

**DATES:** Fax written comments on the collection of information by July 26, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0718. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance for Industry: Assessing User Fees Under the Biosimilar User Fee Amendments of 2017**

OMB Control Number 0910-0718—Revision

This information collection supports the above captioned Agency guidance and implementation of the Biosimilar User Fee Amendments of 2017 (BsUFA II). Under BsUFA II, FDA’s authority is extended to collect user fees from fiscal years 2018–2022 and includes a number of technical revisions that affect what fees and how fees are collected. Fees authorized by this legislation help fund the review process for biosimilar biological product applications and play an important role in expediting the review and approval process.

We have developed the guidance document entitled “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017” to assist industry in understanding when these fees are incurred and the process by which applicants can submit payments. The guidance also provides information on the consequences of failing to pay BsUFA II fees, as well as processes for submitting reconsideration and appeal requests. The guidance document is

available on our website at: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM584984.pdf>.

In the **Federal Register** of November 16, 2017 (82 FR 53505), we published a notice announcing availability of the subject guidance document, including a 60-day notice requesting public comment on the information collection. One comment was received in response to the notice from a trade organization indicating that interested persons “have reviewed the draft guidance and appreciate(s) FDA applying the user fee provisions consistent with the BsUFA II negotiations and Commitment Letter.” In addition, and upon our own review, we believe it is appropriate to include the guidance document under the existing information collection “Biosimilar User Fee Cover Sheet” currently approved under OMB control number 0910-0718 rather than to establish a new collection. FDA is preparing to renew OMB control number 0910-0718 and will include the guidance document accordingly.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Request for discontinuation from biological product development program .....	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list .....	5	1	5	* 0.5	2.5
Small business waiver of the BsUFA application fee .....	1	1	1	16	16
Small business waiver reconsiderations .....	1	1	1	24	24
Small business waiver appeals .....	1	1	1	12	12
Annual Fee Determination Survey .....	35	1	35	1	35
Annual BsUFA Fees Correspondence .....	35	1	35	2	70
<b>Total .....</b>					<b>161.5</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

\* 30 minutes.

Our estimate is based on the number of Biosimilars User Fee submissions we have received since establishing the program.

Dated: June 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-13688 Filed 6-25-18; 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, 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 United States 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 May 1, 2018, through May 31, 2018. 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 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.

Dated: June 19, 2018.

**George Sigounas,**  
*Administrator.*

#### List of Petitions Filed

- Emily Jahn, Millbury, Massachusetts, Court of Federal Claims No: 18-0613V
- Kathy Macaluso, Naples, Florida, Court of Federal Claims No: 18-0614V
- Jason Fey and Heather Fey on behalf of E.P.F., Hudson, Wisconsin, Court of Federal Claims No: 18-0615V
- Jeanne Rudzki, Jefferson, Louisiana, Court of Federal Claims No: 18-0617V
- Michael Schwarz, Walla Walla, Washington, Court of Federal Claims No: 18-0619V
- Ernest Perkins, Salt Lake City, Utah, Court of Federal Claims No: 18-0620V
- Sally Musulin, Cranberry, Pennsylvania, Court of Federal Claims No: 18-0621V
- Katherine L. Alberino, Medford, Massachusetts, Court of Federal Claims No: 18-0622V
- Timothy W. Massa, La Grange, Georgia, Court of Federal Claims No: 18-0623V
- Joseph Davis, Auburn, California, Court of Federal Claims No: 18-0624V
- Tesalia Lyons on behalf of G.L., Douglasville, Georgia, Court of Federal Claims No: 18-0625V
- Matthew T. Manley, Greensboro, North Carolina, Court of Federal Claims No: 18-0626V
- Sherri Paige, Willimantic, Connecticut, Court of Federal Claims No: 18-0627V
- Marie Aagotnes, New York, New York, Court of Federal Claims No: 18-0631V
- Arthur Renfro, Cheyenne, Wyoming, Court of Federal Claims No: 18-0632V
- Thomas D. Taylor, Purcellville, Virginia, Court of Federal Claims No: 18-0633V
- Alia J. Stone, Columbus, Ohio, Court of Federal Claims No: 18-0634V
- Carrine Paulen, Big Rapids, Michigan, Court of Federal Claims No: 18-0635V
- Lovely Varughese, Des Plaines, Illinois, Court of Federal Claims No: 18-0637V
- Melissa K. Woinarowicz, Karlstad, Minnesota, Court of Federal Claims No: 18-0639V
- Adam Crispo, Jersey City, New Jersey, Court of Federal Claims No: 18-0640V
- Cynthia Peterson, Bronx, New York, Court of Federal Claims No: 18-0641V
- Debra Juno, Yardley, Pennsylvania, Court of Federal Claims No: 18-0643V
- Fawne Adams, Frederick, Maryland, Court of Federal Claims No: 18-0644V
- Juliet Ley, Canonsburg, Pennsylvania, Court of Federal Claims No: 18-0645V
- Keria Edwards, Toledo, Ohio, Court of Federal Claims No: 18-0646V
- Frankie Reese, Hickory, North Carolina, Court of Federal Claims No: 18-0647V
- Dana Ochsner, Olympia, Washington, Court of Federal Claims No: 18-0648V

