

a strategy for improving the current system for monitoring medical device safety and effectiveness. In April 2013, the FDA issued an update to the September 2012 report that incorporated public input received and described the next steps towards fulfilling the vision for building a national postmarket surveillance system. These reports can be found at FDA's Web site <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm>.

One of these next steps consisted of establishing a multistakeholder Medical Device Registry Task Force to promote the development of national and international device registries for selected products (Ref. 1). Under a cooperative agreement with the FDA, Duke University convened the Medical Device Registry Task Force as a part of the Medical Device Epidemiology Network public-private partnership in 2014. The Task Force membership included representatives from a broad array of stakeholder groups and areas of expertise including patients, provider organizations, hospitals, health plans, industry, government agencies, as well as methodologists and academic researchers.

The Medical Device Registry Task Force was charged to: (1) Identify existing registries that may contribute to the system; (2) leverage ongoing registry efforts focused on quality improvement, reimbursement, patient-centered outcomes and other activities to best meet the needs of multiple stakeholders; (3) identify priority medical device types for which the establishment of a longitudinal registry is of significant public health importance; (4) define registry governance and data quality practices that promote rigorous design, conduct, analysis, and transparency to meet stakeholder needs; and (5) develop strategies for the use of registries to support premarket approval and clearance (Ref. 1).

This notice announces the availability and Web site location of the Medical Device Registry Task Force's report, entitled "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research." FDA invites interested persons to submit comments on this report. We have established a docket where comments may be submitted (see **ADDRESSES**). We believe this docket is an important tool for receiving feedback on this report from interested parties and for sharing this information with the public. To access "Recommendations for a National Medical Device Evaluation System:

Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research" report, visit FDA's Web site <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm>.

## II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. "Strengthening Our National System for Medical Device Postmarket Surveillance: Update and Next Steps," April 2013, available at <http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf>.

Dated: August 19, 2015.

**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, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (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 Health and Human Services 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 the 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 11C-26, 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 Health and Human Services, 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 July 1, 2015, through July 31, 2015. 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, Room 11C-26, 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: August 19, 2015.

