

requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 26, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

David C. Shonka,

Acting General Counsel.

[FR Doc. 2017-27868 Filed 12-26-17; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From the Regenstrief Center for Healthcare Engineering at Purdue University Patient Safety Organization (RCHE Purdue PSO)

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily

relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from the Regenstrief Center for Healthcare Engineering at Purdue University Patient Safety Organization (RCHE Purdue PSO) of its status as a PSO, and has delisted the PSO accordingly.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on December 15, 2017.

ADDRESSES: Both directories can be accessed electronically at the following HHS website: <http://www.pso.ahrq.gov/> listed.

FOR FURTHER INFORMATION CONTACT:

Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732-70814, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when

a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from RCHE Purdue PSO, a component entity of Purdue University, PSO number P0168, to voluntarily relinquish its status as a PSO. Accordingly, RCHE Purdue PSO was delisted effective at 12:00 Midnight ET (2400) on December 15, 2017.

More information on PSOs can be obtained through AHRQ's PSO website at <http://www.pso.ahrq.gov>.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2017-27803 Filed 12-26-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6784]

Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; Draft Guidance for Industry." The draft guidance document provides blood establishments that collect or process blood and blood components with recommendations for implementing pathogen reduction technology in the manufacture of pathogen-reduced blood components. The guidance also provides answers to frequently asked questions concerning the implementation of the INTERCEPT® Blood System for Platelets and Plasma. The recommendations apply to licensed blood establishments that intend to manufacture pathogen-reduced blood components using an FDA approved pathogen reduction device.

DATES: Submit either electronic or written comments on the draft guidance by March 27, 2018 to ensure that the Agency considers your comment on this

draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-6784 for "Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answer; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; Draft Guidance for Industry." The draft guidance provides blood establishments that collect or process blood and blood components with recommendations for implementing pathogen reduction technology in the manufacture of pathogen-reduced blood components. The draft guidance also provides recommendations to licensed manufacturers on reporting the manufacturing changes associated with implementation of pathogen reduction technology under 21 CFR 601.12. Currently, the INTERCEPT® Blood System for Platelets and Plasma has been approved for the manufacture of certain pathogen-reduced platelet and plasma products. The draft guidance provides answers to frequently asked questions from blood establishments concerning the implementation of the INTERCEPT® Blood System for Platelets and Plasma. If the product platform for this device changes or FDA approves another device with a similar intended use in the future, the Agency will consider providing additional recommendations to blood establishments.

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 implementation of pathogen reduction technology in the manufacture of blood components in blood establishments. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR part 606 have been approved under OMB control number 0910-0116; and the collections of information in 21 CFR

630.10 have been approved under OMB control number 0910-0795.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: December 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-28043 Filed 12-26-17; 8:45 am]

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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, Acting Clerk, 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 November 1, 2017, through November 30, 2017. 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: December 18, 2017.

George Sigounas,
Administrator.

List of Petitions Filed

1. Alina Derkach on behalf of E.E.D., Richmond, Virginia, Court of Federal Claims No: 17-1648V
2. Patsy Gipson on behalf of Alfred J. Gipson, Deceased, Garland, Texas, Court of Federal Claims No: 17-1651V
3. Katie Reaves, Florence, California, Court of Federal Claims No: 17-1655V
4. Maria Vasquez, Washington, District of Columbia, Court of Federal Claims No: 17-1658V
5. Berill Blair, Fairbanks, Alaska, Court of Federal Claims No: 17-1659V
6. Kari Lafferty, Roseville, California, Court of Federal Claims No: 17-1660V
7. Wendi Walter and Phillip Walter on behalf of M.W., Decatur, Georgia, Court of Federal Claims No: 17-1663V
8. Robert Neal, Eagan, Minnesota, Court of Federal Claims No: 17-1690V
9. Angela Kay Stacy, Hazard, Kentucky, Court of Federal Claims No: 17-1691V
10. Elizabeth Argiri and Samuel Argiri on behalf of L.A., Roseville, Michigan, Court of Federal Claims No: 17-1715V
11. Mary Jo Accetta, Seattle, Washington, Court of Federal Claims No: 17-1731V