

## Pharmaceutical Voluntary Consensus Standard Recognition

OMB Control Number 0910—NEW

This information collection helps support implementation of FDA's Center for Drug Evaluation and Research's (CDER) Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality. The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) and Circular A–119 by the Office of Management and Budget (OMB) have established Federal Government policies to improve the internal management of the executive branch by directing agencies to use voluntary consensus standards developed or adopted by a standards developing organization—rather than Government-unique standards—except where these standards are inconsistent with applicable law or otherwise impractical. We have developed Agency

guidance to communicate procedures respondents can follow to submit requests for recognition of a voluntary consensus standard, as well as procedures CDER will follow when a request is received. The draft guidance entitled, “CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality” (February 2019), outlines justifications for why a standard may be recognized wholly, partly, or not at all. (The draft guidance is available on our website at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cders-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality>.)<sup>1</sup> The guidance also communicates that interested parties may request recognition of a standard, allowing CDER to:

- receive a candidate consensus standard, with relevant information

(e.g., the scope of the standard and the purpose), from internal or external parties for informal recognition;

- determine whether to informally recognize a standard in whole or in part following an internal scientific evaluation; and
- list the informally recognized standards in a publicly searchable database on FDA's website, accompanied by an information sheet describing the scope and the extent of informal recognition of that standard and other relevant information.

In the **Federal Register** of February 14, 2019 (84 FR 4076), FDA published a 60-day notice announcing the availability of the draft guidance and invited comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Guidance activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total burden hours	Hourly wage rate	Total respondent costs
Submission of request for recognition of a voluntary consensus standard (page 2, page 5, section B.1) .....	9	1	9	1	9	\$87.12	\$784.08

Based on our experience with similar programs, we assume nine respondents will each submit one request for standard recognition annually, and that it will require 1 hour to prepare. We also assume industry wage rates of \$87.12, for a total cost of \$784.08 annually.

Dated: July 21, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**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, 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, Maryland 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 United States Court of Federal Claims and to serve a copy of the petition to 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

<sup>1</sup> When final, this guidance will represent FDA's current thinking on this topic.

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 May 1, 2022, through May 31, 2022. 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 United States 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, Health Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 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.