29. Kimberly J. Little, Rochester, New York, Court of Federal Claims No: 18-0649V
30. Mary Stewart, Hattiesburg, Mississippi, Court of Federal Claims No: 18-0650V
31. Ida E. SONDY, Mountain Home, Arkansas, Court of Federal Claims No: 18-0651V
32. Jill Corsiglia, Aptos, California, Court of Federal Claims No: 18-0652V
33. Helen Kearns, Clinton, North Carolina, Court of Federal Claims No: 18-0654V
34. Beverly Schick-Cowell, Sylvania, Ohio, Court of Federal Claims No: 18-0656V
35. Sue Ann Chamberlain, Pleasant Grove, Utah, Court of Federal Claims No: 18-0658V
36. Judy Welch, Lapeer, Michigan, Court of Federal Claims No: 18-0660V
37. Brent Pyles, Georgetown, Kentucky, Court of Federal Claims No: 18-0662V
38. Kristina Link, Grand Rapids, Michigan, Court of Federal Claims No: 18-0663V
39. Brooke Konsky, Newark, Delaware, Court of Federal Claims No: 18-0666V
40. Heather Sheehan, Madison, Wisconsin, Court of Federal Claims No: 18-0668V
41. Linda Serra, Springfield, Illinois, Court of Federal Claims No: 18-0672V
42. Paula Rosselet, Spokane, Washington, Court of Federal Claims No: 18-0674V
43. Bradley Haag, Pickering, Ohio, Court of Federal Claims No: 18-0675V
44. Marian Williams, Jacksonville, Florida, Court of Federal Claims No: 18-0676V
45. Douglas Billing, Wichita Falls, Texas, Court of Federal Claims No: 18-0679V
46. Cecelia Keller, Upland, Pennsylvania, Court of Federal Claims No: 18-0680V
47. David Christian Kunz, Nibley, Utah, Court of Federal Claims No: 18-0681V
48. Merrick Brunner, Ventura, California, Court of Federal Claims No: 18-0683V
49. Bonnie Mahayni, Midlothian, Virginia, Court of Federal Claims No: 18-0684V
50. Elizabeth Tregillus, Washington, District of Columbia, Court of Federal Claims No: 18-0688V
51. Jeffrey Strain, Sacramento, California, Court of Federal Claims No: 18-0689V
52. Maria Turkson, Harrisburg, Pennsylvania, Court of Federal Claims No: 18-0690V
53. Laura Guerrie, Tujunga, California, Court of Federal Claims No: 18-0692V
54. Flint Allen, Hill City, Kansas, Court of Federal Claims No: 18-0693V
55. Chad Sheller on behalf of Daniel E. Sheller, Deceased, Santa Maria, California, Court of Federal Claims No: 18-0696V
56. Lari Talbert, Shreveport, Louisiana, Court of Federal Claims No: 18-0699V
57. Robert G. Baker, Rock Hill, North Carolina, Court of Federal Claims No: 18-0701V
58. Randy Leblanc, Salt Lake City, Utah, Court of Federal Claims No: 18-0702V
59. Jill Longworth, St. Louis, Missouri, Court of Federal Claims No: 18-0703V
60. Kevin Radford, Alpharetta, Georgia, Court of Federal Claims No: 18-0704V
61. Judith Bohnenkamp, O'Fallon, Missouri, Court of Federal Claims No: 18-0709V
62. Gerard L. Muensterman on behalf of Cletus J. Muensterman, Deceased, Evansville, Indiana, Court of Federal Claims No: 18-0714V
63. Claudette Guerrero, Edinburg, Texas, Court of Federal Claims No: 18-0716V
64. Sheila Chille, Niagara Falls, New York, Court of Federal Claims No: 18-0718V
65. Alice Lawler, Oak Harbor, Washington, Court of Federal Claims No: 18-0719V
66. Patricia Wright, La Marque, Texas, Court of Federal Claims No: 18-0720V
67. Gerald Jansen, Newport, Pennsylvania, Court of Federal Claims No: 18-0722V
68. Bethanne Hull, Titusville, Florida, Court of Federal Claims No: 18-0723V
69. Sheena Schmacht on behalf of H.S., Silvis, Illinois, Court of Federal Claims No: 18-0724V
70. David M. Roberts, Sioux City, Iowa, Court of Federal Claims No: 18-0725V
71. Judith A. Bridges, St. Charles, Missouri, Court of Federal Claims No: 18-0726V
72. Barbara Murray, Orlando, Florida, Court of Federal Claims No: 18-0728V
73. Vicki Havel, Rockwall, Texas, Court of Federal Claims No: 18-0729V
74. Silvia Hernandez, Washington, District of Columbia, Court of Federal Claims No: 18-0731V
75. Charles Williams, Oroville, California, Court of Federal Claims No: 18-0732V
76. James Seylaz, Bridgewater, New Jersey, Court of Federal Claims No: 18-0733V
77. Laurel Ostiguy, Marlborough, Massachusetts, Court of Federal Claims No: 18-0736V
78. Kathleen Spain, Las Vegas, Nevada, Court of Federal Claims No: 18-0737V
79. Staci McTeigue, Alpharetta, Georgia, Court of Federal Claims No: 18-0740V
80. Jackie Johns, Marshfield, Missouri, Court of Federal Claims No: 18-0741V
81. Erica Schofield, Missoula, Montana, Court of Federal Claims No: 18-0742V
82. Rocco E. Moat, Milwaukee, Wisconsin, Court of Federal Claims No: 18-0743V
83. Raymond Spornhauer, Lufkin, Texas, Court of Federal Claims No: 18-0744V
84. Janice Hodgett, Kewanee, Illinois, Court of Federal Claims No: 18-0745V
85. Carol D'Angelo, Philadelphia, Pennsylvania, Court of Federal Claims No: 18-0747V
86. Cami Perry, Aurora, Colorado, Court of Federal Claims No: 18-0748V
87. Carol Vorwerck, Towson, Maryland, Court of Federal Claims No: 18-0749V
88. Georgia Derr on behalf of M.D., Harrisburg, North Carolina, Court of Federal Claims No: 18-0751V
89. Sheri Henning, Owasso, Oklahoma, Court of Federal Claims No: 18-0752V
90. Patricia Gauthier, Tonasket, Washington, Court of Federal Claims No: 18-0753V
91. Roderick Sanders, Conyers, Georgia, Court of Federal Claims No: 18-0754V
92. Derek Grace, Dayton, Ohio, Court of Federal Claims No: 18-0757V
93. Sarah Flores and Ryan C. Flores on behalf of M.F., Houston, Texas, Court of Federal Claims No: 18-0759V
94. David Daniel, Houston, Texas, Court of Federal Claims No: 18-0760V
95. Raymond Bielak, St. George, Utah, Court of Federal Claims No: 18-0761V
96. Tori Dreyer, Topeka, Kansas, Court of Federal Claims No: 18-0764V
97. Mark D. Scarlette, Greensboro, North Carolina, Court of Federal Claims No: 18-0766V
98. James Louis, Lisbon, Connecticut, Court of Federal Claims No: 18-0767V
99. Dayane Penderis, Pasadena, California, Court of Federal Claims No: 18-0768V

