

information on the cover sheet and not in the body of your comments and you must identify the information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-7699, email: NDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA’s website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss new data regarding the ‘Generally Recognized as Safe and Effective’ (GRASE) status of oral phenylephrine as a nasal decongestant that have become available since FDA last examined the issue.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA’s website at the time of the advisory committee meeting. Background

material and the link to the online teleconference and/or video conference meeting will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before August 25, 2023, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5:30 p.m. Eastern Time on September 11, 2023. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 17, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 18, 2023.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR

14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA’s advisory committee meeting procedures.

Dated: July 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-14713 Filed 7-11-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Rapid Uptake of Disseminated Interventions (RUDI) Evaluation OMB No. 0915-xxxx—[New]

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, 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 ICR should be received no later than September 11, 2023.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 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 or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

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

Information Collection Request Title: Rapid Uptake of Disseminated Interventions (RUDI) Evaluation OMB No. 0915–xxxx—[New].

Abstract: HRSA has dedicated significant resources and effort to developing novel intervention strategies aimed at eliminating disparities and improving HIV-related health outcomes for people with HIV. HRSA encourages and supports Ryan White HIV/AIDS Program (RWHAP) providers to implement interventions developed through its Special Projects of National Significance (RWHAP Part F SPNS) program and technical assistance initiatives that have been found to be effective, with adaptations for priority populations served as applicable. HRSA disseminates its RWHAP Part F SPNS and technical assistance initiative resources and products across a variety of dissemination channels, hoping to reach a maximum number of RWHAP recipients and subrecipients for whom these resources may meet an important need. This mixed-methods Rapid Uptake of Disseminated Interventions (RUDI) evaluation will use a web-based survey and virtual site visits to collect information from RWHAP recipients and subrecipients on the uptake, utility, and efficacy of the resources and products HRSA disseminates; the effectiveness of its dissemination processes; and the reach of its dissemination channels. HRSA will use the information to identify opportunities for strengthening its dissemination channels and resources to improve care and health outcomes for program participants.

Need and Proposed Use of the Information: Currently, HRSA does not

systematically gather information about the resources accessed by RWHAP providers, RWHAP recipients, or AIDS Education and Training Center (AETC) staff and the extent to which they use those resources to inform implementation of interventions.

The mixed-methods RUDI evaluation will help HRSA systematically assess and understand (1) how, where, and why recipients of RWHAP funding access and use its disseminated resources and products; and (2) the utility and effectiveness of the disseminated resources and products in caring for and treating people with HIV. HRSA will use the findings from the RUDI evaluation to develop strategies to maximize the uptake and impact of its disseminated resources and products, contributing to ending the HIV epidemic in the United States.

Likely Respondents: The mixed-methods RUDI evaluation includes a web-based survey of all RWHAP recipients and subrecipients nationally, individual interviews with a sample of RWHAP recipients, virtual site visits with a sample of RWHAP providers, and individual interviews with all AETCs. The RUDI web-based survey design includes two versions of the survey that will be administered to non-overlapping respondents—the RUDI Recipients Survey for RWHAP Part A and B recipient administrative entities—and the RUDI Providers Survey for Part A and B subrecipients and Part C, D, and F recipients who provide direct care. Both versions ask about respondents’ use of HRSA-disseminated resources, how they were helpful, what could be improved, and reasons for non-use where applicable. In addition, the RUDI Recipients Survey asks about the recipients’ role in guiding their subrecipients to needed resources, and the RUDI Providers Survey asks about

the recipients’ experience implementing interventions for which they used the resources. Both surveys are designed to be followed up with additional sets of interviews with a sample of the survey respondents to provide deeper understanding of their experience to support development of actionable recommendations pertaining to dissemination. Virtual site visits to RWHAP providers include interviews with an average of three staff within each provider organization that were part of an intervention implementation with assistance from HRSA resources. Individual interviews for Part A and B recipient administrative entities and AETCs will generate a complete picture of how those organizations use HRSA resources and how the resources or their dissemination could be improved for the future, especially when considered together with the survey responses and virtual site visit data from the RWHAP providers.

Burden Statement: Burden in the context of this study means the time that persons expend to generate, maintain, retain, disclose, and provide the requested information. 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
RUDI Recipient Survey	56	1	56	.25	14
RUDI Provider Survey	1,066	1	1,066	.25	266.5
Interviews	20	2	40	.75	30
Virtual site visit interviews	40	3	120	1.00	120
Interviews AETCs	8	1	8	1.00	8
	1,190	1,290	438.5

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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023-14772 Filed 7-11-23; 8:45 am]

BILLING CODE 4165-15-P

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, Clerk of Court, 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 08N146B, Rockville, Maryland 20857; (301) 443-6593, or visit our website 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 United States Court of Federal Claims and to serve a copy of the petition to 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 May 1, 2023, through May 31, 2023. This list provides the name of the petitioner, city, and state of vaccination (if unknown then the city and state of the person or attorney filing the 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. “[S]ustained, 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. “[S]ustained, 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 United States 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 Injury Compensation Programs, Health Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857. The Court's caption (Petitioner's Name v. Secretary of HHS) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of Title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Carole Johnson,
Administrator.

List of Petitions Filed

1. Delshun Carter, Waupun, Wisconsin, Court of Federal Claims No: 23-0618V
2. Tommie Lee Lanier, Statesboro, Georgia, Court of Federal Claims No: 23-0624V
3. Haley Petz, Clarks Summit, Pennsylvania, Court of Federal Claims No: 23-0625V
4. Denise Bernhang on behalf of B. B., Boca Raton, Florida, Court of Federal Claims No: 23-0627V
5. Torri Kidder, Plaquemine, Louisiana, Court of Federal Claims No: 23-0628V
6. Tessa Needham, Portland, Oregon, Court of Federal Claims No: 23-0630V
7. Lyndzee Weiss, Phoenix, Arizona, Court of Federal Claims No: 23-0633V
8. Mikako Welborn, Springfield, Oregon, Court of Federal Claims No: 23-0635V
9. Sangeetha Gnanasundaram, Colorado Springs, Colorado, Court of Federal Claims No: 23-0636V
10. Erica Jennings, Tupelo, Mississippi, Court of Federal Claims No: 23-0637V
11. Daisy Santiago, San Diego, California, Court of Federal Claims No: 23-0640V
12. Edith Fox, La Luz, New Mexico, Court of Federal Claims No: 23-0646V
13. Ranaye Goff, Luck, Wisconsin, Court of Federal Claims No: 23-0649V
14. Douglas Eberline, Peoria, Arizona, Court of Federal Claims No: 23-0655V
15. Sharee Barber on behalf of A. B., Medford, Oregon, Court of Federal Claims No: 23-0657V
16. Michelle Palazzolo, Staten Island, New York, Court of Federal Claims No: 23-0658V
17. Timothy Johnnies, Waupun, Wisconsin, Court of Federal Claims No: 23-0659V
18. Terry Cooper, Lewisburg, Pennsylvania, Court of Federal Claims No: 23-0661V
19. Tuipine Sofara, San Bruno, California, Court of Federal Claims No: 23-0662V
20. Veronica Madden, North Weymouth, Massachusetts, Court of Federal Claims No: 23-0665V
21. Carissa Photopoulos on behalf of Steven Wedekind, Deceased, Clintonville, Wisconsin, Court of Federal Claims No: 23-0667V