

CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this 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.gpo.gov/fdsys/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.

**FOR FURTHER INFORMATION CONTACT:** Francisco Vicenty, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 3426, Silver Spring, MD 20993, 301-796-5577, email: [Francisco.Vicenty@fda.hhs.gov](mailto:Francisco.Vicenty@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of July 25, 2017 (82 FR 34531), FDA published a notice announcing the public workshop entitled "Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments" with an 85-day comment period to request comments. The public workshop was held on October 10, 2017. FDA is reopening the comment period for the public workshop until December 14, 2017. The Agency believes that this will allow adequate time for interested persons to submit comments without significantly delaying the action by the Agency.

Dated: October 24, 2017.

**Anna K. Abram,**

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

[FR Doc. 2017-23498 Filed 10-27-17; 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 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, Room 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 September 1, 2017, through September 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 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 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: October 24, 2017.

**George Sigounas,**  
Administrator.

#### List of Petitions Filed

1. Jeffery Rowe, Grand Rapids, Michigan, Court of Federal Claims No: 17-1182V.
2. Clifford Reed, Dallas, Texas, Court of Federal Claims No: 17-1183V.
3. Robin Croce, Corona, California, Court of Federal Claims No: 17-1184V.
4. Matthew Jiminez, Boca Raton, Florida, Court of Federal Claims No: 17-1190V.
5. Laura Carson, Washington, District of Columbia, Court of Federal Claims No: 17-1193V.
6. Kristin Leara, Honolulu, Hawaii, Court of Federal Claims No: 17-1197V.
7. Scott Swailes, Holly Springs, North Carolina, Court of Federal Claims No: 17-1198V.
8. Ann Fly, Seattle, Washington, Court of Federal Claims No: 17-1200V.
9. Brenda Booker, Los Angeles, California, Court of Federal Claims No: 17-1201V.
10. Edwin M. Laird, Spokane, Washington, Court of Federal Claims No: 17-1203V.
11. Daniel Silver, Austin, Texas, Court of Federal Claims No: 17-1204V.
12. Kathleen Doherty-Peck, Norwich, Connecticut, Court of Federal Claims No: 17-1205V.
13. Barbara Perry, Arden, North Carolina, Court of Federal Claims No: 17-1207V.
14. Michael Napolitano, New Hyde Park, New York, Court of Federal Claims No: 17-1208V.
15. Laurence Kratzer, Walnut Creek, California, Court of Federal Claims No: 17-1209V.
16. Elizabeth McCrabb, Charleston, South Carolina, Court of Federal Claims No: 17-1210V.
17. Breanna White, Tallahassee, Florida, Court of Federal Claims No: 17-1211V.
18. Jodilyn Druery, Phoenix, Arizona, Court of Federal Claims No: 17-1213V.
19. Cherie J. Sullivan, Minneapolis, Minnesota, Court of Federal Claims No: 17-1214V.
20. Steven Ford, Chicago, Illinois, Court of Federal Claims No: 17-1217V.
21. Kelli Stricklin, Nixa, Missouri, Court of Federal Claims No: 17-1218V.
22. Ronald Brown, Naperville, Illinois, Court of Federal Claims No: 17-1219V.
23. Marlo K. Mayle, Fremont, Ohio, Court of Federal Claims No: 17-1221V.
24. Leslie K. Thompson, Murray, Utah, Court of Federal Claims No: 17-1223V.
25. Kevin Foxx, Newport News, Virginia, Court of Federal Claims No: 17-1224V.
26. Ava Cleaves, Indianapolis, Indiana, Court of Federal Claims No: 17-1225V.
27. Milan Sedlacek, Boston, Massachusetts, Court of Federal Claims No: 17-1226V.
28. James Daniel Parlette, Frankfort, Michigan, Court of Federal Claims No: 17-1227V.
29. Misti Fraser, Evansville, Indiana, Court of Federal Claims No: 17-1229V.
30. Ai Cordero, Torrance, California, Court of Federal Claims No: 17-1230V.
31. Azieb Kidane, Roseville, Minnesota, Court of Federal Claims No: 17-1231V.
32. Ofilia Arechiga, Santa Maria, California, Court of Federal Claims No: 17-1234V.
33. Elenita Alvarez-Tompkins, Washington, District of Columbia, Court of Federal Claims No: 17-1236V.
