

eSTAR Pilot Program through the procedures outlined on the voluntary eSTAR Pilot Program website. Non-pilot participants are welcome to submit feedback to the Docket (see **ADDRESSES**).

During the voluntary eSTAR Pilot Program, CDRH staff intends to be available to answer questions or concerns that may arise.

C. Targeted Questions

FDA requests responses to the following questions about eSTAR from pilot program participants and stakeholders outside the pilot who want to submit comments to the docket.

(1) Is eSTAR able to integrate into your organization's business process?

(2) Are you able to open eSTAR, and are you able to add values to the structured data fields, as well as add attachments? Once entered and added, are the data retained after closing and reopening eSTAR?

(3) If you use Assistive Technology, are you able to navigate through and complete eSTAR?

(4) If eSTAR is not intuitive to use, why?

(5) Is the organization and content in eSTAR as expected, or do you have suggestions for improvement?

(6) Is eSTAR able to accommodate PDF attachments that are of the size you typically would provide in a submission?

(7) If all the required questions (indicated by red or green indicators) are provided values, and all the required attachments are added, does eSTAR properly indicate it is complete on the first page, and are all the sections listed in the "Completed" column in the final section?

(8) Do you have any suggestions to improve the effectiveness of eSTAR in its purpose, or suggestions to improve the usability?

II. Paperwork Reduction Act of 1995

This notice refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120.

III. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**), and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at [https://](https://www.regulations.gov)

www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. MDUFA III Commitment Letter, available at: <https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf>.
2. FDA Guidance for Industry and FDA Staff "eCopy Program for Medical Device Submissions," dated October 10, 2013. This document was superseded by the guidance of the same title dated December 16, 2019, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>.
3. MDUFA IV Commitment Letter, available at: <https://www.fda.gov/media/102699/download>.
4. Quality in 510(k) Review Program Pilot, available at: <https://www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots#quik>.
5. FDA Guidance for Industry and FDA Staff "Refuse to Accept Policy for 510(k)s," dated September 13, 2019, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>.
6. FDA Guidance for Industry and FDA Staff "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," dated July 28, 2014, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

Dated: February 21, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03945 Filed 2–26–20; 8:45 am]

BILLING CODE 4164–01–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 Section 2112(b)(2) of 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 January 1, 2020, through January 31, 2020. 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. “[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, Healthcare 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.

Dated: February 20, 2020.

Thomas J. Engels,
Administrator.

List of Petitions Filed

1. Corey Silvers, Medora, Indiana, Court of Federal Claims No: 20–0001V
2. Kristi Austin, Grand Forks, North Dakota, Court of Federal Claims No: 20–0002V
3. Ruth B. Thompson on behalf of The Estate of Richard D. Thompson, Deceased, Washington, District of Columbia, Court of Federal Claims No: 20–0003V
4. Amy Turner, Englewood, New Jersey, Court of Federal Claims No: 20–0004V
5. Beverly Hathcock, Phoenix, Arizona, Court of Federal Claims No: 20–0005V
6. Elaine Vasilopoulos, Glen Oaks, New York, Court of Federal Claims No: 20–0006V
7. Nancy Clark, Washington, District of Columbia, Court of Federal Claims No: 20–0007V
8. Patricia C. Puccio, Prairieville, Louisiana, Court of Federal Claims No: 20–0008V
9. Jason Berberich, Fargo, North Dakota, Court of Federal Claims No: 20–0010V
10. Amanda Jacobs, Charleston, South Carolina, Court of Federal Claims No: 20–0011V
11. Ana Cruz De Jesus, Denver, Colorado, Court of Federal Claims No: 20–0013V
12. Frank Rosseter, Torrington, Connecticut, Court of Federal Claims No: 20–0014V
13. Nico Ghasemipor, Deceased, Waltham, Massachusetts, Court of Federal Claims No: 20–0017V
14. Loren Lynette Machuca on behalf of J.A.M., San Benito, Texas, Court of Federal Claims No: 20–0018V
15. Pamela Stewart, Louisville, Kentucky, Court of Federal Claims No: 20–0019V
16. Kevin Harris, Ada, Oklahoma, Court of Federal Claims No: 20–0020V
17. Keith Irish, Manchester, New Hampshire, Court of Federal Claims No: 20–0021V
18. Erica Stastny, Louisville, Kentucky, Court of Federal Claims No: 20–0022V
19. Megan Zynkian, San Diego, California, Court of Federal Claims No: 20–0023V
20. Paoshoua Vue, Stockton, California, Court of Federal Claims No: 20–0024V
21. Lexi Kestner, Chicago, Illinois, Court of Federal Claims No: 20–0025V
22. Jamar Simmons, Bagram Air Field, Afghanistan, Court of Federal Claims No: 20–0026V
23. Ron Richards and Samantha Richards on behalf of Caleb Lee/Carter Albert Hall-Richards, Ashtabula, Ohio, Court of Federal Claims No: 20–0028V
24. Sheri Boatwright, Sacramento, California, Court of Federal Claims No: 20–0029V
25. Paula Beyerl, Leesburg, Virginia, Court of Federal Claims No: 20–0032V
26. Loretta Franklin, Webster, New York, Court of Federal Claims No: 20–0033V
27. Stacey Cyrus, Boston, Massachusetts, Court of Federal Claims No: 20–0035V
28. Shavon Dickinson on behalf of Z.D., Sacramento, California, Court of Federal Claims No: 20–0038V
29. Terrance Finefrock, Tucson, Arizona, Court of Federal Claims No: 20–0042V
30. Margo Paluilis, Brattleboro, Vermont, Court of Federal Claims No: 20–0043V
31. Dania Pedraza on behalf of N.Q., Brownsville, Texas, Court of Federal Claims No: 20–0045V
32. Sherry Davis, Longview, Washington, Court of Federal Claims No: 20–0046V
33. John Hutton, Folsom, California, Court of Federal Claims No: 20–0049V
34. Deandrea Austin on behalf of D.F., Detroit, Michigan, Court of Federal Claims No: 20–0050V
35. Janet Jackson, Cerro Gordo, Illinois, Court of Federal Claims No: 20–0051V
36. Angelia Johnson, Winston Salem, North Carolina, Court of Federal Claims No: 20–0054V
37. Rhonda Rose, Berea, Kentucky, Court of Federal Claims No: 20–0056V
38. Josephine Inyang, Golden Valley, Minnesota, Court of Federal Claims No: 20–0057V
39. Racquel Deville, Boston, Massachusetts, Court of Federal Claims No: 20–0058V
40. Marlene Borman, Valley Stream, New York, Court of Federal Claims No: 20–0059V
41. Erin Harland, Franklin, Tennessee, Court of Federal Claims No: 20–0060V
42. Bruce A. Ling, Jr., Quincy, Florida, Court of Federal Claims No: 20–0061V
43. Laura Hamilton on behalf of D.H., Boston, Massachusetts, Court of Federal Claims No: 20–0062V
44. Karen J. Darling, Breeese, Illinois, Court of Federal Claims No: 20–0063V
45. Caprice Angelica Marcum, Modesto, California, Court of Federal Claims No: 20–0065V
46. Karla Knox, Lewistown, Montana, Court of Federal Claims No: 20–0067V
47. Michelle Mott, Dallas, Texas, Court of Federal Claims No: 20–0068V
48. Mallyssa Day, Biddeford, Maine, Court of Federal Claims No: 20–0070V
49. Debra S. DeYoung, Richmond, Virginia, Court of Federal Claims No: 20–0072V
50. Richard Joseph Spahr, Mt. Pleasant, South Carolina, Court of Federal Claims No: 20–0074V
51. Mark Chase on behalf of Barbara Pauley-Chase, Deceased, Goodyear, Arizona, Court of Federal Claims No: 20–0076V
52. Henry Scott McClain, Boston, Massachusetts, Court of Federal Claims No: 20–0078V
53. Laurie A. Sutherland, Fayetteville, New York, Court of Federal Claims No: 20–0082V
54. Natalie Gorham, Memphis, Tennessee, Court of Federal Claims No: 20–0083V
55. Kenneth Leroy Collins, Jr., Fayetteville, North Carolina, Court of Federal Claims No: 20–0084V
56. Tamatha Kelly, Lakeland, Florida, Court of Federal Claims No: 20–0085V
57. Dwight Johnson, Lebanon, Pennsylvania, Court of Federal Claims No: 20–0088V
58. Jaclyn Russo on behalf of Carly Mann, Martinez, California, Court of Federal Claims No: 20–0089V
59. Jody Bidlack, Boston, Massachusetts, Court of Federal Claims No: 20–0093V
60. Jane Doe, Washington, District of Columbia, Court of Federal Claims No: 20–0094V
61. Joanna Villalobos on behalf of A.D., Harlingen, Texas, Court of Federal Claims No: 20–0096V
62. Patricia Snelson, Saint Charles, Missouri, Court of Federal Claims No: 20–0098V
63. Sharon Issertell, Roseville, California, Court of Federal Claims No: 20–0099V
64. Mazin Khayat, Plantation, Florida, Court of Federal Claims No: 20–0101V
65. Kenya Dixon, Jackson, Mississippi, Court of Federal Claims No: 20–0102V
66. Schantel Purvis, Orange Park, Florida, Court of Federal Claims No: 20–0103V

67. Brenda J. Underwood, Richmond, Virginia, Court of Federal Claims No: 20-0104V
68. Dennis Vivians, Bethesda, Maryland, Court of Federal Claims No: 20-0105V
69. Wesley Faske, Houston, Texas, Court of Federal Claims No: 20-0106V
70. Elissa DiPasquale, Commack, New York, Court of Federal Claims No: 20-0108V
71. Eva Gordon, Dallas, Texas, Court of Federal Claims No: 20-0109V
72. Tina Schaum-Hoey, Baltimore, Maryland, Court of Federal Claims No: 20-0110V
73. Camila Wagner, Lone Tree, Colorado, Court of Federal Claims No: 20-0111V
74. Angela Bulan Bogue, Youngsville, North Carolina, Court of Federal Claims No: 20-0112V
75. Angela Bulan Bogue, Youngsville, North Carolina, Court of Federal Claims No: 20-0113V
76. Teresa Washington-Jenkins, Lancaster, Pennsylvania, Court of Federal Claims No: 20-0114V

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

NAME: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

DATES AND TIMES:

Tuesday, March 24, 2020: 9:00 a.m.–5:30 p.m.

Wednesday, March 25, 2020: 8:30 a.m.–3:00 p.m.

PLACE: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 505A, Washington, DC 20201.

STATUS: Open.

PURPOSE: At the March 24–25, 2020 meeting, the Committee will welcome four new NCVHS members, review and discuss a recent request received from the Designated Standard Maintenance Organizations (DSMO), receive briefings from HHS officials to inform discussion of the Committee's workplan, and hold discussions on several health data policy topics.

The Subcommittee on Standards will lead the Committee in a discussion of the most recent change request received from the DSMO taking into consideration input from stakeholders regarding costs and benefits of implementing the most recent version of the National Council for Prescription

drug Programs (NCPDP) pharmacy standard (NCPDP F6).

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, as amended,¹ gives statutory authority to the Secretary of Health & Human Services (HHS) to promulgate regulations adopting standards, code sets, and identifiers to support the exchange of electronic health information between covered entities. The standards are for retail pharmacy and medical transactions. New versions of the adopted standards may be brought forward to NCVHS by the standards development organizations (SDOs) or through the DSMO after completion of a consensus-based review and evaluation process.

The Committee's intent is to understand the changes in version F6 and whether there are substantive changes which need to be evaluated that would significantly change the Committee's recommendation to HHS submitted in 2018. There is no change to the Batch Standard Implementation Guide Version 15 and the Subrogation Implementation Guide for Batch Standard Version 10, which were included in the May 2018 NCVHS recommendation. The Committee requests input and comments from the public in advance of this meeting to inform its deliberations about the benefits or costs of changing to this new version. The change request letter and change log are available for review at <https://ncvhs.hhs.gov/Letter-to-NCVHS-DSMO-Change-Request-January-21-2020>. Please submit comments specific to the impact of the change from version F2 to F6 to NCVHSmal@cdc.gov by close of business Friday, March 13, 2020.

The Subcommittee on Standards will introduce a new project scoping statement for its work on convergence of administrative and clinical data standards using the prior authorization transaction as a use-case. The Subcommittee will also provide an update on its activities in collaboration with the Office of the National Coordinator for Health Information Technology (ONC) and the Health Information Technology Advisory Committee (HITAC) regarding the opportunity for burden reduction through convergence of administrative and clinical data standards using the prior authorization transaction as a use-case.

The Subcommittee on Privacy, Confidentiality and Security will lead a discussion of the full Committee to

¹ Along with Section 1104 (c) of the Affordable Care Act.

assess priority areas for focus and activity. HHS agencies will brief the Committee regarding recent and ongoing work to inform the Committee's discussion of the 2020 workplan.

There will be a public comment period on both meeting days. The times and topics are subject to change. Please refer to the posted agenda for any updates.

CONTACT PERSON FOR MORE INFORMATION:

Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458-4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website: www.ncvhs.hhs.gov, where further information including an agenda and instructions to access the broadcast of the meeting will also be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488-3210 as soon as possible.

Dated: February 20, 2020.

Sharon Arnold,

Associate Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

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BILLING CODE 4150-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special