

Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. 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. The listing from the Society of Hospital Medicine PSO has expired and AHRQ 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 February 15, 2014.

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 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 the 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.

The Society of Hospital Medicine PSO, PSO number P0105, a component entity of the Society of Hospital Medicine, chose to let its listing expire by not seeking continued listing. Accordingly, Society of Hospital Medicine PSO was delisted effective at 12:00 Midnight ET (2400) on February 15, 2014.

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

Dated: March 21, 2014.

Richard Kronick,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Comment Request; National Survey of Older Americans Act Participants

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by April 30, 2014.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.5806 or by email to OIRA_submission@omb.eop.gov, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Elena Fazio at 202-357-3583 or email: elena.fazio@acl.hhs.gov.

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

The National Survey of Older Americans Act (OAA) Participants information collection, which builds on earlier national pilot studies and surveys, as well as performance measurement tools developed by ACL grantees in the Performance Outcomes Measures Project (POMP), will include consumer assessment surveys for the

Congregate and Home-delivered meal nutrition programs; Case Management, Homemaker, and Transportation Services; and the National Family Caregiver Support Program. This information will be used by ACL to track performance outcome measures; support budget requests; comply with GPRAMA Modernization Act of 2010 (GPRAMA) reporting requirements; provide national benchmark information; and inform program development and management initiatives. Descriptions of previous National Surveys of OAA Participants can be found under the section on OAA Performance Outcomes on ACL's Web site at: http://www.aoa.gov/AoARoot/Program_Results/OAA_Performance.aspx. Copies of the survey instruments and data from previous National Surveys of OAA Participants can be found and queried using the AGing Integrated Database (AGID) at <http://www.agid.acl.gov/>. The proposed Ninth National Survey entitled Ninth National Survey of OAA Participants, draft, March 6, 2014 may be found on the ACL Web site at http://www.aoa.gov/AoARoot/Program_Results/OAA_Performance.aspx.

AoA estimates the burden of this collection of information as follows: Respondents: Individuals; Number of Respondents: 6,250; Number of Responses per Respondent: one; Average Burden per Response: 6000 at 40 minutes, 250 at 4 hours: Total Burden: 5,000 hours.

Dated: March 26, 2014.

Kathy Greenlee,
Administrator and Assistant Secretary for Aging.

[FR Doc. 2014-07148 Filed 3-28-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2002-D-0094]

Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for the public, FDA advisory committee members, and

FDA staff, entitled "Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers." We are issuing the guidance to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA procedures regarding public availability of information regarding certain financial interests and waivers granted by FDA to permit individuals to participate in an advisory committee meeting. This guidance replaces the guidance of the same title dated March 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to Advisory Committee Oversight and Management Staff, Office of Special Medical Programs, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993, 301-796-8220, email: Michael.Ortwerth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for the public, FDA advisory committee members, and FDA staff, entitled "Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers."

FDA's advisory committees provide independent expert advice and recommendations to the Agency on scientific, technical, and policy matters related to FDA-regulated products. In March 2012, FDA published a guidance

for the public, FDA advisory committee members, and FDA staff concerning the implementation of Agency-wide procedures regarding disclosure of financial interest information that apply to all special Government employees and regular Government employees invited to participate in FDA advisory committee meetings subject to the Federal Advisory Committee Act.

Effective October 1, 2012, the Food and Drug Administration Safety and Innovation Act amended the statutory provision related to this guidance. The amendments were relatively minor. FDA is revising the March 2012 guidance to reflect these amendments and to make other non-substantive editorial changes.

This level 2 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's thinking on the public availability of waivers relating to the disclosure of conflicts of interest for advisory committee members participating in FDA advisory committee meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/ucm122045.htm> or <http://www.regulations.gov>.

Dated: March 25, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

The Food and Drug Administration and Global Engagement: Progress on the Pathway to Global Product Safety

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Denver District Office, in cosponsorship with the Association of Food and Drug Officials (AFDO), will be hosting the 118th AFDO Annual Educational Conference. During the conference, a 2-day public workshop will be held entitled "FDA and Global Engagement: Progress on the Pathway to Global Product Safety." This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

DATES: *Dates and Times:* The conference will be held from June 21 through June 25. The public workshop, "FDA and Global Engagement: Progress on the Pathway to Global Product Safety," will be held on June 23 and 24, 2014, from 10:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Grand Hyatt Denver, 1750 Welton St., Denver, CO 80202, 1-303-295-1234 or toll free 800-233-1234; <http://granddenver.hyatt.com>. Attendees are responsible for their own accommodations. To make reservations at the Grand Hyatt Denver at the reduced conference rate, please go to <https://resweb.passkey.com/go/afdo2014> or call 1-303-295-1234 and mention "AFDO Conference" before May 21, 2014.

AFDO Contact Information: Randy Young, Association of Food and Drug Officials, 2550 Kingston Rd., Suite 311, York, PA 17402, 1-717-757-2888, FAX: 717-650-3650, ryoung@afdo.org.

Registration: You are encouraged to register by May 23, 2014. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Public workshop space will be filled in order of receipt of registration. Those accepted into the public workshop will receive confirmation. Registration will close after the public workshop is filled. Registration at the site is not guaranteed but may be possible on a space-available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration follows: