

by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is a reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee on Procedures Review was established to aid the ABRWH in carrying out its duty to advise the Secretary, HHS, on dose reconstructions. The Subcommittee on Procedures Review is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor.

Matters To Be Discussed: The agenda for the Subcommittee meeting includes discussion of the following ORAU and DCAS procedures: OTIB-0055 ("Conversion from NCRP Report 38 Neutron Quality Factors to ICRP Pub. 60"), Program Evaluation Report (PER)-0005 ("Misinterpreted Application of the External Dose Factor {Hanford}"), PER 014 ("Construction Trades Workers"), PER 017 ("Evaluation of Incomplete Internal Dose Records from Idaho, Argonne-East and Argonne-West National Laboratories"), PER 020 ("Blockson Technical Basis Document"), PER 029 ("Hanford TBD Revision"), PER 031 ("Y-12 TBD Revisions"), PER 037 ("Ames TBD Revision"), PER 038 ("Hooker Electrochemical TBD Revision"), ORAUT-PROC-0044 ("Special Exposure Cohort"); DCAS Report 0053 ("Stratified Co-Worker Sets"); and a continuation of the comment-resolution process for other dose reconstruction procedures under review by the Subcommittee.

The agenda is subject to change as priorities dictate.

In the event an individual wishes to provide comments, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below in advance of the meeting.

Contact Person for More Information: Theodore Katz, Designated Federal Official, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta Georgia 30333, Telephone (513) 533-6800, Toll Free 1 (800) CDC-INFO, email dcas@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee

management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013-07367 Filed 3-28-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

Notice of Cancellation: This document corrects a notice that was published in the **Federal Register** on March 21, 2013 (78 FR 06434), announcing a teleconference that would include the initial review, discussion, and evaluation of applications received in response to "Indoor Environment of Low-Income Renovated Multifamily Housing in the Western Region of the United States (U01), Funding Opportunity Announcement EH-13-001." This meeting is canceled.

Notice will be provided if the meeting is rescheduled in accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub.L. 92-463).

Contact Person for More Information: J. Felix Rogers, Ph.D., M.P.H., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE., Mailstop F63, Atlanta, Georgia 30341, Telephone: (770) 488-4334.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1457-NC]

Medicare and Medicaid Programs; Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: A hospital has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated Organ Procurement Organization (OPO). The request was made in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 28, 2013.

ADDRESSES: In commenting, refer to file code CMS-1457-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1457-NC, P.O. Box 8010, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1457-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments to a regulations staff member ONLY to the following addresses:

- a. For delivery in Washington, DC—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

- b. For delivery in Baltimore, MD—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Patricia Taft, (410) 786–4561.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations

that are responsible for the procurement, preservation, and transport of organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every participating hospital must have an agreement only with its designated OPO to identify potential donors.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the Secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one initially designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving

the application, and to offer interested parties an opportunity to submit comments during the 60-day comment period beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under sections 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

As permitted by 42 CFR 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

Southern Ocean Medical Center in Manahawkin, New Jersey, is requesting a waiver to work with: New Jersey Sharing Network, 691 Central Avenue, New Providence, NJ 07974.

The Hospital's Designated OPO is: Gift of Life Donor Program, 401 N 3rd Street, Philadelphia, PA 19123.

IV. 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).

V. Response to Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble,

and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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

Dated: March 25, 2013

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013-07343 Filed 3-28-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369; (Formerly Docket No. 2007D-0168)]

Draft Guidance for Industry on Bioequivalence Recommendations for Metronidazole Vaginal Gel; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Bioequivalence Recommendations for Metronidazole Vaginal Gel.” The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for metronidazole vaginal gel.

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 comments 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 May 28, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Kris Andre, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311; FDA-2007-D-0433), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific bioequivalence (BE) recommendations available to the public on FDA’s Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for metronidazole vaginal gel.

New drug application 020208 for MetroGel-Vaginal (metronidazole) vaginal gel, 0.75%, was initially approved by FDA in August 1992. On October 31, 2006, FDA approved ANDA 077264 for a generic version of MetroGel-Vaginal 0.75% (metronidazole). FDA is now issuing a draft guidance for industry on BE recommendations for generic metronidazole vaginal gel (Draft Metronidazole Vaginal Gel BE Recommendations).

In March 2006, Foley & Lardner LLP (the petitioner) submitted a citizen petition requesting that FDA require that any ANDA referencing Metro-Gel Vaginal meet certain conditions, including conditions related to demonstrating BE (Docket No. FDA-2006-P-0080). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the Draft Metronidazole Vaginal Gel BE Recommendations in responding to the citizen petition.

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 the design of BE studies to support ANDAs for metronidazole vaginal gel. 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 written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-07296 Filed 3-28-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number OIG-1302-N]

Special Fraud Alert: Physician-Owned Entities

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Special Fraud Alert addresses physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

DATES: These regulations are effective on March 29, 2013.

FOR FURTHER INFORMATION CONTACT: Patrice S. Drew, Department of Health and Human Services, Office of Inspector General, Congressional and Regulatory Affairs, at (202) 619-1368.