3542. The questions and answers are divided into three topics: (1) Obtaining and Filling out Forms FDA 3542a and FDA 3542, (2) Section 6 of Forms FDA 3542a and FDA 3542 (''Declaration Certification''), and (3) Submitting Patent Information to FDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Forms FDA 3542a and FDA 3542: Questions and Answers.'' 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 final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. 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 (PRA) (44 U.S.C. 3501–3521). The collections of information relating to the submission of NDAs under 21 CFR 314 have been approved under OMB control number 0910–0001. The collections of information from Form FDA 356h have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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. 2026–11966 Filed 6–12–26; 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 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 April 1, 2026, through April 30, 2026. 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 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. Daniel Juanillo, Jr., Centennial, Colorado, Court of Federal Claims No: 26–0501V
2. Angie Loeza, Corona, California, Court of Federal Claims No: 26–0502V
3. Mitchell Powell, Clyde, North Carolina, Court of Federal Claims No: 26–0503V
4. Michael Russo, Swampscott, Massachusetts, Court of Federal Claims No: 26–0504V
5. Adriana Ramirez, Vancouver, Washington, Court of Federal Claims No: 26–0508V
6. Virginia Coleman, Los Angeles, California, Court of Federal Claims No: 26–0511V
7. Vicente Sotelo, Jr., Chicago, Illinois, Court of Federal Claims No: 26–0512V
8. Isidore Johnson, Fairfax, Virginia, Court of Federal Claims No: 26–0513V
9. Robert Pieper, Denton, Texas, Court of Federal Claims No: 26–0514V
10. Jeanne Schmidt, Annandale, Minnesota, Court of Federal Claims No: 26–0515V
11. Wayne Gabaree, Cambridge, Massachusetts, Court of Federal Claims No: 26–0516V
12. Lucellis Wellins, Randolph, New Jersey, Court of Federal Claims No: 26–0520V
13. Anita Lantz, Greeneville, Tennessee, Court of Federal Claims No: 26–0521V
14. Crystal Bullock, Phoenix, Arizona, Court of Federal Claims No: 26–0522V
15. Christine Fleming, St. Louis, Missouri, Court of Federal Claims No: 26–0524V
16. Taylor Johnson, Douglassville, Georgia, Court of Federal Claims No: 26–0525V
17. Jennifer Willett, Reno, Nevada, Court of Federal Claims No: 26–0526V
18. Nahid Sadeghnia, Washington, DC, Court of Federal Claims No: 26–0527V
19. Renee Marie Sloane Alas, Los Angeles, California, Court of Federal Claims No: 26–0529V
20. Christopher Rossi, Encinitas, California, Court of Federal Claims No: 26–0530V
21. Diane Akyelken, Levittown, New York, Court of Federal Claims No: 26–0531V
22. Christian Castaneda, Fort Worth, Texas, Court of Federal Claims No: 26–0533V
23. Parker Smith on behalf of E.S., Champaign, Illinois, Court of Federal Claims No: 26–0536V
24. Lauren Gilmore, Los Angeles, California, Court of Federal Claims No: 26–0540V
25. Karen Gutierrez, Tulare, California, Court of Federal Claims No: 26–0543V
26. Joy Wolf, Iva, South Carolina, Court of Federal Claims No: 26–0544V
27. Catherine Wainwright-Aravosis, Greensboro, North Carolina, Court of Federal Claims No: 26–0545V
28. Ronald Yandell, Lock Haven, Pennsylvania, Court of Federal Claims No: 26–0546V
29. James Walker, Tyler, Minnesota, Court of Federal Claims No: 26–0548V
30. Paolo Thompson, Katy, Texas, Court of Federal Claims No: 26–0549V
31. Rasha Mohamed, Woodridge, Illinois, Court of Federal Claims No: 26–0551V
32. Christina Foster, Houston, Texas, Court of Federal Claims No: 26–0552V
33. Jennifer Petersen, San Bernadino, California, Court of Federal Claims No: 26–0553V
34. Bridget DeBreto, Morris, Illinois, Court of Federal Claims No: 26–0554V
35. Donna Emison, Las Vegas, Nevada, Court of Federal Claims No: 26–0555V
36. Karen Barnes, Elyria, Ohio, Court of Federal Claims No: 26–0556V
37. Mattie Johnson, Elkhorn, Nebraska, Court of Federal Claims No: 26–0558V
38. Michael Rose, St. Louis, Missouri, Court of Federal Claims No: 26–0559V
39. Stacey Bagaglio, Northbridge, Massachusetts, Court of Federal Claims No: 26–0560V
40. Deborah Jindra, Hennepin, Minnesota, Court of Federal Claims No: 26–0563V
41. Keisha L. Stephens, Richardson, Texas, Court of Federal Claims No: 26–0566V
42. Diane Starling, Colorado Springs, Colorado, Court of Federal Claims No: 26–0571V
43. Miguel Pagan, Providence, Rhode Island, Court of Federal Claims No: 26–0572V
44. Leycester Zissler, Black River Falls, Wisconsin Court of Federal Claims No: 26–0573V
45. Helen Belete, Beverly Hills, California, Court of Federal Claims No: 26–0574V
46. Timothy Becker, Philadelphia, Pennsylvania, Court of Federal Claims No: 26–0575V
47. Kelly Pfeilsticker, Los Angeles, California, Court of Federal Claims No: 26–0577V
48. Dawn Howard, Wauwatosa, Wisconsin, Court of Federal Claims No: 26–0579V
49. Helen Hickey, Kansas City, Missouri, Court of Federal Claims No: 26–0580V
50. Dominique Yamada, Santa Monica, California, Court of Federal Claims No: 26–0581V
51. Dana Price, New York, New York, Court of Federal Claims No: 26–0583V
52. Alyssa Kieschnick on behalf of E.K., Houston, Texas, Court of Federal Claims No: 26–0584V
53. Enrique Triana, Richmond, Virginia, Court of Federal Claims No: 26–0585V
54. Latondra Davis, Woodridge, Illinois, Court of Federal Claims No: 26–0586V
55. Markyahnee Boyd, Chicago, Illinois, Court of Federal Claims No: 26–0588V
56. Carol Rathfelder, New York, New York, Court of Federal Claims No: 26–0592V
57. Marilyn Teague, Phoenix, Arizona, Court of Federal Claims No: 26–0593V
58. Angela Shelton, Scottsdale, Arizona, Court of Federal Claims No: 26–0596V
59. Kaley Beavers on behalf of O.B., Indianapolis, Indiana, Court of Federal Claims No: 26–0598V
60. Maria Polsinelli-Dean, Albany, New York, Court of Federal Claims No: 26–0600V
61. Christina Dorsett, Woodridge, Illinois, Court of Federal Claims No: 26–0603V
62. Katrina Sickler, Wauwatosa, Wisconsin, Court of Federal Claims No: 26–0604V
63. Jennifer Grant, Katy, Texas, Court of Federal Claims No: 26–0605V
64. Mark Newman, Philadelphia, Pennsylvania, Court of Federal Claims No: 26–0607V
65. Jeannette Urena, Dresher, Pennsylvania, Court of Federal Claims No: 26–0608V

