

information to investigators will take 1 hour per disclosure. FDA estimates that disclosing information to any committee or group formally designated to oversee research involving human subjects will average 10 minutes per disclosure.

The revised draft guidance also references examples of disclosing information to study subjects such as informed consent. On average, two disclosures per respondent will be provided to study subjects. FDA estimates this will take 30 minutes per disclosure.

The total burden for the collection of information under this revised draft guidance is estimated to be approximately 2,158 hours.

The revised draft guidance also refers to previously approved collections of information. The revised draft guidance includes a recommendation that persons who intend to study tobacco products meet with FDA to discuss research plans. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance "Meetings with Industry and Investigators on the Research and Development of Tobacco Products" (<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM305282.pdf>).

The collections of information in the guidance referenced have been approved under OMB control number 0910-0731. The collections of information in section 801(e) of the FD&C Act and 21 CFR 1.101(b) have been approved under OMB control number 0910-0482; the collections of information for the Safety Reporting Portal have been approved under OMB control number 0910-0645; the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910-0673.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the revised draft guidance at either <https://www.regulations.gov> or <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: February 15, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-02971 Filed 2-20-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Migrant Health

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

ACTION: Notice.

SUMMARY: The Secretary's National Advisory Council on Migrant Health (NACMH) has scheduled a public meeting. Information about NACMH and the agenda for this meeting can be found on the NACMH website at <https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html>.

DATES: May 22, 2019, 9:00 a.m. to 5:00 p.m. Eastern Time (ET), and May 23, 2019, 9:00 a.m. to 5:00 p.m. ET.

ADDRESSES: The meeting will be held in-person. The address for the meeting is The College at Brockport, State University of New York (SUNY), Cooper Hall, 350 New Campus Drive, Brockport, New York 14420.

FOR FURTHER INFORMATION CONTACT: Esther Paul, Designated Federal Official, (DFO), Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, 16N38B, Rockville, Maryland 20857; (301) 594-4300; or epaul@hrsa.gov.

SUPPLEMENTARY INFORMATION: NACMH provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 217 of Title 42 U.S.C. 218 of the Public Health Service (PHS) Act.

During the May 22-23, 2019, meeting, NACMH will hear presentations from a federal official and experts, and discuss issues facing migrant and seasonal agricultural workers, including the status of agricultural worker health at the local and national levels. Topics addressed at this meeting include health care for aging farmworkers, oral health, and sexual harassment in the agricultural industry. In addition, during the first day of the meeting, on May 22, 2019, the council will hear public comments from migratory and seasonal agricultural workers regarding matters affecting their health. Agenda items are subject to change as priorities dictate. Refer to the NACMH website for any updated information concerning the meeting at <https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html>.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACMH should be sent to Esther Paul, DFO, using the contact information above at least three business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Esther Paul at the address and phone number listed above at least 10 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-02927 Filed 2-20-19; 8:45 am]

BILLING CODE 4165-15-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, 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 January 1, 2019, through January 31, 2019. 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: February 13, 2019.

George Sigounas,
Administrator.