34. Theresa Cusolito, San Pedro, California, Court of Federal Claims No: 17-1237V.
35. Belinda Dawson-Savard, Salem, Oregon, Court of Federal Claims No: 17-1238V.
36. Sean Kelleher, Windsor, Connecticut, Court of Federal Claims No: 17-1239V.
37. Nick Koropatny, Washington, District of Columbia, Court of Federal Claims No: 17-1240V.
38. Carrie Schmatz, Manitowoc, Wisconsin, Court of Federal Claims No: 17-1241V.
39. Andrea Dixon on behalf of J. D., Farmington Hills, Michigan, Court of Federal Claims No: 17-1244V.
40. Correne Johnson, Blaine, Minnesota, Court of Federal Claims No: 17-1249V.
41. Stuart Weaver, Luray, Virginia, Court of Federal Claims No: 17-1251V.
42. Kehkhsan Khatoon, Farmington Hills, Michigan, Court of Federal Claims No: 17-1253V.
43. William Bartoszek, Hamburg, New York, Court of Federal Claims No: 17-1254V.
44. Breana Porcello, Medford, Massachusetts, Court of Federal Claims No: 17-1255V.
45. Lynn Johnson, Belgrade, Montana, Court of Federal Claims No: 17-1256V.
46. Glenn Reinhardt, San Antonio, Texas, Court of Federal Claims No: 17-1257V.
47. Michael O'Conner, Akron, Ohio, Court of Federal Claims No: 17-1259V.
48. Joan Smith, St. Louis, Missouri, Court of Federal Claims No: 17-1262V.
49. Judith Wilson, Madison, Wisconsin, Court of Federal Claims No: 17-1264V.
50. Sarah Stone, New York, New York, Court of Federal Claims No: 17-1265V.
51. Christine Ann Birch, Port Angeles, Washington, Court of Federal Claims No: 17-1266V.
52. Laurie Bloyer, Albuquerque, New Mexico, Court of Federal Claims No: 17-1267V.
53. Sara D'Angelo, Albuquerque, New Mexico, Court of Federal Claims No: 17-1268V.
54. Margaret DeLorenzo, Syracuse, New York, Court of Federal Claims No: 17-1269V.
55. Frances Lee, Graham, North Carolina, Court of Federal Claims No: 17-1270V.
56. Sandra Loydpierson, Charlotte, North Carolina, Court of Federal Claims No: 17-1271V.
57. Nicole Marshall, Exeter, New Hampshire, Court of Federal Claims No: 17-1272V.
58. Naomi Miller, Washington, District of Columbia, Court of Federal Claims No: 17-1273V.
59. Dolores Millican, Houston, Texas, Court of Federal Claims No: 17-1274V.
60. Jennifer Richey, North Kansas City, Missouri, Court of Federal Claims No: 17-1276V.
61. Ronald Beckman, Minneapolis, Minnesota, Court of Federal Claims No: 17-1279V.
62. Erika Hicks on behalf of A. C., Aurora, Colorado, Court of Federal Claims No: 17-1282V.
63. Larry Edge, Tavares, Florida, Court of Federal Claims No: 17-1283V.
64. Angela M. Andricks, Fostoria, Ohio, Court of Federal Claims No: 17-1284V.
65. Ralph Putnam, Putnam, Connecticut, Court of Federal Claims No: 17-1285V.
66. Marie Altema, Jersey City, New Jersey, Court of Federal Claims No: 17-1286V.
67. Barbara M. McDaniel, Washington, District of Columbia, Court of Federal Claims No: 17-1287V.
68. Larry Moranda, Eureka, California, Court of Federal Claims No: 17-1288V.
69. Caroline DiFrancesco, Reno, Nevada, Court of Federal Claims No: 17-1289V.
70. William Bartman on behalf of Angeline Bartman, Deceased, Pittsburgh, Pennsylvania, Court of Federal Claims No: 17-1290V.
71. Jon Flaig, Waverly, Iowa, Court of Federal Claims No: 17-1291V.
72. Patricia Feight, Mount Pleasant, Michigan, Court of Federal Claims No: 17-1292V.
73. Marc Barnet, Miramar, Florida, Court of Federal Claims No: 17-1293V.
74. Janet H. Stuchal, Lansdale, Pennsylvania, Court of Federal Claims No: 17-1294V.
75. Pamela M. Shaffer, Troy, Ohio, Court of Federal Claims No: 17-1295V.
76. Joan M. Douglass, Puyallup, Washington, Court of Federal Claims No: 17-1296V.
77. Cathy Mullen, Farmington Hills, Michigan, Court of Federal Claims No: 17-1297V.
78. Carrie Sadowski Ferguson, Arnold, Maryland, Court of Federal Claims No: 17-1299V.
79. Joyce Popwell, Pamona, New Jersey, Court of Federal Claims No: 17-1301V.
80. Gail Tomashefski, Indianapolis, Indiana, Court of Federal Claims No: 17-1302V.
81. Selwyn Hervey and Marylou Catee Hervey on behalf of T. H., Rancho Santa Margarita, California, Court of Federal Claims No: 17-1305V.
82. Kristen Holmes, Houston, Texas, Court of Federal Claims No: 17-1306V.
83. Erika Colpaert on behalf of R. C., Farmington Hills, Michigan, Court of Federal Claims No: 17-1307V.
84. Elisabeth Link, Haddon Heights, New Jersey, Court of Federal Claims No: 17-

