

it against unauthorized use or disclosure. The Privacy Act requires that personal information be secured against potential misuse by unauthorized persons (5 U.S.C. 552a(e)(10)). The Federal Information Security Management Act of 2002 (FISMA), enacted as Title III of the E-Government Act of 2002 (44 U.S.C. 3541 *et seq.*), requires that agencies protect data and information systems from unauthorized use, disclosure, disruption, modification and destruction, in order to preserve data integrity, confidentiality, and availability.

2. "Disclosure may be made to the National Archives and Records Administration and/or the General Services Administration for the purpose of records management inspections conducted under authority of 44 U.S.C. 2904 and 2906."

This routine use is necessary to enable the National Archives and Records Administration (NARA) and/or the General Services Administration (GSA) to carry out records management functions.

3. "Disclosure may be made to contractors and other persons who perform services for the agency related to this system of records and who need access to the records to perform those services. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a."

Where FDA engages a contractor to carry out a function related to a system of records, this routine use permits disclosure to those individuals who require access to the records in order to perform the contracted work. The routine use is necessary to enable FDA to function in an effective and coordinated fashion. Additionally, OMB directs agencies to include such a routine use for disclosure to contractor personnel (Appendix I to OMB Circular A-130—Federal Agency Responsibilities for Maintaining Records About Individuals, available at <http://www.whitehouse.gov/omb/circulars/a130/a130trans4>). FDA will require that individuals to whom records are disclosed comply with the information handling obligations imposed on Federal Agencies by the Privacy Act.

4. "When a record on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, disclosure may be made to the appropriate public authority, whether federal, foreign, state, local, or tribal, or otherwise, responsible for enforcing, investigating

or prosecuting such violation, if the information disclosed is relevant to the responsibilities of the agency or public authority."

When a record in an agency system of records by itself or in combination with other records indicates a violation of law, this routine use allows FDA to provide the record to the appropriate law enforcement entity in order to maintain the integrity of the program and ensure trust in the system.

5. "In the event HHS/FDA deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice."

DOJ is the lead Agency on Federal implementation of the Freedom of Information Act (FOIA). This routine use enables FDA to share Privacy Act records with DOJ to effectively consult with DOJ regarding the potential disclosure of the records under the FOIA as permitted under the relevant provision of the Privacy Act, 5 U.S.C. 552a(b)(2).

#### *B. FDA Systems of Records Notices to Which New Routine Uses Will Be Added*

FDA will add the specified routine uses to the remaining FDA SORNs that do not already contain the same or similar provisions. A list of these SORNs is as follows:

- 09-10-0002 Regulated Industry Employee Enforcement Records.
- 09-10-0003 FDA Credential Holder File.
- 09-10-0004 Communications (Oral and Written) With the Public.
- 09-10-0005 State Food and Drug Official File.
- 09-10-0009 Special Studies and Surveys on FDA-Regulated Products. Only the first, second, fourth, and fifth routine uses described in this document will be added to this SORN. It already contains a routine use covering disclosure to contractors who perform services for FDA.
- 09-10-0010 Bioresearch Monitoring Information System. Only the second, fourth, and fifth routine uses described in this document will be added to this SORN. It already contains the routine uses regarding limited disclosure to contractors and other Agencies.
- 09-10-0013 Employee Conduct Investigative Records.
- 09-10-0018 Employee Identification Card Information Records.
- 09-10-0019 Mammography Quality Standards Act (MQSA) Training Records.

09-10-0020 FDA Records Related to Research Misconduct Proceedings. Only the fifth routine use listed in this document will be added to this SORN. It already contains routine uses that are the same as or similar to the other four.

09-10-0021 User Fee System. Only the fourth routine use listed in this document will be added to this SORN. It already contains routine uses that are the same as or similar to the other four.

### III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 23, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this Information Collection Request must be received no later than August 26, 2014.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915–0172—Revision.

*Abstract:* HRSA is revising the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report*. The Guidance is used annually by the 50 states and nine jurisdictions in applying for Block Grants under Title V of the Social Security Act and in preparing the required Annual Report. In partnership with the leadership in State Title V Maternal and Child Health (MCH) programs as well as with other national MCH leaders and stakeholders, HRSA’s Maternal and Child Health Bureau (MCHB) has been working over the past year to develop and refine a vision for transforming the MCH Block Grant to States Program to better meet current and future challenges facing our nation’s mothers and children, including children with special health care needs (CSHCN) and their families. The proposed revisions to the Application and Annual Reporting requirements and to the data forms that are contained in the revised Guidance reflect this vision.