**James Macrae,**

*Acting Administrator.*

**List of Petitions Filed**

1. Penny Walden, Urbana, Illinois, Court of Federal Claims No: 15-0685V
2. Wendy Norris, Irvine, California, Court of Federal Claims No: 15-0686V
3. Whitney Hill on behalf of C. T., Deceased, Piermont, New York, Court of Federal Claims No: 15-0687V
4. Anton Schumacher, Norristown, Pennsylvania, Court of Federal Claims No: 15-0692V
5. Lisa Davis, Annapolis, Maryland, Court of Federal Claims No: 15-0693V
6. Michael Rishwain, Stockton, California, Court of Federal Claims No: 15-0695V
7. Arlyne Rothenberg, New York, New York, Court of Federal Claims No: 15-0696V
8. Eve Dineen and Daniel Dineen on behalf of Ennio Dell Dineen, Napa, California, Court of Federal Claims No: 15-0700V
9. Adele Hamilton, Manchester Township, New Jersey, Court of Federal Claims No: 15-0701V
10. Judith Schultz, Glen Falls, New York, Court of Federal Claims No: 15-0702V
11. Jenine Gail Fugate, Huntington, West Virginia, Court of Federal Claims No: 15-0703V
12. Thomas Shinskey, Glen Rock, New Jersey, Court of Federal Claims No: 15-0713V
13. Sasha Martin on behalf of A. N. M., Deceased, Toledo, Ohio, Court of Federal Claims No: 15-0715V
14. Katie Davis on behalf of J.L.D., Baxley, Georgia, Court of Federal Claims No: 15-0716V
15. Steven Pancoast, Hampton, Virginia, Court of Federal Claims No: 15-0718V
16. Leonora Bantugan on behalf of Manuel Bolotaolo, Deceased, Simi Valley, California, Court of Federal Claims No: 15-0721V
17. John M. Dallas, Mason City, Iowa, Court of Federal Claims No: 15-0722V
18. Thomas Reece, Crossville, Tennessee, Court of Federal Claims No: 15-0724V
19. Jasmatie Hardeen and Ryon Hardeen on behalf of R. H., Vienna, Virginia, Court of Federal Claims No: 15-0726V
20. John Deselm, Highland, Texas, Court of Federal Claims No: 15-0727V
21. Constance Wadkins, Clackamas, Oregon, Court of Federal Claims No: 15-0728V
22. Darlene Steele, Uniontown, Pennsylvania, Court of Federal Claims No: 15-0729V
23. Stefenie Hilario, San Antonio, Texas, Court of Federal Claims No: 15-0730V
24. Michelle Fisher and Ricky Fisher on behalf of C. F., Omaha, Nebraska, Court of Federal Claims No: 15-0731V
25. Dana Cohen, Glen Rock, New Jersey, Court of Federal Claims No: 15-0733V
26. Amy N. Heddens, Seattle, Washington, Court of Federal Claims No: 15-0734V
27. Yvette Hill, Philadelphia, Pennsylvania, Court of Federal Claims No: 15-0735V
28. Gladys Guzman, New York, New York, Court of Federal Claims No: 15-0736V
29. Lauren Briggs on behalf of E. B., Commack, New York, Court of Federal Claims No: 15-0737V
30. Michael Mulligan, Jacksonville, Florida, Court of Federal Claims No: 15-0738V
31. Ninebeth Gal, Woodland Hills, California, Court of Federal Claims No: 15-0739V
32. Amy Loeding, Billings, Montana, Court of Federal Claims No: 15-0740V
33. Candice Cheung on behalf of A.N., Beverly Hills, California, Court of Federal Claims No: 15-0741V
34. Kellie M. DiPietro, Washington, District of Columbia, Court of Federal Claims No: 15-0742V
35. Cindy M. Del Tufo, Franklin Lakes, New Jersey, Court of Federal Claims No: 15-0745V
36. Amanda Green, Largo, Florida, Court of Federal Claims No: 15-0748V
37. Gary Bondi, Dallas, Texas, Court of Federal Claims No: 15-0749V
38. Paul Balek, Chicago, Illinois, Court of Federal Claims No: 15-0750V
39. Allison Holland, Cincinnati, Ohio, Court of Federal Claims No: 15-0751V
40. Peter C. Harrington, Pensacola, Florida, Court of Federal Claims No: 15-0752V
41. Jennifer Arnett, Dayton, Ohio, Court of Federal Claims No: 15-0753V
42. Ashley Encinias, Albuquerque, New Mexico, Court of Federal Claims No: 15-0755V
43. Dean Waasted, Orange, California, Court of Federal Claims No: 15-0757V
44. Sandra G. Price, Wichita, Kansas, Court of Federal Claims No: 15-0759V
45. Richard D. Epperson, Lee’s Summit, Missouri, Court of Federal Claims No: 15-0760V