- 1309V.
85. Rodolfo Monterroso, Inglewood, California, Court of Federal Claims No: 17-1310V.
86. Julia Wade, Lafayette, Louisiana, Court of Federal Claims No: 17-1311V.
87. Sally Jo Delpha, Liverpool, New York, Court of Federal Claims No: 17-1313V.
88. Joan Fram, Attleboro, Massachusetts, Court of Federal Claims No: 17-1314V.
89. Mindy Puckett, South Fargo, North Dakota, Court of Federal Claims No: 17-1316V.
90. Ralph Mueller, Boston, Massachusetts, Court of Federal Claims No: 17-1318V.
91. Richard Brandell, Springfield, Missouri, Court of Federal Claims No: 17-1319V.
92. Robert Malwitz, Grand Rapids, Minnesota, Court of Federal Claims No: 17-1320V.
93. David T. McDaniel, North Bend, Washington, Court of Federal Claims No: 17-1322V.
94. James Struck, Evanston, Illinois, Court of Federal Claims No: 17-1326V.
95. Angela Tavolacci on behalf of L. T., Washington, District of Columbia, Court of Federal Claims No: 17-1327V.
96. Jonathan McDougald, Fayetteville, North Carolina, Court of Federal Claims No: 17-1328V.
97. Richard Kadry, South Fargo, North Dakota, Court of Federal Claims No: 17-1330V.
98. Harry Cobb, Virginia Beach, Virginia, Court of Federal Claims No: 17-1331V.
99. Dave W. Highland, Louisville, Colorado, Court of Federal Claims No: 17-1333V.
100. Kay B. Harvey, Roanoke, Virginia, Court of Federal Claims No: 17-1334V.
101. Lindsey Denwiddie, Manchester, New Hampshire, Court of Federal Claims No: 17-1335V.
102. Barbara Kern, Gladwyne, Pennsylvania, Court of Federal Claims No: 17-1337V.
103. Cris D. Salazar, Santa Fe, New Mexico, Court of Federal Claims No: 17-1338V.
104. Geraldine Abel, Bridgeville, Delaware, Court of Federal Claims No: 17-1339V.
105. Mark Palmore, Frankfort, Indiana, Court of Federal Claims No: 17-1340V.
106. Stefanie Hoffman, Eugene, Oregon, Court of Federal Claims No: 17-1341V.
107. Timothy Flaig, Seattle, Washington, Court of Federal Claims No: 17-1342V.
108. Kathleen Purvis, Phenix City, Alabama, Court of Federal Claims No: 17-1343V.
109. Heather Russell-Lang, Naples, Florida, Court of Federal Claims No: 17-1344V.
110. Rosanna Massucci, Morristown, New Jersey, Court of Federal Claims No: 17-1345V.
111. Cristina K. Biesold on behalf of C. P. B., New York, New York, Court of Federal Claims No: 17-1346V.
112. Amber Wilson on behalf of A. W., Washington, District of Columbia, Court of Federal Claims No: 17-1349V.
113. Yukiko Boquet, Washington, District of Columbia, Court of Federal Claims No: 17-1351V.
114. Caprice Britt, Washington, District of Columbia, Court of Federal Claims No: 17-1352V.
115. Amy Dunlap, Washington, District of Columbia, Court of Federal Claims No: 17-1353V.
116. Barbara Easter, Washington, District of Columbia, Court of Federal Claims No: 17-1354V.
117. Herbert Geller, Washington, District of Columbia, Court of Federal Claims No: 17-1355V.
118. Nickol Marta, San Francisco, California, Court of Federal Claims No: 17-1356V.
119. Tracy Murray, Washington, District of Columbia, Court of Federal Claims No: 17-1357V.
120. Monika Nuon, Washington, District of Columbia, Court of Federal Claims No: 17-1358V.
121. Mary Perry, Washington, District of Columbia, Court of Federal Claims No: 17-1359V.
122. Amber Quintal, Washington, District of Columbia, Court of Federal Claims No: 17-1360V.
123. Wilma Rivers, Washington, District of Columbia, Court of Federal Claims No: 17-1361V.
