

Medical News

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FDA and HCFA Propose Rules for Handling HCV-Infected Blood

The FDA and the Health Care Financing Administration (HCFA) have issued new proposed rules for institutions that handle blood and blood products in an attempt to prevent patients from contracting hepatitis C virus (HCV). Both the FDA's proposed rule and the HCFA's proposed rule appeared in the *Federal Register* on November 16, and both require hospitals and other facilities to develop and adhere to written procedures for appropriate action in handling HCV-infected blood. The rules are intended to create consistent industry standards for potentially infectious blood and blood products. Among the requirements, facilities would establish a "look back," similar to that in effect for HIV, requiring hospitals, when notified by blood banks, to quarantine prior collections from a donor who later tested repeatedly reactive for HCV and to notify transfusion recipients based on further testing of such a donor. HCFA would require the procedures as part of the conditions of participation for Medicare and Medicaid providers.

Comments on the HCFA rule are due January 16, 2001. Send them to HCFA, Department of Health and Human Services, PO Box 8010, Attn: HCFA-3014-P, 7500 Security Blvd, Baltimore, MD 21244-8010.

Both agencies are proposing to extend the record-retention period to 10 years. To read the proposed rules, refer to the November 16 *Federal Register* online, at http://www.access.gpo.gov/su_docs/fedreg/a001116c.html.

JCAHO to Collect Information on Reuse of Single-Use Devices

Beginning in November 2000 and running through approximately March 2001, JCAHO will assist the FDA by distributing educational material regarding the reuse of single-use medical devices to hospitals and by collecting information during on-site surveys about hospital reuse activities.

During the first day of survey, the on-site JCAHO survey team will distribute FDA information regarding the reprocessing of single-use devices and a short questionnaire. Hospital staff will be given the duration of the survey

to review the materials, complete the questionnaire, and return it to the survey team. The FDA information and questionnaire also will be sent to hospitals surveyed in September and October 2000. Those organizations will be asked to return the questionnaire directly to JCAHO in a pre-addressed envelope.

JCAHO is acting solely in a role to disseminate and gather information in this project. The results of the questionnaire will not have an impact on an organization's accreditation status. All information gathered will remain anonymous and will be provided to the FDA in aggregate form.

The FDA's main objective in this project is to gather data on the individual devices that fall under the Class III designation, ie, those determined to pose the highest risk.

For questions regarding the Joint Commission's role in this project, contact Kevin Hickey, khickey@jcaho.org or 630-792-5872. More detailed information on device classifications can be accessed on the US Food and Drug Administration Center for Devices and Radiological Health's web site, <http://www.fda.gov/cdrh/>.

FROM: JCAHO. Inside Perspectives. November 2000. www.jcaho.org.

Alcohol Rubs: CDC's New Hand-Hygiene Guidelines

Waterless alcohol rubs may replace soap and water as the leading recommended tools for hand disinfection in the 2002 Guideline for Hand Hygiene of the CDC's Healthcare Infection Control Practices Advisory Committee (HIC-PAC). In November the committee met in Atlanta, Georgia, to review the first draft of the guideline. A second-draft review is tentatively scheduled for May 2001. The shift toward recommending primarily waterless agents stems from the observation that improper handwashing techniques and low compliance with handwashing protocols by healthcare workers (HCWs) make current hand-hygiene recommendations ineffective.

Most handwashing protocols, which call for 30 to 60 seconds of handwashing, bear no resemblance to what actually occurs in healthcare settings. Of 11 studies referenced in the draft that evaluated the average duration of hand washing by HCWs, 8 found averages shorter than 15