

separate guidance;² or opioid or opioid-containing analgesic products.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Development of Non-Opioid Analgesics for Chronic Pain.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. As we develop any final guidance on this topic, FDA will consider comments on

the applicability of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

II. Supplementary Information on Comment Submissions

In addition to the instructions on submitting electronic or written comments provided above, FDA is providing suggestions for organizing comments to help facilitate FDA’s review and analysis.

It is helpful to distinguish comments that are general in nature from comments that pertain to a specific section or specific text in the guidance.

Note that each line of text in the guidance is numbered. If your comments pertain to a particular section or line number of the guidance, please include the section and/or line number(s) with your comment. Following is an example format that could be used to organize comments. Note that use of this format is optional.

The following is an example comment format (with example text and instructions *italicized*):

- 1. General Comments
[Include general comment]
[Include general comment]
- 2. Specific Comments on Text

Document section	Line No.	Comment
<i>I. Introduction</i>	<i>Lines 27–30</i>	<i>[Include comment, rationale, and proposed changes (if any)].</i>
<i>I. Introduction</i>	<i>Lines 39–42</i>	<i>[Include comment, rationale, and proposed changes (if any)].</i>
<i>II. Background</i>	<i>Line 80</i>	<i>[Include comment, rationale, and proposed changes (if any)].</i>

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved 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. 3501–3521).

The collections of information in 21 CFR parts 50 and 56 for protection of human subjects and institutional review boards have been approved under OMB control number 0910–0130. The collections of information in 21 CFR 58 for good laboratory practice have been approved under OMB control number 0910–0119. The collections of information in 21 CFR 210 and 211 for current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 for investigational new drug applications, conducting clinical trials, good clinical practice, and collecting data for such trials have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for new drug applications and abbreviated new drug applications trials have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 201.56 and 201.57 regarding content and format requirements for labeling for human prescription drug and biological products have been approved under OMB control number 0910–0572. The collections of information in 21 CFR

parts 601 and 610 for biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 11 regarding electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information for expedited pathways for development programs of drugs and biologics for serious conditions have been approved under OMB control number 0910–0765.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–17442 Filed 9–10–25; 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, 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, Division of Injury Compensation Programs, 5600 Fishers Lane, Room 14W–18, Rockville, Maryland 20857; 1–800–338–2382, or visit our website at: <https://www.hrsa.gov/vaccine-compensation>.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specific 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

² See the draft guidance for industry “Development of Local Anesthetic Drug Products

With Prolonged Duration of Effect,” available at <https://www.fda.gov/media/166210/download>.

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 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, 2025, through July 31, 2025. This list provides the name of the petitioner, city, and state of vaccination (if unknown then the city and state of the person or attorney filing the 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, 14W-18, 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.

Thomas J. Engels,
Administrator.

