

#### 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This draft guidance refers to previously approved collections of information found in FDA regulations.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Persons with access to the internet may obtain the draft guidance at either 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

1. Ronald Discher, Gales Ferry, Connecticut, Court of Federal Claims No: 18–0777V
2. Thomas Becktold, Soddy Daisy, Tennessee, Court of Federal Claims No: 18–0782V
3. Fay Bleier, Salamanca, New York, Court of Federal Claims No: 18–0783V
4. Adriane Davis and Sylvester Davis on behalf of E.D., Springfield, Missouri, Court of Federal Claims No: 18–0784V
5. Marie Brow. Stanley, North Carolina, Court of Federal Claims No: 18–0786V
6. Karen Knepp, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–0790V
7. Andrew Trujillo, Las Cruces, New Mexico, Court of Federal Claims No: 18–0791V
8. Jennifer Jackson, Columbia, South Carolina, Court of Federal Claims No: 18–0793V
9. Lynann Raymer on behalf of J.R., Phoenix, Arizona, Court of Federal Claims No: 18–0794V
10. 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. Purtill, 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