

++ Assess AOA/HFAP's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ Establish AOA/HFAP's ability to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of staff and other resources.

++ Confirm AOA/HFAP's ability to provide adequate funding for performing required surveys.

++ Confirm AOA/HFAP's policies with respect to whether surveys are announced or unannounced.

++ Obtain AOA/HFAP's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the June 25, 2013 proposed notice also solicited public comments regarding whether AOA/HFAP's requirements met or exceeded the Medicare conditions of participation for CAHs. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AOA/HFAP's Standards and Requirements for Accreditation and Medicare's Conditions and Survey requirements

We compared AOA/HFAP's CAH requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of AOA/HFAP's CAH application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 485.623(b)(5), AOA/HFAP revised its standards to require all ventilation systems, both new and existing, supplying operating rooms to meet the humidity control requirements..

- To meet the requirements at § 485.623(c)(1), AOA/HFAP revised its standards to incorporate specific staff training requirements for protection in place or methods for the evacuation of patients, when necessary.

- To meet the requirements at § 485.635(e), AOA/HFAP revised its standards to include staff qualification requirements for rehabilitation therapy services.

- To meet the requirements at § 488.4(a)(6), AOA/HFAP revised its "Complaint/Incident Management Policy," to ensure all onsite complaint

surveys are documented on a survey report.

- To meet the requirements of section 2728 of the SOM, AOA/HFAP will continue to use its internal monitoring plan to ensure timeframes for sending or receiving a plan of correction (PoC) are met.

- To meet the requirements of section 2728B of the SOM, AOA/HFAP will continue to conduct monthly internal audits to ensure accepted PoC's contain all of the required elements.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that AOA/HFAP's CAH accreditation program requirements meet or exceed our requirements. Therefore, we approve AOA/HFAP as a national AO for CAHs that request participation in the Medicare program, effective December 27, 2013 through December 27, 2019.

V. Collection of Information Requirements

This document does not impose information collection, recordkeeping or third party disclosure requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 12, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1439]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information regarding the Adverse Event Program for medical devices.

DATES: Submit either electronic or written comments on the collection of information by January 28, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adverse Event Program for Medical Devices (Medical Product Safety Network)—(OMB Control Number 0910-0471)—Extension

Among other things, section 519 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) authorizes FDA to require: (1) manufacturers to report medical device-related deaths, serious injuries, and malfunctions and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of

deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a “. . . subset of user facilities that constitutes a representative profile of user reports” for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called the Medical Product Safety Network (MedSun).

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on Form FDA 3500A (approved under OMB control number 0910-0291) related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities,

and for additional questions which will permit FDA to better understand the cause of reported adverse events. Participation in the program is voluntary and currently includes 250 facilities.

In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same Web site as the report information.

The burden estimate is based on the number of facilities currently participating in MedSun (250). FDA estimates an average of 15 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
MedSun facilities participating in the electronic reporting of adverse events program (Form FDA 3670)	250	15	3,750	0.75	2,813

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

Dated: November 22, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1422]

Agency Information Collection Activities; Proposed Collection; Comment Request; Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, “Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing.” This study is designed to use eye tracking technology to explore how consumers view direct-to-consumer (DTC) prescription drug advertisements (ads) that include text regarding risk information and reporting side effects and that vary in the amount of distracting audio and visual content during the presentation of the risk information.

DATES: Submit either electronic or written comments on the collection of information by January 28, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written

comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal