

death information that can be used to guide program and policy decisions at the state and local levels.

**Child Death Review (CDR)**

Child Death Review (CDR) programs function in every state, and the program is often mandated by the state. Case reviews occur at the local and state level, depending on the state. States use their data to inform prevention strategies and to evaluate the success of state programs in reducing infant and child deaths as well as producing annual reports.

The National Center for the Review and Prevention of Child Death (NCRPCD) provides support and technical assistance to CDR programs. This program is funded by the Health Resources and Services Administration (HRSA). The NCRPCD support covers a broad array of process-oriented CDR issues such as forming multi-disciplinary teams, moving from state to local reviews and strengthening partnerships with the local forensic community. In addition, the NCRPCD provides support to CDR programs who

voluntarily participate in the web-based NCRPCD Case Reporting System. This Case Reporting System provides a standardized way to compile infant and child death information, already accessed and reviewed by state and local teams. Local and state teams own their data and identifiable data (if entered at all) is not available to anyone but the state that owns the data. The NCRPCD Case Report (Version 4.0), available to all CDR programs that use the Case Reporting System, will include new SDY variables. The CDC is asking SDY Registry grantees to enter new SDY variables into this pre-existing system and to use an advanced review to provide a more in-depth review of a sub-set of cases.

**Information Collection Request (ICR)**

The activities relevant to this Information Collection Request (ICR) are that SDY Registry (*i.e.*, grantee) CDR programs will convene an advanced clinical review team of physicians with specialties relevant to SDY, and will, through the advanced clinical review

and its usual CDR process, enter new SDY variables specific to SDY deaths. The data will be entered into the NCRPCD Case Reporting System, version 4.0. The SDY variables are available to all users of the Case Reporting System, grantees and non-grantees alike. In addition, unfunded local and state CDR teams may wish to conduct specialized advanced clinical reviews and are not prohibited from doing so. The SDY Registry aims to improve data completeness and timeliness of the data entered by providing technical assistance to grantees only.

For the purposes of this ICR, a “respondent” is a SDY Registry grantee funded by CDC. As a grantee for CDC’s cooperative agreement, the respondent agrees to compile a specifically defined set of SDY information about a defined set of deaths of children through the state’s CDR program. CDC estimates that 900 cases will be reported over a three-year period. There are no costs to respondents other than their time. The total annualized burden hours are 2,250.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)
State health personnel .....	SDY Module .....	9	300	30/60
Pediatric cardiologists .....	SDY Module .....	9	300	5/60
Epileptologists .....	SDY Module .....	9	300	5/60
Neurologists .....	SDY Module .....	9	300	5/60
Forensic pathologists .....	SDY Module .....	9	300	5/60

**Leroy A. Richardson,**

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[FR Doc. 2015-18146 Filed 7-23-15; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-15-0576]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for

the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920-0576, Expiration Date 11/30/2015)—Revision—Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the Agricultural Bioterrorism Protection Act of 2002), (7 U.S.C. 8401), requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents

and toxins). Accordingly, HHS and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the CDC or the Animal and Plant Health Inspection Service (APHIS). See 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. The FSAP administers the select agent regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS). Accordingly, CDC and APHIS have adopted an identical system to collect

information for the possession, use, and transfer of select agents and toxins.

CDC is requesting OMB approval to continue to collect information under the select agent regulations for the next three years. Information will be collected via fax, email and hard copy mail from respondents.

The revisions to the data collection are primarily changes to the forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms. Changes were made to the following forms: Report of Identification of a Select Agent or Toxin, Request for Exemption, Application for Registration, Request to Transfer Select Agents and Toxins, and Administrative Review.

There is no cost to respondents other than their time. The total estimated annualized burden hours are 8,527.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Regulation sections	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
73.3 & 73.4	Request for Exclusions	3	1	1
73.5 & 6	Report of Identification of a Select Agent or Toxin.	303	3	1
73.5 & 73.6	Request for Exemption	1	1	1
73.7	Application for Registration	5	1	5
73.7	Amendment to a Certificate of Registration ...	277	7	1
73.9	Documentation of self-inspection	277	1	1
73.10	Request for Expedited Review	1	1	30/60
73.11	Security Plan	277	1	5
73.12	Biosafety Plan	277	1	5
73.13	Request Regarding a Restricted Experiment	20	2	1
73.14	Incident Response Plan	277	1	5
73.15	Training	277	1	1
73.16	Request to Transfer Select Agents and Toxins.	156	2	1
73.17	Records	277	1	30/60
73.19	Notification of Potential Theft, Loss, or Release.	215	2	1
73.20	Administrative Review	5	4	1

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[FR Doc. 2015-18094 Filed 7-23-15; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-437A & CMS-437B and CMS-10488]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect

information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of