

ability to investigate and respond appropriately to complaints against accredited facilities.

++ Evaluate AOA/HFAP's procedures for monitoring hospitals out of compliance with AOA/HFAP's program requirements. The monitoring procedures are used only when AOA/HFAP identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

++ 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 CMS 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 CMS 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 March 22, 2013 proposed notice also solicited public comments regarding whether AOA/HFAP's requirements met or exceeded the Medicare conditions of participation for hospitals. 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 hospital requirements and survey process with the Medicare conditions of participation and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of AOA/HFAP's hospital application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 482.41(a)(1), AOA/HFAP revised its standards to include the requirement for Type 1 Essential Electrical Systems (EES) generators in all hospitals.
- To meet the requirements at § 482.41(b)(1)(ii), AOA/HFAP revised its standards to ensure roller latches no longer exist on hospital corridor doors.

- To meet the requirements at § 482.41(c)(4), AOA/HFAP revised its standards to include the National Fire Protection Association (NFPA) 99:1999: 5-4.1.1 requirement that addresses the capability of controlling the relative humidity at a level of 35 percent or greater within anesthetizing locations.

- 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 hospital accreditation program requirements meet or exceed our requirements. Therefore, we approve AOA/HFAP as a national accreditation organization for hospitals that request participation in the Medicare program, effective September 25, 2013 through September 25, 2019.

#### V. Collection of Information Requirements

This document does not impose information collection and recordkeeping 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. 35).

(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: July 19, 2013.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services, HHS.*

[FR Doc. 2013-21008 Filed 8-23-13; 4:15 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Health Resources and Services Administration

#### Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation; Notice of Meeting

**ACTION:** Notice of Meeting: Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation (MIECHVE).

**Authority:** Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

**Name:** Advisory Committee on the Maternal, Infant, and Early Childhood Home Visiting Program Evaluation.

**Date and Time:** September 12, 2013, 2-6 PM ET.

**Place:** Webinar.

The Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation (Committee) will meet for its fourth session on September 12, 2013, 2-6 PM ET. The purpose of the meeting is to allow the Committee to comment on the progress of the analysis plan of the MIHOPE project. The general public can join the meeting via webinar by logging onto <https://www4.gotomeeting.com/register/330659039>, and then follow the instructions for registering. Participants should launch the webinar no later than 1:40 a.m. EST in order for the logistics to be established for participation in the call. If there are technical problems gaining access to the call or webinar, please call 888-569-3848 or press \*0 during the call, and for GoToWebinar technical support call (800 263 6317)

**Meeting Registration:** General public participants are asked to register for the conference by going to the registration Web site at <https://www4.gotomeeting.com/register/330659039>.

**Special Accommodations:** Attendees with special needs requiring accommodations such as large print materials or other accommodations may make requests when registering at the online Web site by answering the "Special accommodations" question on the registration page: <https://www4.gotomeeting.com/register/330659039>.

**Agenda:** The meeting will include updates on the progress of the evaluation, the outline for the report,

and the plan for analyzing the states' needs assessment and baseline family, staff and program data that will be the focus of the report. Agenda items are subject to change as priorities dictate.

**Public Comments:** Members of the public may submit written comments that will be distributed to Committee members prior to the meeting. Written comments must be received by Monday, September 9, 2013 for consideration. Comments can be submitted to T'Pring Westbrook at [Tpring.Westbrook@acf.hhs.gov](mailto:Tpring.Westbrook@acf.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Any person interested in obtaining other information relevant to joining the webinar can contact Carolyn Swaney at [Carolyn.Swaney@icfi.com](mailto:Carolyn.Swaney@icfi.com).

**SUPPLEMENTARY INFORMATION:** The Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation is authorized by subsection 511(g)(1) of Title V of the Social Security Act (42 U.S.C. 701 et seq.) as amended by section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) (Affordable Care Act). The purpose of the Committee is to advise the Secretary of Health and Human Services on the design, plan, progress, and findings of the evaluation required for the home visiting program under the Affordable Care Act. More specifically, the Committee is to review, and make recommendations on, the design and plan for this evaluation; maintain and advise the Secretary regarding the progress of the evaluation; and comment, if the Committee so desires, on the report submitted to Congress under subsection 511(g)(3) of Title V.

The Department of Health and Human Services has contracted with MDRC, formerly known as Manpower Demonstration Research Corporation, a nonprofit, nonpartisan education and social policy research organization, to conduct the evaluation of the MIECHV program.

As specified in the legislation, the evaluation will provide a state-by-state analysis of the needs assessments and the States' actions in response to the assessments. Additionally, as specified in the legislation, the evaluation will provide an assessment of: (a) The effect of early childhood home visiting programs on outcomes for parents, children, and communities with respect to domains specified in the Affordable Care Act (such as maternal and child health status, school readiness, and domestic violence, among others); (b) the effectiveness of such programs on different populations, including the extent to which the ability to improve

participant outcomes varies across programs and populations; and (c) the potential for the activities conducted under such programs, if scaled broadly, to enhance health care practices, eliminate health disparities, improve health care system quality, and reduce costs.

**Naomi Goldstein,**

*Director, Office of Planning, Research, and Evaluation, ACF.*

**Rebecca Slifkin,**

*Director, Office of Planning, Analysis and Evaluation, HRSA.*

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**BILLING CODE 4184-22-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-0918]

#### **The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions and Answers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions & Answers." This draft guidance answers commonly asked questions about the applicability of good laboratory practice (GLP) to nonclinical laboratory studies conducted in support of research and marketing applications for medical devices. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 26, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions & Answers" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration (CDRH), 10903

New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002; or Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft 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. Identify comments with the docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Victoria Hampshire, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1218, Silver Spring, MD 20993-0002, 301-796-6375; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA issued the GLP regulations in response to public concerns that several important studies supporting the safety of FDA-regulated products were seriously flawed due to poor research practices and laboratory misconduct. The GLP regulations apply to nonclinical laboratory studies supporting the safety of FDA-regulated products (21 CFR 58.1). The draft guidance provides clarification on GLP terminology, the types of medical device research or marketing applications that are subject to the GLP regulation, and, if applicable, the types of information related to GLP that should be provided to FDA.

##### **II. Significance of Guidance**

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 Agency's current thinking on good laboratory practices. 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 statute and regulations.