

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

21 CFR section or activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
202.1(j)(1)(iii); assuring that adverse information be publicized	0	0	0	12	0
202.1(j)(4); voluntary submission of ad to FDA	5	1	5	20	100
Total					11,466

¹ There are no capital costs or operating and maintenance costs associated with this collection.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section or activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
CDER					
202.1; ad prepared in accordance with part 202	394	105.3	41,494	400	16,597,600
202.1(j)(1); info. included re. fatalities or serious damage ..	1	1	1	40	40
CBER					
202.1; ad prepared in accordance with part 202	47	63.4	2,984	400	1,193,600
202.1(j)(1); info. included re. fatalities or serious damage ..	0	0	0	40	0
CVM					
202.1; ad prepared in accordance with part 202	25	36	900	400	360,000
202.1(j)(1); info. included re. fatalities or serious damage ..	0	0	0	40	0
Total					18,151,240

¹ There are no capital costs or operating and maintenance costs associated with this collection.

Dated: August 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: AIDS Drug Assistance Program Data Report, OMB No. 0915-0345—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for

review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 6, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: AIDS Drug Assistance Program Data Report OMB No. 0915-0345—Extension.

Abstract: HRSA's AIDS Drug Assistance Program (ADAP) is funded through the Ryan White HIV/AIDS Program (RWHAP), Part B, Title XXVI of the Public Health Service Act, which provides grants to states and territories. The ADAP provides medications for the treatment of HIV. Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access, adherence, and monitoring of HIV drug treatments. The following states, territories, and Pacific Island jurisdictions are eligible to apply for RWHAP ADAP funding: All 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. As part of the funding requirements, ADAP grant recipients submit reports concerning information on patients served, eligibility requirements, pharmaceuticals prescribed, pricing and other sources of support to provide HIV medication treatment, cost data, and coordination with Medicaid. The ADAP Data Report (ADR) will be submitted

annually and consists of a Grantee Report and a client-level data file. HRSA is requesting an extension of the ADR with minor revisions to patient/client eligibility requirements, which will align data reporting with the Ryan White HIV/AIDS Services Report. Specifically, within Client Variables in the client-level data file:

- Deletion of variable ID 7, “Transgender”
- Addition of “Transgender Male to Female”, “Transgender Female to Male”, and “Transgender Other” as response options for variable ID 6, “Gender”

Need and Proposed Use of the Information: The RWHAP requires the submission of annual reports by the Secretary of Department of Health and

Human Services (HHS) to the appropriate committees of Congress. The collection of recipient-level and client level data enables HRSA to more effectively respond to requests from the Secretary of HHS. In addition, client-level information is needed by HRSA to review program performance and inform strategic planning. Client-level data is also needed to support the monitoring of national goals to end the HIV epidemic: Reduce new HIV infections; increase access to care and optimize health outcomes for people living with HIV; reduce HIV-related health disparities and health inequities; and achieve a more coordinated national response to the HIV epidemic.

Likely Respondents: State ADAP grant recipients of Ryan White HIV/AIDS Program Part B funding.

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 ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Grantee Report	54	1	54	6	324
Client-level File	54	1	54	81	4,374
Total	* 54	54	4,698

* The same respondents complete the Grantee Report and the Client-level Report.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

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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 (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS 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 Lisa L. Reyes, Acting 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, Rm. 08N146B, Rockville, MD 20857; (301) 443-6593, or visit our Web site at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

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 HHS, 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 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that 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 June 1, 2017, through June 30, 2017. 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