The aims of the MCH Block Grant to States Program transformation are threefold: (1) Reduce burden to states, (2) maintain state flexibility, and (3) improve accountability. Revisions to this edition are intended to enable the state to tell a more cohesive and comprehensive Title V story and to better reflect on the program’s

leadership role and its contributions to the state’s public health system in building improved and expanded systems of care for the MCH population. It is recognized that the full extent of the anticipated burden reduction will be realized over time as states become more familiar with the new instructions and reporting requirements. The burden estimates presented in the table below are based on previous burden estimates and consultations with a few states on the proposed changes. HRSA plans to solicit additional information from no more than nine states to derive more accurate estimates.

Specific changes to this edition of the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* include the following:

(1) Narrative reporting will be organized by six population health domains (i.e., maternal and women’s health, perinatal health, child health, CSHCN, adolescent health, and life course); (2) Revised National Performance Measure (NPM) framework will be implemented with states selecting 8 of 15 NPMs for their programmatic focus; (3) State-level data for the selected NPMs will be provided by MCHB from national data sources thus reducing burden; (4) For each selected NPM, the state will establish and report only on a Structural/Process Measure (S&PM); (5) Revised instructions for the State Application/Annual Report process reflect the need for state priority needs and national MCH priority areas to drive the state’s reporting on the 5-year (and ongoing) Needs Assessment findings, the selection of NPMs which target the state-identified priority needs, the development of evidence-based strategies and S&PMs for addressing the selected NPMs, and the establishment of State Performance Measures which respond to the state’s identified unique needs; (6) State Application/Annual Report will include a 5-year Action Plan for addressing the identified MCH priority areas; (7) An Executive Summary will be included with each submitted Application/Annual Report; (8) A 5-year Needs Assessment Summary will be integrated into the State’s Application/Annual Report and will replace the more comprehensive,

standalone 5-year Needs Assessment document that the state previously submitted; (9) Health System Capacity Indicators will be eliminated; (10) Data for Health Status Indicators will be provided by the MCHB, as available, rather than collected and reported by the state; and (11) Federal and State Title V Program budget and expenditures will be reported separately by the state.

*Need and Proposed Use of the Information:* Each year, all states and jurisdictions are required to submit an Application/Annual Report for federal funds for their Title V MCH Services Block Grant to States Program to HRSA’s MCHB (Section 505(a) of Title V of the Social Security Act). In addition, the state/jurisdictional MCH Block Grant programs are required to conduct a statewide, comprehensive Needs Assessment every 5 years. The information and instructions for the preparation and submission of this Application/Annual Report are contained in the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report*.

*Likely Respondents:* By legislation (Section 505(a) of Title V of the Social Security Act), the MCH Block Grant Application/Annual Report must be developed by, or in consultation with, the State MCH Health agency.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

*Total Estimated Annualized burden hours:*

Form name	Number of respondents	Number of responses per respondent	Total responses	Burden per response (in hours)	Total burden hours
Application and Annual Report without 5-Year Needs Assessment .....	59	1	59	123.0	7,257

Form name	Number of respondents	Number of responses per respondent	Total responses	Burden per response (in hours)	Total burden hours
Application and Annual Report with 5-Year Needs Assessment .....	59	1	59	189.3	11,169
Average Total Annual Burden .....	59	.....	59	.....	* 8,561

\*(Reflects the average of one Application/Annual Report with Needs Assessment and two Application/Annual Reports without Needs Assessment.)

In fiscal year (FY) 2016, states and jurisdictions will be submitting an application and annual report with a 5-year needs assessment for a total estimated burden of 11,169 hours. In FY 2017 and FY 2018, states and jurisdictions will be submitting an application and annual report without a 5-year needs assessment for a total estimated burden of 14,514.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: June 20, 2014.

**Jackie Painter,**

*Acting Director, Division of Policy and Information Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program; List of Petitions Received

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

**FOR FURTHER INFORMATION CONTACT:** For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C-26, Rockville, MD 20857; (301) 443-6593.

**SUPPLEMENTARY INFORMATION:** The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that "[w]ithin 30 days after the Secretary receives service of any petition filed

under section 2111 the Secretary shall publish notice of such petition in the **Federal Register.**" Set forth below is a list of petitions received by HRSA on May 1, 2014, through May 31, 2014. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," and

2. Any allegation in a petition that the petitioner either:

(a) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by" one of the vaccines referred to in the Table, or

(b) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Director, Division of Vaccine Injury Compensation Program, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C-26, Rockville, MD 20857. The Court's caption