

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 14, 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-0001]

Changing Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Obesity and Metabolic Diseases: How To Estimate and Reward True Patient-Centric Value in Innovation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled “Changing Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Obesity and Metabolic Diseases: How to Estimate and Reward True Patient-Centric Value in Innovation.” FDA is cosponsoring the workshop with the American Gastroenterological Association (AGA). The purpose of the workshop is to facilitate discussion between FDA, AGA, and other interested parties of the development of medical devices for the treatment of morbid obesity and other metabolic diseases and evolving approaches for the regulation and reimbursement of minimally invasive procedures. The public workshop is being rescheduled due to the government shutdown. The title of the workshop has also been changed.

DATES AND TIMES: The public workshop will be held on December 19, 2013, from 8:30 a.m. to 5 p.m. and on December 20, 2013, from 8:30 a.m. to 12:15 p.m.

Location: The public workshop will be held at the Grand Hyatt Washington, DC, 1000 H St. NW., Washington, DC 20001, 202-582-1234.

Contact Person: Herbert Lerner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66,

Rm. G114, Silver Spring, MD 20993-0002, 301-796-6511, email: herbert.lerner@fda.hhs.gov.

Registration: Registration is limited and is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. (EDT), December 10, 2013. Onsite registration will be available after this date. To register for the public workshop, please visit the American Gastroenterological Association (AGA) Web site: <http://www.gastro.org/education-meetings/live-meetings/aga-fda-regulation-and-reimbursement-workshop>. For more information on the workshop, please see the FDA’s Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

The AGA will collect a registration fee to cover its share of the expenses associated with the public workshop, which is included in the registration information on the AGA Web site.

If you need special accommodations due to a disability, please contact Herbert Lerner (see *Contact Person*) at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public workshop is to facilitate discussion between FDA, the AGA and other interested parties on the issues of device development, public and private payer reimbursement, venture capital, and regulatory pathways for device innovation and marketing. The workshop will provide a forum for discussing new approaches for the treatment of morbid obesity and other metabolic diseases as well as evolving approaches for the regulation and reimbursement of minimally invasive procedures.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Challenges to MedTech Innovation in the United States;
- Evolving Approaches for the Regulation of Minimally Invasive Procedures: The FDA Benefit/Risk Paradigm;
- Evolving Approaches for the Reimbursement of Minimally Invasive Procedures: How to Put a Price on Value;

- Obesity as a Disease: Redefining the Regulatory and Reimbursement Context; and

- The “Process”—Investigational Device Exemption Review.

Dated: November 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The National Health Service Corps and NURSE Corps Interest Capture Form.
OMB No.: 0915-0337—Revision.

Abstract: The National Health Service Corps (NHSC) and the NURSE Corps of