124. Andrew J. Kaltenmark on behalf of Addison Judith Kaltenmark, Valdosta, Georgia, Court of Federal Claims No: 17-1362V.
125. Prentissa Rodrigue, Chalmette, Louisiana, Court of Federal Claims No: 17-1364V.
126. Robert J. Schaefer, St. Louis, Missouri, Court of Federal Claims No: 17-1365V.
127. Gayle Foshee-Naughton, Clearwater, Florida, Court of Federal Claims No: 17-1366V.
128. Benjamin S. Maxwell, Spokane, Washington, Court of Federal Claims No: 17-1367V.
129. Mechelle Head, Dresher, Pennsylvania, Court of Federal Claims No: 17-1368V.
130. Charles Gensmer, Coon Rapids, Minnesota, Court of Federal Claims No: 17-1369V.
131. Lauren Rettig, Memphis, Tennessee, Court of Federal Claims No: 17-1370V.
132. Laura Weishaar on behalf of Loretta Nordtvedt, Deceased, Seattle, Washington, Court of Federal Claims No: 17-1372V.
133. Emily Conger, Fort Worth, Texas, Court of Federal Claims No: 17-1373V.
134. Nathan Coulter, Garden City, New York, Court of Federal Claims No: 17-1376V.
135. Maria Swicki, Warwick, Rhode Island, Court of Federal Claims No: 17-1377V.
136. Jodi Fiske, Delray Beach, Florida, Court of Federal Claims No: 17-1378V.
137. John Alves and Virginia Alves on behalf of B. A., Gloucester, Massachusetts, Court of Federal Claims No: 17-1379V.
138. Jennifer Martindale, Glen Falls, New York, Court of Federal Claims No: 17-1380V.
139. James Blute, Lowell, Massachusetts, Court of Federal Claims No: 17-1381V.
140. Naomi Delgado, West Palm Beach, Florida, Court of Federal Claims No: 17-1382V.
141. John Mason, Merced, California, Court of Federal Claims No: 17-1383V.
142. Lisa Spencer, Buffalo, New York, Court of Federal Claims No: 17-1384V.
143. Toni Ragusa, White Plains, New York, Court of Federal Claims No: 17-1385V.
144. Becky Wiethorn, Independence, Kentucky, Court of Federal Claims No: 17-1386V.
145. Nichole Wagner, Boston, Massachusetts, Court of Federal Claims No: 17-1388V.
146. Teresa Stine, South Mountain, Pennsylvania, Court of Federal Claims No: 17-1389V.

[FR Doc. 2017-23558 Filed 10-27-17; 8:45 am]

BILLING CODE 4165-15-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

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

**ACTION:** Notice.

The Health Resources and Services Administration (HRSA) is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

Section 100.2 of the VICP's implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary, is effective upon its delivery by the Secretary to the United States Court of Federal Claims (the Court), and will be published periodically in a notice in the **Federal Register**. This figure is calculated using the most recent Medical Expenditure Panel Survey-Insurance Component (MEPS-IC) data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation and Health Research and Educational Trust (KFF/HRET) Employer Health Benefits survey or other authoritative source that may be more accurate or appropriate.

In 2017, MEPS-IC, available at [www.meps.ahrq.gov](http://www.meps.ahrq.gov), published the annual 2016 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$6,101. This figure is divided by 12-months to determine the cost per month of \$508.42. The \$508.42 is increased or decreased by the percentage change reported by the most recent KFF/HRET Employer Health Benefits Survey, available at [www.kff.org](http://www.kff.org). The percentage increase