46. Brenda K. Barbee, Raleigh, North Carolina, Court of Federal Claims No: 15-0761V
47. Tina Lazicki, Philadelphia, Pennsylvania, Court of Federal Claims No: 15-0762V
48. Mary Jo Maleport, Kentwood, Michigan, Court of Federal Claims No: 15-0763V
49. Dawn Kelly, Midway, Georgia, Court of Federal Claims No: 15-0765V
50. John M. Robinson, Napa, California, Court of Federal Claims No: 15-0766V
51. Shawn Shorkey, Dallas, Texas, Court of Federal Claims No: 15-0768V
52. Michael Purcell, Rochester, New York, Court of Federal Claims No: 15-0770V
53. Carrie Payne, Beaver, Pennsylvania, Court of Federal Claims No: 15-0771V
54. Hannah Marie Robinson, Moore, Oklahoma, Court of Federal Claims No: 15-0772V
55. Brynn Contino on behalf of G. C., New Market, Maryland, Court of Federal Claims No: 15-0773V
56. Melissa Jones, Lexington, Kentucky, Court of Federal Claims No: 15-0774V
57. Jane K. Baker, Lewisburg, Pennsylvania, Court of Federal Claims No: 15-0775V
58. Heather Caron on behalf of A. C., Waterville, Maine, Court of Federal Claims No: 15-0777V
59. Thomas Dyroff, Devon, Pennsylvania, Court of Federal Claims No: 15-0780V
60. Kelly Dillon, Leesburg, Virginia, Court of Federal Claims No: 15-0781V
61. Brenda Benjamin, Dublin, California, Court of Federal Claims No: 15-0782V
62. Teresa Cook, Rochester, New York, Court of Federal Claims No: 15-0783V
63. Cheri Fox, Bonney Lake, Washington, Court of Federal Claims No: 15-0784V
64. Christina Nolen on behalf of Nicholas Nolan, Louisa, Virginia, Court of Federal Claims No: 15-0787V
65. Lindsey Martin and Raynard Martin on behalf of I.R.M., Deceased, Powell, Ohio, Court of Federal Claims No: 15-0789V
66. Heathe Heller and Jenna Heller on behalf of H. H., Decatur, Texas, Court of Federal Claims No: 15-0792V
67. Sherry Harrison, Mount Pleasant, Pennsylvania, Court of Federal Claims No: 15-0795V
68. Amy Uscher on behalf of M. U., Phoenix, Arizona, Court of Federal Claims No: 15-0798V
69. Christina Brethauer, Monroeville, Pennsylvania, Court of Federal Claims No: 15-0800V
70. Jennifer Cirillo, Tucson, Arizona, Court of Federal Claims No: 15-0801V
71. Asharam Tamang, Albany, California, Court of Federal Claims No: 15-0802V
72. Samuel Webb, Phoenix, Arizona, Court of Federal Claims No: 15-0803V
73. Jeff Curran, Denver, Colorado, Court of Federal Claims No: 15-0804V
74. Melissa Lee Madsen, Hopewell, New Jersey, Court of Federal Claims No: 15-0807V
75. Karl Zimmerman, Sandwich, Illinois, Court of Federal Claims No: 15-0809V
76. George Hendrickson on behalf of E. H., Sioux Falls, South Dakota, Court of Federal Claims No: 15-0812V
77. Jean Mann, New York, New York, Court of Federal Claims No: 15-0813V
78. Christi Canada on behalf of L. C., Beverly Hills, California, Court of Federal Claims No: 15-0814V
79. James Wright, Beverly Hills, California, Court of Federal Claims No: 15-0815V
80. Jennifer Toole, San Antonio, Texas, Court of Federal Claims No: 15-0816V
81. Shanna Molina, Providence, Rhode Island, Court of Federal Claims No: 15-0817V
82. Kevin Sanford, Wyomissing, Pennsylvania, Court of Federal Claims No: 15-0818V
83. Dorothy Linginfelter, Knoxville, Tennessee, Court of Federal Claims No: 15-0819V

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of

Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than September 24, 2015.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Rural Outreach Benefits Counseling Program Measures OMB No. 0915-XXXX-NEW.

*Abstract:* The Rural Outreach Benefits Counseling Program (Benefits Counseling Program) is authorized by Section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)), Public Law 113-76 as amended to “promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas.” The purpose of the 3-year Benefits Counseling Program is to expand outreach, education and enrollment efforts to eligible uninsured individuals and families, and newly insured individuals and families in rural communities.

The overarching goal of this grant program is to coordinate and conduct innovative outreach activities through a strong consortium in order to: (1) Identify and enroll uninsured individuals and families who are eligible for public health insurance such as Medicare, Medicaid, and Children’s Health Insurance Program; qualified health plans offered through Health Insurance Marketplaces; and/or private health insurance plans in rural communities; and (2) educate the newly insured individuals in rural communities about their health insurance benefits, help connect them to primary care and preventive services to which they now have access, and help them retain their health insurance coverage.

*Need and Proposed Use of the Information:* For this program, performance measures were drafted to provide data to the program and to