

reprocess (i.e., clean and disinfect or sterilize) a reusable device are critical to ensuring a reusable device is appropriately prepared for its next use.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on processing and reprocessing labeling for medical devices. 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.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability is available for all CDRH guidance documents at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, and for CBER guidance documents at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1748 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910-0120; the collections of information in part 801 are approved under OMB control number 0910-0485; and the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is

only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: April 26, 2011.

**Nancy K. Stade**,

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0294]

#### Reprocessing of Reusable Medical Devices; Public Workshop

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

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Reprocessing of Reusable Medical Devices Workshop." The purpose of the workshop is to discuss factors affecting the reprocessing of reusable medical devices and FDA's plans to address the identified issues. This workshop is part of an ongoing FDA effort to address patient exposure to inadequately reprocessed reusable medical devices with the overall goal to reduce the risk of infection. The topics to be discussed are: Factors affecting reprocessing quality, device design as it relates to reprocessing reusable medical devices, reprocessing methodologies, validation methodologies, and healthcare facility best practices.

**Date and Time:** The public workshop will be held on June 8, 2011, from 8:30 a.m. to 5:30 p.m. and June 9, 2011, from 8:30 a.m. to 5 p.m.

**Location:** The public workshop will be held in the Great Room at the FDA White Oak Conference Center, Bldg. 31, Rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993.

**Contact Person:** Carol Krueger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5437, Silver Spring, MD 20993, 301-796-3241, FAX: 301-847-8510, or e-mail: [Carol.Krueger@fda.hhs.gov](mailto:Carol.Krueger@fda.hhs.gov).

**Registration and Requests for Oral Presentations:** Registration is free and on a first-come, first-served basis. Persons interested in attending this

workshop must register online by 5 p.m. on June 1, 2011. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, on-site registration on the day of the public workshop will be provided beginning at 7:30 a.m. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. If you need special accommodations due to a disability, please contact Susan Monahan (e-mail: [Susan.Monahan@fda.hhs.gov](mailto:Susan.Monahan@fda.hhs.gov) or phone: 301-796-5661) no later than June 1, 2011.

This workshop will also be Web cast. Persons interested in participating by Web cast must register online by 5 p.m. on June 1, 2011. Early registration is recommended because Web cast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Web cast participants will be sent connection requirements.

To register for the public workshop, please visit the following Web site: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (or go to the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including: Name, title, affiliation, address, email, telephone and FAX number. For those without Internet access, please call the contact person to register. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist.

This workshop includes a public comment session. During online registration you may indicate if you wish to make an oral presentation during a public comment session at the public workshop, and which topic you wish to address in your presentation. FDA has included general topics for comment in this document. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin. All requests to make oral presentations, as well as presentation materials, must be sent to the contact person by June 1, 2011.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Various types of medical devices used in healthcare settings, from surgical suction tips to complex endoscopes, are designed and labeled for use on multiple patients. The workshop will focus on medical devices that are intended for reuse after reprocessing, rather than third-party reprocessing of single-use-only medical devices.

Thousands of reusable medical devices requiring reprocessing are used every day in diagnosing and treating patients. FDA has received a number of reports of patient exposure to inadequately reprocessed medical devices and subsequent healthcare-associated infections (HAIs). Several reports contained evidence suggesting that inadequate reprocessing may have been a contributing factor in microbial transmission and subsequent infection. A definitive causal relationship between reusable device reprocessing and any patient infection is difficult to establish, because inadequate reprocessing is not often investigated as a cause when an HAI is diagnosed. Ensuring adequate reprocessing of reusable medical devices could reduce the incidence of HAIs associated with the use of a reprocessed medical device. This will decrease the public health burden of HAIs in terms of morbidity, mortality and cost.

The adequate reprocessing of reusable medical devices is a critically important factor in protecting patient safety. Inadequate reprocessing between patients can result in the retention of blood, tissue, and other biological debris (soil) in reusable medical devices. This soil can allow microbes to survive the high level disinfection or sterilization process, potentially resulting in HAIs or other adverse patient outcomes. FDA receives reports of problems in all steps of medical device reprocessing<sup>1</sup>, including cleaning, disinfecting and sterilizing. Manufacturers, healthcare facilities, healthcare professionals, and the FDA all have a role in reducing the risk of inadequately reprocessed medical devices.

Because of the critical importance of adequate reprocessing of medical devices, the FDA has launched an initiative to focus on improvements in device design, reprocessing procedures and validation methodologies, and healthcare facility quality assurance practices. To help address these issues,

<sup>1</sup> A more comprehensive description of reprocessing steps is available in FDA's draft guidance "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" at <http://www.fda.gov/reprocessingreusabledevices>.

the FDA has engaged partners at the Centers for Disease Control and Prevention (CDC), the Centers for Medicaid and Medicare Services (CMS), the Veterans Health Administration (VHA), and The Joint Commission (JC), who bring valuable expertise in disease control and healthcare practices to this initiative.

**II. Topics for Discussion at the Public Workshop**

The public workshop will be organized to discuss the following topic areas:

1. What are the nature, scope, and impact of reusable medical device reprocessing problems that have been observed? What are the causes of these problems?
2. What factors or criteria to facilitate reprocessing should be considered when designing reusable medical devices? How can the design process be improved to better incorporate cleanability as a design endpoint?
3. What factors or criteria should be considered when developing reprocessing instructions and validation protocols for devices to be used in various healthcare environments (e.g., hospital, ambulatory surgical center, physician's office), based on the draft guidance document "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" at <http://www.fda.gov/reprocessingreusabledevices>.
4. What factors or criteria should be considered by a healthcare facility when developing reusable device reprocessing procedures and quality assurance processes?
5. How should problems with reusable medical device reprocessing be identified, reported, and acted upon by industry and users?

**III. Transcripts**

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A link to the transcripts will also be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/>

*default.htm* (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated April 26, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Reimbursement Rates for Calendar Year 2011**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83-568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2011 for Medicare and Medicaid beneficiaries and beneficiaries of other Federal programs. The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient rates set forth below do not include all physician services and practitioner services, additional payment may be available to the extent that those services meet applicable requirements.

**Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services)**

Calendar Year 2011	
Lower 48 States .....	\$2,034
Alaska .....	2,269

**Outpatient Per Visit Rate (Excluding Medicare)**

Calendar Year 2011	
Lower 48 States .....	294
Alaska .....	490

**Outpatient Per Visit Rate (Medicare)**

Calendar Year 2011	
Lower 48 States .....	256
Alaska .....	447