

options exist; these options are identified in Attachment 2 of a letter included with the new draft guidance. Comments on the new draft guidance should indicate and explain the option(s) preferred.

On May 17, 1995, the new draft guidance was presented at the Indiana Medical Device Manufacturers Council seminar. This seminar focused on the development of medical device software in a regulated environment. The new draft guidance was again presented on September 21, 1995, at the 19th Annual Regulatory Affairs Professional Society Exhibition and Conference.

The intent of the final version of this guidance will be to provide applicants specific additional directions regarding information and data that should be submitted to FDA in a 510(k) submission for medical device software.

This guidance, when finalized, will apply to all software, which includes embedded software, operator assisted software, and software accessories to medical devices. The new draft guidance excludes pure hospital information systems and manufacturing process control software.

Although this guidance does not create or confer any rights on or for any person and does not operate to bind the agency in any way, it does represent FDA's current thinking on the content of premarket submissions for medical devices containing software.

Interested persons may, on or before January 23, 1997, submit to the Dockets Management Branch (address above) written comments on the "ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software." Comments should: (1) Refer to specific line numbers, sections, and page numbers in the document; (2) discuss the issue; and (3) propose a recommended change. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the docket number found in brackets in the heading of this document. The new draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether further revisions to the draft guidance are warranted.

Dated: December 13, 1996.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 96-32683 Filed 12-23-96; 8:45 am]
BILLING CODE 4160-01-F

Health Resources and Services Administration

Notice of Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92-463, the Annual Report for the following Health Resources and Services Administration's Federal Advisory Committee has been filed with the Library of Congress:

National Advisory Council on Nurse Education and Practice Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading Room, Room 1026, Thomas Jefferson Building, Second Street and Independence Avenue, S.E., Washington, D.C. Copies may be obtained from: Melaine Timberlake, Executive Secretary, National Advisory Council on Nurse Education and Practice, Room 9-36, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-5786.

Dated: December 19, 1996.
Jackie E. Baum,
Advisory Committee Management Officer,
HRSA.
[FR Doc. 96-32685 Filed 12-23-96; 8:45 am]
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Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

The National Health Service Corps (NHSC) Application Process (OMB No. 0915-0146); Revision and Extension

The National Health Service Corps (NHSC) Scholarship Program was established to help alleviate the geographical and specialty maldistribution of physicians and other health practitioners in the United States. Under this program, health professions students are offered scholarships in return for service in a federally-designated Health Professional Shortage Area (HPSA).

In an effort to improve the procedures for selecting NHSC scholars, a revised application process was pilot tested in the spring of 1996. The revised application process is designed to broaden the scope of the information available on applicants in order to improve the Agency's ability to identify those applicants with the greatest potential to fulfill the objectives of the Scholarship Program. OMB approval is now being requested for full-scale implementation of the revised application process.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form name	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Application	3000	1	1.0	3000
Interview	900	1	1.67	1500

Estimated Total Annual Burden: 4500 hours. The interview burden includes 1 hour for travel time to the interview site.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to:

Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 18, 1996.
J. Henry Montes,
Associate Administrator for Policy Coordination.
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