List of Petitions Filed

1. Theresa Collins, Grantsville, West Virginia, Court of Federal Claims No: 19-0001V
2. Cecilia Ortiz, Houston, Texas, Court of Federal Claims No: 19-0002V
3. Sarah K. Jones, Wilmington, North Carolina, Court of Federal Claims No: 19-0003V
4. Tushar Master, Lowell, Massachusetts, Court of Federal Claims No: 19-0006V
5. Paul Christensen, Redmond, Washington, Court of Federal Claims No: 19-0007V
6. Elizabeth Wurdell, Hutchinson, Minnesota, Court of Federal Claims No: 19-0008V
7. Branden Richter, Waupun, Wisconsin, Court of Federal Claims No: 19-0009V
8. Kathryn Keeney, Wesley Chapel, Florida, Court of Federal Claims No: 19-0011V
9. Amy Skopak, Jacksonville, Florida, Court of Federal Claims No: 19-0012V
10. Gary Tucker, Phoenix, Arizona, Court of Federal Claims No: 19-0013V
11. Ann Schnitzer, Melbourne, Florida, Court of Federal Claims No: 19-0015V
12. Lauren Wood, Pittsfield, Massachusetts, Court of Federal Claims No: 19-0016V
13. Anthony Lawler, Brewer, Maine, Court of Federal Claims No: 19-0017V
14. Marie T. Haufler, Evanston, Illinois, Court of Federal Claims No: 19-0018V
15. George Nava, San Antonio, Texas, Court of Federal Claims No: 19-0019V
16. Duane Hutton, Baker City, Oregon, Court of Federal Claims No: 19-0020V
17. Dennis Schmitt, Richardson, Texas, Court of Federal Claims No: 19-0021V
18. Rebecca Smith, Washington, District of Columbia, Court of Federal Claims No: 19-0022V
19. Lesia Jones, Birmingham, Alabama, Court of Federal Claims No: 19-0023V
20. Jolene Snyder, Boone, North Carolina, Court of Federal Claims No: 19-0024V
21. Barry Negri, Howell, New Jersey, Court of Federal Claims No: 19-0028V
22. Mark Zwartz, Chicago, Illinois, Court of Federal Claims No: 19-0029V
23. Matthew Spencer, Washington, District of Columbia, Court of Federal Claims No: 19-0030V
24. Debra L. Sargent, Minneapolis, Minnesota, Court of Federal Claims No: 19-0031V
25. Shirley Tarrant, Greenville, South Carolina, Court of Federal Claims No: 19-0032V
26. Joel Tarantal, Tucson, Arizona, Court of Federal Claims No: 19-0033V
27. Susan TeHennepe, Murfreesboro, Tennessee, Court of Federal Claims No: 19-0034V
28. Linda Wilson, Charleston, South Carolina, Court of Federal Claims No: 19-0035V
29. Saum Eshraghi, Irvine, California, Court of Federal Claims No: 19-0039V
30. Ennis H. Pratcher, Toledo, Ohio, Court of Federal Claims No: 19-0044V
31. Jean Wingard, McMurray, Pennsylvania, Court of Federal Claims No: 19-0045V
32. Susan Martin, San Jose, California, Court of Federal Claims No: 19-0050V
33. Kathleen Schmid, St. Paul, Minnesota, Court of Federal Claims No: 19-0051V
34. Ryan Larsen and Samantha Glover on behalf of D.L., Newburgh, Indiana, Court of Federal Claims No: 19-0056V
35. Javier Colon on behalf of S.C., Rochester, New York, Court of Federal Claims No: 19-0057V
36. Behrooz Mozaffarian, La Mesa, California, Court of Federal Claims No: 19-0060V
37. Leah Polaske, Wellesley Hills, Massachusetts, Court of Federal Claims No: 19-0062V
38. Susan B. Acon on behalf of Agnes Biagini, Deceased, Charleroi, Pennsylvania, Court of Federal Claims No: 19-0064V
39. Kelsey Pomare, Somerville, Massachusetts, Court of Federal Claims No: 19-0065V
40. Heather Geldbach on behalf of Wendy G. Strickland, Deceased, Greensboro, North Carolina, Court of Federal Claims No: 19-0066V
41. William Kritz, Saint Cloud, Florida, Court of Federal Claims No: 19-0068V
42. Jeffrey Barton, Woodland Hills, California, Court of Federal Claims No: 19-0069V
43. Sally Herms, New York, New York, Court

