

PSO. Accordingly, The Connecticut Hospital Association Federal Patient Safety Organization was delisted effective at 12:00 Midnight ET (2400) on December 1, 2012.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Dated: January 17, 2013.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From Ryder Trauma Center

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of delisting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), Public Law 109-41, 42 U.S.C. 299b-21—b-26, provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule), 42 CFR Part 3, 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 no longer to meet the requirements of the Patient Safety Act and Patient Safety Rule, or when a PSO chooses to voluntarily relinquish its status as a PSO for any reason. AHRQ has accepted a notification of voluntary relinquishment from Ryder Trauma Center 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 November 20, 2012.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.AHRQ.gov/index.html>.

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; 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 Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is 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 (PDF file, 450 KB. PDF Help) 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 no longer to meet the requirements of the Patient Safety Act and Patient Safety Rule, or when a PSO chooses to voluntarily relinquish its status as a PSO for any reason. 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 Ryder Trauma Center, PSO number P0019, which is a component entity of

Jackson Memorial Hospital, to voluntarily relinquish its status as a PSO. Accordingly, Ryder Trauma Center was delisted effective at 12:00 Midnight ET (2400) on November 20, 2012.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Dated: January 17, 2013.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Annual Financial Report (ACF-696T) for Tribes.

OMB No.: 0970-0195.

Description: Tribes use the Financial Report Form ACF-696T to report Child Care and Development Fund (CCDF) expenditures. Authority to collect and report this information is found in Section 658G of the Child Care and Development Block Grant Act of 1990, as revised. In addition to the Program Reporting Requirements set forth in 45 CFR part 98, subpart H, the regulations at 45 CFR 98.65(g) and 98.67(c)(1) authorize the Secretary to require financial reports as necessary.

Tribal grantees submit the ACF-696T report on an annual basis on behalf of the Tribal Lead Agency administering the Child Care and Development Fund (CCDF).

The previous information collection requirements related to the American Recovery and Reinvestment Act (ARRA) of 2009 (Pub. L. 111-5) have been deleted from this reporting form.

Respondents: Tribes and Tribal Organizations that are CCDF grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Estimated average burden hours per response	Estimated total burden hours
ACF-696T CCDF Financial Reporting Form for Tribes	260	1	6	1560

Estimated Total Annual Burden Hours: 1560.

Additional Information: Copies of the proposed collection may be obtained by

writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370

L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be

identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, *Email: OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 4, 2013.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0510. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@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.

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002—(OMB Control Number 0910-0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107-250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph (g) to section 704 of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program. FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria."

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

In the **Federal Register** of May 09, 2012 (77 FR 27234), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

Section of the FD&C Act	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
704(g)	Request for accreditation ...	1	1	1	80	80
Total	80

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