	1	15/60
ALS Service Organization .....	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

### Centers for Disease Control and Prevention

[30Day-19-19AUK]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Promoting Adolescent Health through School-Based HIV Prevention*, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on Wednesday, June 5, 2019 to obtain comments from the public and affected agencies. CDC received 2 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC 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 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). 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

Promoting Adolescent Health through School-Based HIV Prevention—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Many young people engage in sexual behaviors that place them at risk for HIV infection, other sexually transmitted diseases (STD), and pregnancy. According to the 2017 Youth Risk Behavior Survey (YRBS), 39.5% of high school students in the United States had ever had sexual intercourse and 28.7% were currently sexually active. Among currently sexually active students, 46.2% did not use a condom, and 13.8% did not use any method to prevent pregnancy the last time they had sexual intercourse. While the proportion of high school students who are sexually active has steadily declined, half of the 20 million new STDs reported each year are among young people between the ages of 15 and 24. Young people aged

13-24 account for 21% of all new HIV diagnoses in the United States, with most occurring among 20-24 year olds.

Establishing healthy behaviors during childhood and adolescence is easier and more effective than trying to change unhealthy behaviors during adulthood. One venue that offers valuable opportunities for improving adolescent health is at school. Schools have direct contact with over 50 million students for at least six hours a day over 13 key years of their social, physical, and intellectual development. In addition, schools often have staff with knowledge of critical health risk and protective behaviors and have pre-existing infrastructure that can support a varied set of healthful interventions. This makes schools well-positioned to help reduce adolescents' risk for HIV infection and other STD through sexual health education (SHE), access to sexual health services (SHS), and safe and supportive environments (SSE).

Since 1987, the Division of Adolescent and School Health (DASH) in the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention of the Centers for Disease Control and Prevention (CDC), has worked to support for HIV prevention efforts in the nation's schools. CDC requests OMB approval to collect data over a three-year period from funded agencies under award PS18-1807: Promoting Adolescent Health through School-Based HIV Prevention. Funded agencies are local education agencies (LEAs), also known as school districts. The fundamental purposes of PS18-1807 are to build and strengthen the capacity of LEAs and their priority schools to effectively contribute to the reduction of HIV infection and other STD among adolescents; the reduction of disparities in HIV infection and other STD experienced by specific adolescent sub-population. Priority schools are middle and high schools within the funded LEAs in which youth are at risk for HIV infection and other STDs. This funding supports a multi-component, multilevel effort to support youth reaching