100. Kathleen Cooper-Loher, Marshfield, Wisconsin, Court of Federal Claims No: 18–0769V
101. Kerstina Alexander on behalf of M.A., Deceased, Woodbridge, Illinois, Court of Federal Claims No: 18–0770V
102. Henry Milligan, Jr., Orlando, Florida, Court of Federal Claims No: 18–0771V
103. Cheryl Thompson, South Bend, Indiana, Court of Federal Claims No: 18–0772V
104. Olivia Gallegos, Fresno, California, Court of Federal Claims No: 18–0773V
105. Jacie Albanez and Mario Albanez on behalf of N.A., San Diego, California, Court of Federal Claims No: 18–0774V
106. Scott Kelbick, Avondale, Arizona, Court of Federal Claims No: 18–0775V
107. Elizabeth Phenneger, Spokane, Washington, Court of Federal Claims No: 18–0776V

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BILLING CODE 4165–15–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Proposed Standards for the Children's Hospitals Graduate Medical Education Payment Program's Quality Bonus System

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

**ACTION:** Final response.

**SUMMARY:** HRSA published a notice in the *Federal Register* on October 11, 2017, soliciting feedback on the establishment of the Children's Hospitals Graduate Medical Education Payment (CHGME) Program's Quality Bonus System (QBS). In particular, HRSA requested feedback on the Fiscal Year (FY) 2019 and beyond multi-step implementation of the system, including demonstration of engagement in state or regional-level initiatives, documentation, and payment structure. This notice summarizes and responds to the comments received during the 60-day comment period.