**Carole Johnson,**  
*Administrator.*

#### List of Petitions Filed

1. Carolyn Sawyer, Campti, Louisiana, Court of Federal Claims No: 22-0489V
2. Salvatore Scire, Long Branch, New Jersey, Court of Federal Claims No: 22-0492V
3. Lindsay A. Mack, Yakima, Washington, Court of Federal Claims No: 22-0493V
4. Evelyn Newey, Phoenix, Arizona, Court of Federal Claims No: 22-0494V
5. Leah Dean, Minnetonka, Minnesota, Court of Federal Claims No: 22-0495V
6. Ann Smith, Colorado Springs, Colorado, Court of Federal Claims No: 22-0498V
7. Kathryn T. Ward, Rochester, New York, Court of Federal Claims No: 22-0503V
8. Kelly Chisholm, Greensboro, North Carolina, Court of Federal Claims No: 22-0504V
9. Mary Little, Statesville, North Carolina, Court of Federal Claims No: 22-0505V
10. Mercedes Kotalik and Andrew Brabec on behalf of Z.B., Norfolk, Nebraska, Court of Federal Claims No: 22-0507V
11. Bernadette Rogers on behalf of Willie Lee Williams, Deceased, Tampa, Florida, Court of Federal Claims No: 22-0510V
12. Marco Ramos, Santa Monica, California, Court of Federal Claims No: 22-0512V
13. Sameh Tawfik, New York, New York, Court of Federal Claims No: 22-0514V
14. Gayla Dreith, Las Vegas, Nevada, Court of Federal Claims No: 22-0517V
15. Joan Kresl, Downers Grove, Illinois, Court of Federal Claims No: 22-0518V
16. Marilyn Hartogh, Cedar Rapids, Iowa, Court of Federal Claims No: 22-0519V
17. Dorota Szkol, Plainville, Connecticut, Court of Federal Claims No: 22-0520V
18. Kaitlin Wagner, Appleton, Wisconsin, Court of Federal Claims No: 22-0521V
19. Joseph Hegedus, Maitland, Florida, Court of Federal Claims No: 22-0522V
20. Genevieve Watson, Woodland Park, Colorado, Court of Federal Claims No: 22-0523V
21. Lorne Nix, Woodland Hills, California, Court of Federal Claims No: 22-0524V
22. Donna Tinch, Hanford, California, Court of Federal Claims No: 22-0525V
23. Stephanie McCoy, Phoenix, Arizona, Court of Federal Claims No: 22-0527V
24. Erika Snell, Phoenix, Arizona, Court of Federal Claims No: 22-0528V
25. Joshua D. Howard, Ashburn, Virginia, Court of Federal Claims No: 22-0530V
26. Corey Shaw, Raleigh, North Carolina, Court of Federal Claims No: 22-0532V
27. Simon Myers, Lafayette, Indiana, Court of Federal Claims No: 22-0534V
28. Taylor White on behalf of T.J., Lake Stevens, Washington, Court of Federal Claims No: 22-0535V
29. Dakota Palmore, Vancouver, Washington, Court of Federal Claims No: 22-0536V
30. Grace Eger, Chicago, Illinois, Court of Federal Claims No: 22-0540V
31. Michael Veytsel, Newark, New Jersey, Court of Federal Claims No: 22-0544V
32. Viola Taylor, Newport News, Virginia, Court of Federal Claims No: 22-0545V
33. John Holubowicz, Jackson, Michigan, Court of Federal Claims No: 22-0549V
34. Kevin Heckathorn, La Vista, Nebraska, Court of Federal Claims No: 22-0550V
35. Madeleine Chapman, Phoenix, Arizona, Court of Federal Claims No: 22-0551V
36. Christine Stangarone, Elmhurst, Illinois, Court of Federal Claims No: 22-0552V
37. Harmony Calhoun, Phoenix, Arizona, Court of Federal Claims No: 22-0554V
38. Holly Rolley, Williamsburg, Virginia, Court of Federal Claims No: 22-0556V
39. Jose Sanchez, New York, New York, Court of Federal Claims No: 22-0557V
40. Kevin Scherer, Buffalo, New York, Court of Federal Claims No: 22-0558V
41. Rocio Blanco, Pasadena, California, Court of Federal Claims No: 22-0559V
42. Peter Kouzmov, San Francisco, California, Court of Federal Claims No: 22-0561V
43. Iris Rivera Morales, Fort Myers, Florida, Court of Federal Claims No: 22-0563V
44. Warren Knecht, Metairie, Louisiana, Court of Federal Claims No: 22-0564V
45. Patricia Alanis on behalf of I.A., Berwyn, Illinois, Court of Federal Claims No: 22-0565V
46. Momen Ahmed, Palmetto, Florida, Court of Federal Claims No: 22-0566V
47. Lynnette Westbrook, Newton Grove, North Carolina, Court of Federal Claims No: 22-0568V
48. Kathy Frye, Gastonia, North Carolina, Court of Federal Claims No: 22-0569V
49. Johanne Lapointe, Spokane Valley, Washington, Court of Federal Claims No: 22-0572V
50. Venkata Maddula, New York, New York, Court of Federal Claims No: 22-0574V
51. Bethany Bier, Wilson, North Carolina, Court of Federal Claims No: 22-0577V
52. John M. Anderson, Waupun, Wisconsin, Court of Federal Claims No: 22-0580V
53. Deborah Casteel, Johnstown, Pennsylvania, Court of Federal Claims No: 22-0588V
54. Ninette Hanna Holbrook, Orlando, Florida, Court of Federal Claims No: 22-0589V
55. Mary Conklin, Brodheadsville, Pennsylvania, Court of Federal Claims No: 22-0591V
56. Barbara Gowdy, Jacksonville, Florida, Court of Federal Claims No: 22-0592V
57. Christian Turner-Stallings, El Paso, Texas, Court of Federal Claims No: 22-0593V
58. Katherine Miller, Langhorne, Pennsylvania, Court of Federal Claims No: 22-0594V
59. Dennis Spicer, Hazard, Kentucky, Court of Federal Claims No: 22-0595V
60. Megan Hartz, Alhambra, California, Court of Federal Claims No: 22-0596V
61. Dianne Greene, McKinney, Texas, Court of Federal Claims No: 22-0597V

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