66. Emily Dworkin, Seattle, Washington, Court of Federal Claims No: 26–0609V
67. Paula Taylor, Washington, DC, Court of Federal Claims No: 26–0610V
68. Dariane Walker, Dresher, Pennsylvania, Court of Federal Claims No: 26–0612V
69. Jenny Gentry, Moscow, Idaho, Court of Federal Claims No: 26–0615V
70. Robert Deal, Phoenix, Arizona, Court of Federal Claims No: 26–0617V
71. Tom Thomas, Beverly Hills, Florida, Court of Federal Claims No: 26–0618V
72. James Hoy, Cottonwood, Arizona, Court of Federal Claims No: 26–0620V
73. Jody Anzalone, Las Vegas, Nevada, Court of Federal Claims No: 26–0625V
74. Eric Margolin, Washington, DC, Court of Federal Claims No: 26–0626V
75. Adam Rolnick, Chicago, Illinois, Court of Federal Claims No: 26–0627V
76. Neta-Li Almagor-Friedlander, Charlotte, North Carolina, Court of Federal Claims No: 26–0628V
77. Parvin Farahani, Beverly Hills, California, Court of Federal Claims No: 26–0629V
78. Sharon Dennard, Woodridge, Illinois, Court of Federal Claims No: 26–0631V
79. Christopher Wright, Chicago, Illinois, Court of Federal Claims No: 26–0633V
80. Marylex Lopez-Sarraff, Washington, DC, Court of Federal Claims No: 26–0634V
81. Alethea Harris, Dresher, Pennsylvania, Court of Federal Claims No: 26–0635V
82. Steven Klobucarich, Milwaukee, Wisconsin, Court of Federal Claims No: 26–0636V

