

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.*

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**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](mailto: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.*

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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