List of Petitions Filed

1. Jermarro Dantzler, Black River Falls, Wisconsin, Court of Federal Claims No: 25-1107V
2. Lisa Thompson, Suwanee, Georgia, Court of Federal Claims No: 25-1113V
3. Jonathan David Wilke, Boscobel, Wisconsin, Court of Federal Claims No: 25-1116V
4. Rodolfo Alcantar on behalf of D.A., Phoenix, Arizona, Court of Federal Claims No: 25-1117V
5. Naureen Fayyaz, Woodrige, Illinois, Court of Federal Claims No: 25-1119V
6. Alfred Boland, Hot Springs Village, Arkansas, Court of Federal Claims No: 25-1122V
7. Caira Conner, Brooklyn, New York, Court of Federal Claims No: 25-1123V
8. Travis Williams, Boscobel, Wisconsin, Court of Federal Claims No: 25-1124V
9. Beverly Bell, Houston, Texas, Court of Federal Claims No: 25-1125V
10. Robert Fugate, Phoenix, Arizona, Court of Federal Claims No: 25-1127V
11. Nancy Vazquez Campoverde, New Haven, Connecticut, Court of Federal Claims No: 25-1133V
12. Sheva Ehrenfeld, Brooklyn, New York, Court of Federal Claims No: 25-1135V
13. Linda Gil, San Antonio, Texas, Court of Federal Claims No: 25-1136V
14. Ramata Balo, Philadelphia, Pennsylvania, Court of Federal Claims No: 25-1137V
15. Corene French and Jonathan de Vargas on behalf of R.D., Salem, Oregon, Court of Federal Claims No: 25-1138V
16. Diane Mkitarian, Beverly Hills, California, Court of Federal Claims No: 25-1139V
17. David T. Duncan, Salisbury, North Carolina, Court of Federal Claims No: 25-1141V
18. Larry L. Brown, Oshkosh, Wisconsin, Court of Federal Claims No: 25-1142V
19. Lilia Vallin, Las Vegas, Nevada, Court of Federal Claims No: 25-1143V
20. Brynn Henry, Lancaster, Pennsylvania, Court of Federal Claims No: 25-1144V
21. Diane Racho, Arlington, Texas, Court of Federal Claims No: 25-1147V
22. Leslie Garrett, New York, New York, Court of Federal Claims No: 25-1148V
23. Rosa Colombo on behalf of Francesco Colombo, Deceased, Phoenix, Arizona, Court of Federal Claims No: 25-1151V
24. William Schulte, Littleton, Colorado, Court of Federal Claims No: 25-1152V
25. Travis Kirwan, Washington, DC, Court of Federal Claims No: 25-1153V
26. Lamon Akagbor, Morrisville, North Carolina, Court of Federal Claims No: 25-1154V
27. Angelene M. Hampton, Winston Salem, North Carolina, Court of Federal Claims No: 25-1156V
28. Sharon Stefanoni, Aliso Viejo, California, Court of Federal Claims No: 25-1157V
29. Antonio Martinez, Albuquerque, New Mexico, Court of Federal Claims No: 25-1158V
30. Anastasia Caso on behalf of J.A.C., Encinatas, California, Court of Federal Claims No: 25-1159V
31. Dawn Stewart, Tampa, Florida, Court of Federal Claims No: 25-1160V
32. Jack Wingo III, Boscobel, Wisconsin, Court of Federal Claims No: 25-1161V
33. Tina Marie Vargas, Torrence, California, Court of Federal Claims No: 25-1163V
34. Willis J. Fittry Sr., Richmond, Virginia, Court of Federal Claims No: 25-1165V
35. Constance Gooding, Hamilton, Ohio, Court of Federal Claims No: 25-1169V
36. Mapleton, Illinois, Court of Federal Claims No: 25-1170V
37. Marilyn Biela on behalf of Alvin Biela, Deceased, San Antonio, Texas, Court of Federal Claims No: 25-1171V
38. David Harder, Wichita, Kansas, Court of Federal Claims No: 25-1172V
39. Jessica Byrd, Aurora, Colorado, Court of Federal Claims No: 25-1173V
40. Omethrice Johnson-Curtis, Homewood, Illinois, Court of Federal Claims No: 25-1174V
41. Mason Cowart, Stockbridge, Georgia, Court of Federal Claims No: 25-1175V
42. John Idzikowski, Milwaukee, Wisconsin, Court of Federal Claims No: 25-1176V
43. Marie Temple, Corunna, Michigan, Court of Federal Claims No: 25-1178V
44. Tamara J. Elhardt, Charlotte, North Carolina, Court of Federal Claims No: 25-1180V
45. Maddison Blair Addington Ayala, Lakewood, California, Court of Federal Claims No: 25-1181V
46. Rose Martin, Portland, Oregon, Court of Federal Claims No: 25-1183V
47. Ralph McKellar, Brentwood, Tennessee, Court of Federal Claims No: 25-1184V
48. Buffy Pellerito, Newburgh, Indiana, Court of Federal Claims No: 25-1185V
49. Ronald Hawkins, Manning, South Carolina, Court of Federal Claims No: 25-1186V