- of Federal Claims No: 19-0070V
44. Andrea Morgan, Glendale, Arizona, Court of Federal Claims No: 19-0071V
 45. John Hendricks, Kirkland, Washington, Court of Federal Claims No: 19-0072V
 46. Irma Carmona, Santa Ana, California, Court of Federal Claims No: 19-0073V
 47. Karena Harrison on behalf of A.N., Jacksonville, Florida, Court of Federal Claims No: 19-0074V
 48. Galia Greenberg, Bethesda, Maryland, Court of Federal Claims No: 19-0075V
 49. Maxine Paul, Dallas, Texas, Court of Federal Claims No: 19-0076V
 50. Valorie Scamyhorn Hodges, Columbus, Ohio, Court of Federal Claims No: 19-0078V
 51. Emily Meacham and Christopher Ryan St. Andre on behalf of Joey Lynn Bates, Deceased, Waynesboro, Tennessee, Court of Federal Claims No: 19-0079V
 52. Tina D'Errico and Paul D'Errico on behalf of R.D., Rockville Center, New York, Court of Federal Claims No: 19-0081V
 53. Wade Hutton, Ironwood, Michigan, Court of Federal Claims No: 19-0082V
 54. Elaine Mercante, Hammond, Louisiana, Court of Federal Claims No: 19-0084V
 55. Hector A. Licon, Jr., San Antonio, Texas, Court of Federal Claims No: 19-0088V
 56. Matthew Doye and Renee Doye on behalf of J.R.D., Carmel, Indiana, Court of Federal Claims No: 19-0089V
 57. Charles Shane Roberson, Evansville, Indiana, Court of Federal Claims No: 19-0090V
 58. Michael Bisceglia and Lori Bisceglia on behalf of N.E.B., North Charleston, South Carolina, Court of Federal Claims No: 19-0091V
 59. Michele Solari, Norwell, Massachusetts, Court of Federal Claims No: 19-0092V
 60. Daniel Ferrari, Joliet, Illinois, Court of Federal Claims No: 19-0093V
 61. Matthew Golitko and Raygan Golitko on behalf of G.M.G., Carmel, Indiana, Court of Federal Claims No: 19-0096V
 62. Lisa Egger, Louisville, Kentucky, Court of Federal Claims No: 19-0098V
 63. Cheryl Kowal, Reading, Pennsylvania, Court of Federal Claims No: 19-0099V
 64. Ana Galan, Kansas City, Missouri, Court of Federal Claims No: 19-0100V
 65. Brian Van Vickle, Forest Lake, Minnesota, Court of Federal Claims No: 19-0101V
 66. Chester Godek, Garden City, New York, Court of Federal Claims No: 19-0106V
 67. Bernaleo Henderson, Sarasota, Florida, Court of Federal Claims No: 19-0107V
 68. Christine Heil, Flint, Michigan, Court of Federal Claims No: 19-0109V
 69. Duane Hoffman, Marion, Ohio, Court of Federal Claims No: 19-0111V
 70. Riley Truttman, Mequon, Wisconsin, Court of Federal Claims No: 19-0112V
 71. Leticia L. Lafosse, White Plains, New York, Court of Federal Claims No: 19-0113V
 72. Laurie Bishara, Parkland, Florida, Court of Federal Claims No: 19-0115V
 73. James D. Daughtery, Richmond, Kentucky, Court of Federal Claims No: 19-0116V
 74. Steven E. Ovenden, Townshend, Vermont, Court of Federal Claims No: 19-0117V
 75. Theresa Marich, East Brunswick, New Jersey, Court of Federal Claims No: 19-0119V
 76. Zahra Aden, Centreville, Virginia, Court of Federal Claims No: 19-0120V
 77. Jane Reininger, San Diego, California, Court of Federal Claims No: 19-0122V
 78. Meghan Kouba, Columbia, Missouri, Court of Federal Claims No: 19-0123V
 79. Andrea Miller, Dallas, Texas, Court of Federal Claims No: 19-0128V
 80. Mamie Porter, Waukegan, Illinois, Court of Federal Claims No: 19-0130V
 81. Rebecca Reske and Timothy Reske on behalf of J.R., Reisterstown, Maryland, Court of Federal Claims No: 19-0131V
 82. Karl Tiedemann, Jr., Port Charlotte, Florida, Court of Federal Claims No: 19-0132V
 83. Sueann Staskewicz, Tabernacle, New Jersey, Court of Federal Claims No: 19-0133V
