DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2004

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice of availability and request for public comment.

SUMMARY: This notice is a request for review of and comment on the *Draft Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2004,* available on the CDC Web site at *www.cdc.gov/ncidod/hip/isoguide.htm.* This document is for use by infection control staff, healthcare epidemiologists, healthcare administrators, and other persons responsible for developing, implementing, and evaluating infection control programs for healthcare settings across the continuum of care. The guideline updates and expands the 1996 *Guideline for Isolation Precautions in Hospitals.*

DATES: Comments on the *Draft Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2004* must be received in writing on or before August 13, 2004.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the *Draft Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2004* should be submitted to the Resource Center, Attention: ISOGuide, Division of Healthcare Quality Promotion, CDC, Mailstop E–68, 1600 Clifton Rd., NE., Atlanta, Georgia 30333; fax 404 498–1244; e-mail: *isorequests@cdc.gov;* or Internet: *www.cdc.gov/ncidod/hip/isoguide.htm.*

ADDRESSES: Comments on the *Draft Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2004* should be submitted to the Resource Center, Attention: ISOGuide, Division of Healthcare Quality Promotion, CDC, Mailstop E–68, 1600 Clifton Road, NE., Atlanta, Georgia 30333; fax 404 498–1244; e-mail: *isocomments@cdc.gov;* or Internet: *www.cdc.gov/ncidod/hip/isoguide.htm.*

SUPPLEMENTARY INFORMATION: The *Draft Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2004* addresses new concerns about transmission of infection to patients and healthcare workers in hospitals and in long-term care, outpatient, home care, and other healthcare settings in the United States. The primary objective of the 5-part guideline is to improve the safety of the nation's healthcare delivery system. Part I reviews the scientific data regarding the transmission of infectious agents in healthcare settings and discusses emerging pathogens of special concern, including multidrug-resistant organisms and agents of bioterrorism. Part II discusses the fundamental infection control elements needed to prevent transmission of these agents. Part III reviews the two tiers of transmission precautions (*i.e.,* Standard Precautions and Expanded Precautions) developed by the Healthcare Infection Control Practices Advisory Committee (HICPAC). New issues addressed in the guideline include Respiratory Hygiene/Cough Etiquette, which is intended to prevent transmission of respiratory pathogens at the first point of contact within a healthcare setting; Protective Environment, which is designed to protect allogeneic hematopoietic stem cell transplant patients; and strategies for control of multidrug-resistant organisms. Part IV contains the consensus recommendations of HICPAC for preventing the transmission of infectious agents in healthcare settings. Part V provides suggested performance measures to assist healthcare facility staff in monitoring success in implementation of key recommendations in the guideline.

HICPAC was established in 1991 to provide advice and guidance to the Secretary and the Assistant Secretary for Health, DHHS; the Director, CDC; and the Director, National Center for Infectious Diseases, regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections in U.S. healthcare facilities. The committee advises CDC on guidelines and other policy statements regarding prevention of healthcare-associated infections and related adverse events.

Dated: June 3, 2004.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0017]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Pilot Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 14, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Adverse Event Pilot Program for Medical Devices—(OMB Control Number 0910–0471—Extension)

FDA is requesting approval from OMB for clearance to continue to conduct a pilot project to evaluate aspects of a national reporting system mandated by the Food and Drug Modernization Act (FDAMA) of 1997. Under section 519(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(b)), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions; user facilities (hospitals, nursing homes, ambulatory surgical facilities and outpatient diagnostic and treatment facilities) to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the