50. Sarah Hughart, Buckley, West Virginia, Court of Federal Claims No: 25–1187V
51. Karen Goodman, Mount Vernon, Washington, Court of Federal Claims No: 25–1188V
52. James Glasco, Burton, Michigan, Court of Federal Claims No: 25–1190V
53. Linda Sundquist, Richmond, Virginia, Court of Federal Claims No: 25–1192V
54. Ivette Nieves, Trumbull, Connecticut, Court of Federal Claims No: 25–1194V
55. Thomas Bond, Edinburg, Indiana, Court of Federal Claims No: 25–1196V
56. Pamela Parker, La Crosse, Wisconsin, Court of Federal Claims No: 25–1199V
57. Vicki Buttrum on behalf of S.B., Morton, Illinois, Court of Federal Claims No: 25–1200V
58. Linda Roark on behalf of B.T., Los Angeles, California, Court of Federal Claims No: 25–1201V
59. Raquel Lugo, Middletown, Connecticut, Court of Federal Claims No: 25–1202V
60. Jacob Palmer on behalf of A.P., Harrisburg, Illinois, Court of Federal Claims No: 25–1205V
61. Leeann Fitzgerald, Wichita, Kansas, Court of Federal Claims No: 25–1206V
62. Rebecca Kleven, Oshkosh, Wisconsin, Court of Federal Claims No: 25–1207V
63. Donna Mayer, Boston, Massachusetts, Court of Federal Claims No: 25–1208V
64. Glenda Evans, Greenville, North Carolina, Court of Federal Claims No: 25–1210V
65. Tamara Tanninen, Richland, Washington, Court of Federal Claims No: 25–1213V
66. Meadria McIntyre, Grove Hill, Alabama, Court of Federal Claims No: 25–1214V
67. Crystal Campbell, Bossier City, Louisiana, Court of Federal Claims No: 25–1216V
68. Nigel Jackson, Springfield, Virginia, Court of Federal Claims No: 25–1217V
69. Eric Chavis, Halethorpe, Maryland, Court of Federal Claims No: 25–1220V
70. Lindsay Schofield, Erie, Pennsylvania, Court of Federal Claims No: 25–1221V
71. Betty Sanfratello, Seattle, Washington, Court of Federal Claims No: 25–1222V
72. Ellie Grabow, Maple Grove, Minnesota, Court of Federal Claims No: 25–1224V
73. Selena Rice, Charleston, West Virginia, Court of Federal Claims No: 25–1228V
74. John Alexander, Woodridge, Illinois, Court of Federal Claims No: 25–1230V
75. Charles Fontana, Woodridge, Illinois, Court of Federal Claims No: 25–1231V
76. Kim Dunn on behalf of the estate of Otto Schwab, Deceased, Indianapolis, Indiana, Court of Federal Claims No: 25–1233V
77. Christopher Jackson, Sturtevant, Wisconsin, Court of Federal Claims No: 25–1237V
78. Patricia Ramsey, Kingman, Arizona, Court of Federal Claims No: 25–1239V
79. Brenda Cosby, Richmond, Virginia, Court of Federal Claims No: 25–1242V
80. Brooklyn Laverne Zen, Towson, Maryland, Court of Federal Claims No: 25–1243V
81. Peggy Hill, Jackson, Michigan, Court of Federal Claims No: 25–1244V
82. Cherisse Weekly, Woodstock, Georgia, Court of Federal Claims No: 25–1246V
83. Tyson Hayes, Overland Park, Kansas, Court of Federal Claims No: 25–1247V
84. David Sjurson, Hartford, Wisconsin, Court of Federal Claims No: 25–1248V
85. Maria Rodriguez, San Antonio, Texas, Court of Federal Claims No: 25–1250V
86. Yamzey Gonzalez, North Port, Florida, Court of Federal Claims No: 25–1251V
87. Stacey Vore, Washington, DC, Court of Federal Claims No: 25–1254V
88. Sylvia Caravetta, Delray Beach, Florida, Court of Federal Claims No: 25–1255V
89. Essie Anderson, New York, New York, Court of Federal Claims No: 25–1257V
90. Virginia Commander, Englewood, New Jersey, Court of Federal Claims No: 25–1258V
91. Isaiah N. Triggs, Milwaukee, Wisconsin, Court of Federal Claims No: 25–1259V
92. Teresa Bellanger, Washington, DC, Court of Federal Claims No: 25–1260V
93. Kathy Veazey, Oklahoma City, Oklahoma, Court of Federal Claims No: 25–1261V

[FR Doc. 2025–17530 Filed 9–10–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. OS–0945–New–60D]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the Information Collection Request (ICR) must be received on or before November 10, 2025.

ADDRESSES: Submit your comments to Conner O'Brien at OCRPrivacy@hhs.gov.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, such as a free copy of the form to be used for the information collection, please include the document identifier OS–0945–New–60D and project title for reference, to Conner O'Brien, email: OCRPrivacy@hhs.gov, or call (202) 240–3110.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Confidentiality of Substance Use Disorder Patient Records Complaint.

Type of Collection: New Collection.

OMB No. 0945–New: Office for Civil Rights (OCR)—Health Information Privacy, Data, and Cybersecurity Division.

Abstract: OCR is requesting Office of Management and Budget (OMB) approval for a new information collection. Under OCR's delegated civil enforcement authority, a person may file a complaint with OCR for alleged noncompliance with 42 CFR part 2 ("Part 2"). OCR will collect information from individuals using the form, Confidentiality of Substance Use Disorder Patient Records Complaint, to allow OCR to collect the minimum information needed from individuals who file complaints with OCR to form the basis for the initial processing of such complaints to satisfy the right for an individual to file a complaint under 42 CFR 2.4(b).

I. Authority

OCR has delegated civil enforcement authority under 42 U.S.C. 290dd–2(f), as amended by section 3221 of the Coronavirus Relief, Aid, and Economic Security Act, that applies section 1176 of the Social Security Act ("the Act"), 45 U.S.C. 1320d–5, to a violation of Part 2 in the same manner as it applies to a violation of part C of title XI of the Act, Administrative Simplification. The Administrative Simplification provisions were added to the Act by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). OCR currently applies its HIPAA enforcement authority under section 1176 of the Act in accordance with 45 CFR part 160. To implement 42 U.S.C. 290dd–2, the Department published a final rule modifying Part 2, 89 FR 12472 (February 16, 2024) ("2024 Part 2 Final Rule"), that included, among other provisions, a new right to file complaints of noncompliance and applied 45 CFR part 160, subparts C, D, and E, as the enforcement regulation for Part 2.

II. Method of Collection

Individuals will be able to submit a Part 2 complaint using the HHS OCR online complaint portal or by filling out a copy of the form obtained from OCR's website and submitting it to OCR electronically or by postal mail.