 84. Kristan McMahon, Clifton Park, New York, Court of Federal Claims No: 19-0134V
 85. Marguerite Bradley, Spring Hill, Florida, Court of Federal Claims No: 19-0135V
 86. Burnell Buckwalter, Florence, South Carolina, Court of Federal Claims No: 19-0136V
 87. Britta Schwartz, Portland, Oregon, Court of Federal Claims No: 19-0137V
 88. Madison Edwards, Lake Charles, Louisiana, Court of Federal Claims No: 19-0138V
 89. Dana Chambers, Phoenix, Arizona, Court of Federal Claims No: 19-0140V
 90. Marsha Goldberg, Cockeysville, Maryland, Court of Federal Claims No: 19-0142V
 91. Sean Farrelly, Portland, Oregon, Court of Federal Claims No: 19-0143V
 92. Cynthia Thomas, Atlanta, Georgia, Court of Federal Claims No: 19-0144V
 93. Rene Reaska, Buffalo, New York, Court of Federal Claims No: 19-0145V
 94. Mohamed Idli, Charlotte, North Carolina, Court of Federal Claims No: 19-0146V
 95. Lisa M. Jackson, Eagan, Minnesota, Court of Federal Claims No: 19-0147V
 96. Kathie M. Hale, Salyersville, Kentucky, Court of Federal Claims No: 19-0154V
 97. Noah Scott Campbell, Dresher, Pennsylvania, Court of Federal Claims No: 19-0156V
 98. Tina McFarlin, San Juan Capistrano, California, Court of Federal Claims No: 19-0157V
 99. Jeffrey Dobyns, Birmingham, Alabama, Court of Federal Claims No: 19-0158V
 100. Barbara Miller, Appleton, Wisconsin, Court of Federal Claims No: 19-0160V
 101. Victor Velazquez, White Plains, New York, Court of Federal Claims No: 19-0162V
 102. Amy J. Johnson on behalf of P.J., Jefferson City, Missouri, Court of Federal Claims No: 19-0163V
 103. David Sazera, Dallas, Texas, Court of Federal Claims No: 19-0164V
 104. Amy Moreno, Riverside, California, Court of Federal Claims No: 19-0170V
 105. Brian Hahn, Cheektowaga, New York, Court of Federal Claims No: 19-0172V
 106. Richard Booth, Amarillo, Texas, Court of Federal Claims No: 19-0174V
 107. Bonnie Locke, Punta Gorda, Florida, Court of Federal Claims No: 19-0175V
 108. Jessica R. Boatwright, Greensboro, North Carolina, Court of Federal Claims No: 19-0176V
 109. Samantha Frost, Phoenix, Maryland, Court of Federal Claims No: 19-0177V
 110. Cynthia McVeigh, Eustis, Florida, Court of Federal Claims No: 19-0178V
 111. Teresa Leon, Yuba City, California, Court of Federal Claims No: 19-0179V
 112. Misty Lotz, Brownsville, Texas, Court of Federal Claims No: 19-0180V
 113. Valerie Eldridge, Little Rock, Arkansas, Court of Federal Claims No: 19-0181V
 114. Michael Kahn, Berlin, New Jersey, Court of Federal Claims No: 19-0182V
 115. Dulce Concepcion Muller-Carillo, Los Angeles, California, Court of Federal Claims No: 19-0183V
 116. Janis Edminster, Placerville, California, Court of Federal Claims No: 19-0184V
 117. Christopher Agard, Victorville, California, Court of Federal Claims No: 19-0185V
 118. Diana Schmauder, Newberg, Oregon, Court of Federal Claims No: 19-0186V

[FR Doc. 2019-02948 Filed 2-20-19; 8:45 am]

BILLING CODE 4165-15-P

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; MCH Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906-xxxx-NEW

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. A 60-day **Federal Register** Notice related to this proposed ICR was published in the **Federal Register** on November 16, 2018. No comments were received. OMB will accept comments from the public during the 30-day review and approval period.

DATES: Comments on this ICR should be received no later than March 25, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to 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 Lisa