**ADDRESSES:** Additional information about the CHGME is available at <https://bhwh.hrsa.gov/grants/medicine/chgme>.

**FOR FURTHER INFORMATION CONTACT:** Malena Crawford, Project Officer, Children's Hospitals Graduate Medical Education Payment Program, Division of

Medicine and Dentistry, HRSA at [MCrawford@hrsa.gov](mailto:MCrawford@hrsa.gov) or (301) 443–7334.

**SUPPLEMENTARY INFORMATION:** The CHGME statute was amended in 2013. The amendments permit up to 25 percent of the total amount appropriated annually in excess of \$245 million, but not to exceed \$7,000,000, to provide payments to newly qualified hospitals, as defined in section 340E(h) of the Public Health Service Act. The statute additionally states that the Secretary may establish a quality bonus system for CHGME hospitals using any remaining funds after payments are made to newly qualified hospitals. In FY 2018, Congress appropriated \$315 million to the CHGME Program. Of this, approximately \$4 million in payments were made to newly qualified hospitals. If funding levels and mechanisms remain constant in FY 2019, it is estimated that approximately \$3 million may be available annually for the CHGME QBS.

On October 16, 2017, through a *Federal Register* Notice (FRN), HRSA announced a 60-day public comment period to solicit input on the CHGME QBS proposed standards. HRSA proposed a multi-step implementation beginning in FY 2019 that initially will recognize high-level engagement of CHGME hospitals in state and regional health care transformation, as well as engagement of resident trainees in these activities. HRSA sought public comment on the timeline, eligibility, standards, documentation, and payment structure as described in the FRN. HRSA also requested comment on proposed QBS measures, potential data sources, and tiering of QBS payments for FY 2020 and beyond. HRSA received feedback on the following program components in response to the FRN:

- QBS Goals
- Qualifying Initiatives for the FY 2019 QBS
- Measures and Metrics
- Payment Structure
- Documentation, Reporting Requirements and Reducing Reporting Burden
- Implementation Timeline for FY 2020 and Beyond

HRSA carefully reviewed the comments received and used them to guide the development of the FY 2019 CHGME QBS and to inform future iterations of the CHGME QBS. Final guidance for the FY 2019 CHGME QBS will be published in the FY 2019 CHGME Notice of Funding Opportunity (NOFO).

#### Comments on the Proposed Standards of the Quality Bonus System

HRSA received 17 responses to the request for comments. Thirteen commenters are current CHGME hospitals and four are state/national associations. Comments are summarized below.

##### QBS Goals

##### Summary of Comments

Nearly all commenters supported establishing the CHGME QBS to recognize and reward quality training programs for residents supported by the CHGME program and agreed with the approach to recognize engagement in initiatives geared towards transforming pediatric health care to improve access, quality, and cost effectiveness. However, many commenters questioned whether there was enough information about these initiatives to establish a baseline, draw comparisons between children's hospitals, and make judgements about relative performance. Several suggested the proposed approach could be enhanced by starting with documentation of transformation activities in which residents are involved. Specifically, one commenter recommended "that HRSA work to identify current residents' engagement in quality initiatives and how residents can further engage on broader based initiatives before transitioning the Quality Bonus Program to other criteria in FY 2020 and beyond." A few commenters also requested that HRSA offer more clear and specific goals for the multi-step implementation of the QBS.

##### Response

After considering feedback from stakeholders, the revised goal of the QBS will be to recognize hospitals for quality improvement & GME transformation efforts in high priority focus areas and build standards to increase engagement and involvement of residents in broader initiatives. HRSA will implement a baseline phase for CHGME QBS in FY 2019. Information collected during this baseline phase will be used to establish QBS standards for implementation in FY 2021. In order to qualify for the QBS payment, CHGME awardees must submit documentation in the FY 2019 reconciliation application describing the hospital's initiatives, resident curriculum, and direct resident involvement in the following areas: Integrated care models, telehealth/HIT, population health, social determinants of health, and additional initiatives to improve access