

in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of the device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. The specific criteria used to categorize the IDE's are set forth in Attachment A of the HCFA/FDA interagency agreement. In order to facilitate the processing of Medicare claims, FDA and HCFA encourage IDE sponsors to provide the IDE application numbers to the hospitals and clinical investigators participating in the sponsors' clinical investigations.

According to the September 19, 1995, HCFA final rule, IDE's which have been placed in Category B by FDA would be eligible for Medicare coverage consideration. The final coverage decision, however, will encompass other factors and thus will be made by HCFA.

By this notice, FDA is making available a list of all FDA-approved IDE's, the corresponding categorization determination (Category A or Category B), and the rationale for the determination. FDA will update this list as circumstances require and will make the revised list available through the electronic docket and Facts on Demand (details above), and in the Dockets Management Branch (address above). As set forth in the September 19, 1995, final rule, an IDE sponsor may seek reconsideration of a categorization determination by submitting a request for re-evaluation to FDA. Requests for re-evaluation should be submitted in the same manner as an IDE supplement to the IDE Document Mail Center (address above). IDE sponsors may submit this request for re-evaluation at any time, i.e., there is no time limit for submitting a reconsideration request to FDA. Further information about categorization, its effect on Medicare reimbursement, and appeal of a categorization determination, is contained in the September 19, 1995, final rule cited above.

Dated: February 12, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health

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Health Care Financing Administration

Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and the Clinical Laboratory Improvement Act (CLIA) Exemption Under State Laboratory Programs; *Form No.:* HCFA R-185; *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is equal to or more stringent than those of CLIA; *Frequency:* Other (initial application/as needed); *Affected Public:* Not-for-profit institutions, State, local, or tribal government.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 24, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96-4105 Filed 2-22-96; 8:45 am]

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Submitted for Collection of Public Comment: Submission for OMB Review

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension; *Title of Information Collection:* Sole Community Home Health Agencies (HHA) at 42 CFR424.22(b)(2), (f) and (g); *Form No.:* HCFA R-85; *Use:* These regulations implement the rules for participation of HHAs in Medicare and the establishment and review of plans of care for home health services. These regulations make it easier for certain HHAs to meet certification and plan of care requirements. *Frequency:* Annually; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 20; *Total Annual Hours:* 40.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch,