

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: July 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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, 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, MD 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 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, 2018, through June 30, 2018. 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 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 Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, MD 20857. The Court’s caption (*Petitioner’s Name v. Secretary of Health and Human Services*) 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: July 18, 2018.

George Sigounas,
Administrator.

List of Petitions Filed

- Ronald Discher, Gales Ferry, Connecticut, Court of Federal Claims No: 18–0777V
- Thomas Beckett, Soddy Daisy, Tennessee, Court of Federal Claims No: 18–0782V
- Fay Bleier, Salamanca, New York, Court of Federal Claims No: 18–0783V
- Adriane Davis and Sylvester Davis on behalf of E.D., Springfield, Missouri, Court of Federal Claims No: 18–0784V
- Marie Brow. Stanley, North Carolina, Court of Federal Claims No: 18–0786V
- Karen Knepp, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–0790V
- Andrew Trujillo, Las Cruces, New Mexico, Court of Federal Claims No: 18–0791V
- Jennifer Jackson, Columbia, South Carolina, Court of Federal Claims No: 18–0793V
- Lynann Raymer on behalf of J.R., Phoenix, Arizona, Court of Federal Claims No: 18–0794V
- Molly Anderson, Washington, District of

- Columbia, Court of Federal Claims No: 18-0797V
11. Lisa Taylor, Elyria, Ohio, Court of Federal Claims No: 18-0798V
 12. Scott Germaine on behalf of C.G., Richmond, Texas, Court of Federal Claims No: 18-0800V
 13. Crystal Jensen, Tacoma, Washington, Court of Federal Claims No: 18-0802V
 14. Christian M. Hayes, Helena, Montana, Court of Federal Claims No: 18-0804V
 15. Matthew Hussong, Davenport, Iowa, Court of Federal Claims No: 18-0805V
 16. Gordon Ernst, Washington, District of Columbia, Court of Federal Claims No: 18-0806V
 17. Susan V. Torrey, Nampa, Idaho, Court of Federal Claims No: 18-0807V
 18. George Segal, Austintown, Ohio, Court of Federal Claims No: 18-0809V
 19. Balbina Ibe, Fountain Valley, California, Court of Federal Claims No: 18-0810V
 20. James Clark, Marietta, Georgia, Court of Federal Claims No: 18-0813V
 21. Jiaqian Wu, Houston, Texas, Court of Federal Claims No: 18-0814V
 22. Michelle Marie Cobenias, Red Lake, Minnesota, Court of Federal Claims No: 18-0815V
 23. Ali Fadhil, M.D., Chicago, Illinois, Court of Federal Claims No: 18-0816V
 24. Calvin Johnson, Washington, District of Columbia, Court of Federal Claims No: 18-0817V
 25. Willis H. Gibbs, Murfreesboro, Tennessee, Court of Federal Claims No: 18-0818V
 26. Edward A. Clendon, Greensboro, North Carolina, Court of Federal Claims No: 18-0819V
 27. Daniel Hedlund, Minneapolis, Minnesota, Court of Federal Claims No: 18-0820V
 28. Ashley T. Hunsucker, Stanfield, North Carolina, Court of Federal Claims No: 18-0821V
 29. Esther Mutema, Poughkeepsie, New York, Court of Federal Claims No: 18-0822V
 30. Mary Ligouri, Phoenix, Arizona, Court of Federal Claims No: 18-0824V
 31. Jerome Debeltz, Ely, Minnesota, Court of Federal Claims No: 18-0825V
 32. Brandi Blessike and Barry Blessike on behalf of B.B., Alpharetta, Georgia, Court of Federal Claims No: 18-0827V
 33. Erica Turner, Macon, Georgia, Court of Federal Claims No: 18-0828V
 34. Kimberly A. Purtil, Charlotte, North Carolina, Court of Federal Claims No: 18-0832V
 35. Susan Wigley, Aurora, Colorado, Court of Federal Claims No: 18-0834V
 36. Donald Sipes, Camp Hill, Pennsylvania, Court of Federal Claims No: 18-0835V
 37. Ana Marie Provencio, Phoenix, Arizona, Court of Federal Claims No: 18-0836V
 38. Angela Overall, Vancouver, Washington, Court of Federal Claims No: 18-0838V
 39. Mary Miceli, Staten Island, New York, Court of Federal Claims No: 18-0839V
 40. Ronald Schneider, Union Grove, Wisconsin, Court of Federal Claims No: 18-0843V
 41. Michelle Daniels, Marysville, Washington, Court of Federal Claims No: 18-0850V
 42. Dennis Long, Springfield, Illinois, Court of Federal Claims No: 18-0857V
 43. Bruce A. Ling, J.R., Quincy, Florida, Court of Federal Claims No: 18-0858V
 44. Marianne Simeneta, Augusta, Georgia, Court of Federal Claims No: 18-0859V
 45. Donna Skwiat, Jackson, New Jersey, Court of Federal Claims No: 18-0865V
 46. Elizabeth McCann, Huntington Valley, Pennsylvania, Court of Federal Claims No: 18-0866V
 47. Rhett Malpass, Troy, Michigan, Court of Federal Claims No: 18-0867V
 48. Kellee Matlock, Washington, District of Columbia, Court of Federal Claims No: 18-0868V
 49. Morgan Tirone, Englewood, New Jersey, Court of Federal Claims No: 18-0869V
 50. Tonya DeCoursey, Washington, District of Columbia, Court of Federal Claims No: 18-0870V
 51. Jim B. Bynum, Panama City Beach, Florida, Court of Federal Claims No: 18-0874V
 52. Timothy J. Loken on behalf of G.L., Charlotte, North Carolina, Court of Federal Claims No: 18-0876V
 53. Tiffany Wilson, Phoenix, Arizona, Court of Federal Claims No: 18-0877V
 54. Christy L. Harrup, Greensboro, North Carolina, Court of Federal Claims No: 18-0880V
 55. Mindy Lawson, Washington, District of Columbia, Court of Federal Claims No: 18-0882V
 56. Kelsey Reed, London, Kentucky, Court of Federal Claims No: 18-0884V
 57. Patricia L. Guzowski, Notre Dame, Indiana, Court of Federal Claims No: 18-0885V
 58. Janardhana Donga, Sacramento, California, Court of Federal Claims No: 18-0886V
 59. Lisa Sargent, Washington, District of Columbia, Court of Federal Claims No: 18-0888V
 60. Daniel E. Bragg, Portland, Maine, Court of Federal Claims No: 18-0890V
 61. Margaret Mitchell, Woodbury, Massachusetts, Court of Federal Claims No: 18-0892V
 62. Candace M. Berlin, Winter Haven, Florida, Court of Federal Claims No: 18-0893V
 63. Jeffrey Foster on behalf of B.N.F., Chattanooga, Tennessee, Court of Federal Claims No: 18-0904V
 64. Catherine M. Raby, Nampa, Idaho, Court of Federal Claims No: 18-0906V
 65. Audrey Henning, Ocean City, New Jersey, Court of Federal Claims No: 18-0907V
 66. Carla Pavao, Hudson, Massachusetts, Court of Federal Claims No: 18-0908V
 67. Rachelle Meyers, Summit, New Jersey, Court of Federal Claims No: 18-0909V
 68. Charles W. Morrill, West Covina, California, Court of Federal Claims No: 18-0910V
 69. Michael Volle, Burgettstown, Pennsylvania, Court of Federal Claims No: 18-0911V
 70. Nicole Webb, Chicago, Illinois, Court of Federal Claims No: 18-0912V
 71. Anderson Roy Dunn, III, North Bend, Washington, Court of Federal Claims No: 18-0913V
 72. Adam Salky, Los Angeles, California, Court of Federal Claims No: 18-0914V
 73. Brandon Keck and Jessica Cook on behalf of A.K., Fort Riley, Kansas, Court of Federal Claims No: 18-0915V
 74. Jessica Sobczyk on behalf of I.S., San Antonio, Texas, Court of Federal Claims No: 18-0917V
 75. Mary Freehling, Vienna, Virginia, Court of Federal Claims No: 18-0918V
 76. Maria Jill Vandergriff and Jon-Michael Vandergriff on behalf of Roark Vandergriff, Deceased, Vienna, Virginia, Court of Federal Claims No: 18-0919V
 77. Kevin Delapaz, Vienna, Virginia, Court of Federal Claims No: 18-0922V
 78. Jacqueline Robinson, Vienna, Virginia, Court of Federal Claims No: 18-0924V
 79. Jose Gamboa-Avila, Denver, Colorado, Court of Federal Claims No: 18-0925V
 80. David Colucci, Henderson, Nevada, Court of Federal Claims No: 18-0926V
 81. Ligia Gairdo, Cranberry Township, Pennsylvania, Court of Federal Claims No: 18-0929V
 82. Donna Carmichael, Mankato, Minnesota, Court of Federal Claims No: 18-0930V
 83. Susanna J Howard, Greensboro, North Carolina, Court of Federal Claims No: 18-0931V
 84. Vanessa Nelson, Dresher, Pennsylvania, Court of Federal Claims No: 18-0932V
 85. Terry Catching, White Plains, New York, Court of Federal Claims No: 18-0933V
 86. Renee Smith, Beverly Hills, California, Court of Federal Claims No: 18-0936V
 87. Michael Patton, Beverly Hills, California, Court of Federal Claims No: 18-0937V
 88. James Owens, Beverly Hills, California, Court of Federal Claims No: 18-0938V
 89. Theresa Ukpo, Beverly Hills, California, Court of Federal Claims No: 18-0939V
 90. Kailey Kinslow, Beverly Hills, California, Court of Federal Claims No: 18-0940V
 91. Barbara Goldman, Beverly Hills, California, Court of Federal Claims No: 18-0941V
 92. Barbara A. Brown, White Plains, New York, Court of Federal Claims No: 18-0943V
 93. Tracey Harris on behalf of C.H., Boston, Massachusetts, Court of Federal Claims No: 18-0944V
 94. Sandra Williams, Dresher, Pennsylvania, Court of Federal Claims No: 18-0947V

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Draft Indian Health Service Strategic Plan Fiscal Year 2018-2022

AGENCY: Indian Health Service, IHS.

ACTION: Request for comments; notice of Tribal Consultation and Urban Indian Confer.

SUMMARY: The Indian Health Service (IHS) is developing an Agency-wide Strategic Plan to guide the work and strengthen partnerships with Tribes and Urban Indian Organizations. The IHS is