[FR Doc. 2026–11972 Filed 6–12–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–NEW

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, HRSA 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 15, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906–NEW.

Abstract: HRSA's Office of Pharmacy Affairs (OPA) intends to introduce a revised 340B Rebate Model Pilot Program (Pilot) as a mechanism for qualifying drug manufacturers, who wish to participate, to effectuate the 340B ceiling price on a limited set of drugs sold to covered entities using rebates. OPA plans to publish a **Federal Register** Notice to notify 340B stakeholders of criteria and standards for implementation of the Pilot. This ICR includes the collection of Pilot plans from drug manufacturers, the collection of purchase data reports from drug manufacturers for OPA's monitoring of the Pilot and for overall 340B Program surveillance and program integrity monitoring, and the collection of data submitted by covered entities to manufacturers to request rebates.

A 60-day notice was published in the **Federal Register** for this ICR on February 26, 2026, vol. 91, No. 2026–03833, pp. 9632–9633. There were 180 timely public comments. Commenters included hospitals, health systems, community health centers, pharmacies, manufacturers, vendors, and national associations. HRSA accepted comments on the following topics: (1) burden on drug manufacturers to submit 340B Rebate Pilot Plans to OPA; (2) burden on drug manufacturers to submit reports to OPA; and (3) burden on covered entities to submit data to manufacturers. HRSA also received comments including general opposition to implementing a rebate model and requests to maintain the current upfront discount structure; concerns about financial impacts such as cash flow constraints, increased drug acquisition costs, and loss of 340B savings; potential downstream effects on patient care, including reduced access to medications and elimination of services supported by 340B savings; legal and statutory arguments regarding HRSA's authority to implement a rebate model; and recommendations for alternative program designs, such as use of a centralized clearinghouse or other approaches to address duplicate discount concerns. While HRSA acknowledges these concerns, they do not directly address the necessity, practical utility, or burden of the information collection under the PRA and therefore were not considered in revising burden estimates or data collection requirements. Other out of scope comments were related to manufacturer contract pharmacy policies, third-party platforms, and broader program integrity issues. The concerns raised that are not directly related to burden as outlined in this ICR will be addressed in a separate **Federal Register** notice.

HRSA received a few comments related to the burden on manufacturers to submit Pilot plans to OPA. These commenters generally focused on administrative considerations associated with OPA's collection and review of such plans rather than on actual burden on drug manufacturers. HRSA did not receive any comments on the burden associated with drug manufacturers submitting reports to OPA. While some commenters provided input on reporting structure and data processes, these comments did not address the estimated burden hours for manufacturer reporting.

A significant number of commenters raised concerns about the burden on covered entities to submit data to manufacturers. Commenters consistently indicated that the proposed data submission requirements would impose substantial administrative, operational, and systems-related burdens. Specifically, commenters noted that compliance would require additional staffing, new or modified information technology systems, increased data tracking and reconciliation efforts, and ongoing