SUPPLEMENTARY INFORMATION:

I. Background

FDA assumes primary responsibility for performing the CLIA complexity categorization functions that includes requests for waiver. Responsibility for determining whether a particular device is waived was transferred from the CDC to FDA on January 21, 2000. At the same time, HCFA is responsible for financial management operations of the CLIA program. In the Federal Register of September 13, 1995 (60 FR 47334), HCFA and CDC published a notice of proposed rulemaking that proposed criteria for obtaining CLIA waiver (the 1995 proposed rule). FDA believes, based on its interpretation of the legislative history and the changes to the CLIA statute enacted by Congress on November 21, 1997, as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA), that alternative criteria to the criteria proposed by HCFA and CDC can be used to determine whether a device can be waived. HCFA, CDC, and FDA are continuing to discuss whether the criteria contained in this guidance appropriately reflect the intent of the statute. In an effort to get additional perspective on these criteria, this draft guidance will be discussed at the Clinical Laboratory Improvement Advisory Committee ( CLIAC) meeting to obtain their advice and recommendations. FDA is publishing this draft guidance so that it can be reviewed, and our interactions with stakeholders of this program from CDC to FDA. One of the interactions with stakeholders is that the recommendations made by HCFA and CDC in their 1995 proposed rule. As stated in this draft guidance, FDA will continue to review requests for waiver that follow the criteria contained in the 1995 proposed rule; however, we will also review requests for waiver that follow the criteria contained in this draft guidance document. The most significant difference between the criteria proposed by CDC and HCFA, and the criteria outlined in this draft guidance, is that this draft guidance allows studies that compare the performance of the device in the hands of untrained users with the performance of the device in the hands of laboratory professionals to demonstrate accuracy.

This draft guidance represents the agency’s current thinking on criteria for obtaining CLIA waiver. 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 applicable statutes and regulations.

The agency has adopted good guidance practices regulations (GGP’s), which set forth the agency’s policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance is issued as a Level 1 draft guidance consistent with the GGP regulations.

III. Electronic Access

In order to receive the draft guidance entitled “Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver” via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1147) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the draft document entitled “Guidance for Clinical Laboratory Improvement Amendments...
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children’s Hospitals Graduate Medical Education (CHGME) Payment Program: Final Eligibility and Funding Criteria and List of Eligible Hospitals and Proposed Methodology for Determining FTE Resident Count, Treatment of New Children’s Teaching Hospitals, and Calculating Indirect Medical Education Payment

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice and additional provisions proposed for comment.

SUMMARY: This notice sets forth final eligibility, funding criteria, payment methodology and performance measures for the Children’s Hospitals Graduate Medical Education Payment (CHGME) program, authorized by section 340E of the Public Health Service Act (42 U.S.C. 256e), amended by Pub. L. 106–310, The Children’s Health Act, 2000. It includes a list of hospitals potentially eligible for the CHGME program. The notice also requests comments on proposed criteria for: determining FTE resident count, the treatment of new children’s teaching hospitals, and the methodology for indirect medical education (IME) payments. In compliance with the Paperwork Reduction Act of 1995, the Department obtained Office of Management and Budget (OMB) approval on an emergency clearance to any data collections imposed on the public (OMB No. 0915–0247). The Department has requested approval for extension of OMB clearance to any data collections imposed on the public by this notice. Any changes to this collection will not become effective until approved by OMB.

DATES: Interested persons are invited to comment by April 2, 2001. All comments received on or before April 2, 2001 will be considered in the development of the final notice concerning the proposed methodology. The Department will address comments individually or by group and publish a final notice on these comments in the Federal Register.

ADDRESSES: Submit all written comments concerning this notice to Barbara Brookmyer, Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; or by