

DATES: The workshop will be held on January 26, 1996, from 9 a.m. to 4:30 p.m. Participants and other persons who want to be heard must be present by 9 a.m. Submit written notices of participation on or before January 15, 1996.

ADDRESSES: The workshop will be held at the Parklawn Bldg., conference room D, 5600 Fishers Lane, Rockville, MD. Written comments, identified with the docket number found in brackets in the heading of this document, regarding reviewer guidance for CADx devices may be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary P. Anderson, Center for Devices and Radiological Health (HFZ-142), 12720 Twinbrook Pkwy., Rockville, MD 20852, 301-443-5020 ext. 40, FAX 301-443-9101.

Contact Mary Anderson (address above) for a registration form for the workshop. There is no registration fee but advance registration is required. Interested persons are encouraged to register early because space is limited. Persons with disabilities who require special assistance to attend or participate in the workshop can be accommodated if advance notification is provided. If you have a disability that affects your attendance at, or participation in, this meeting, please contact Mary Anderson (address and telephone number above), in writing and identify your needs. The availability of appropriate accommodations cannot be assured unless prior written notification is provided.

SUPPLEMENTARY INFORMATION:

I. Background

FDA anticipates receiving increasing numbers of premarket submissions for CADx medical devices. Some of these devices are accessories that analyze data produced by diagnostic medical devices, such as digital radiography systems, and highlight possible findings which assist the device user in interpreting such data. An example of such a device is an automated Pap smear reader. In order to develop reviewer guidance for appropriate device description and assessment methodologies in premarket submissions for these devices, FDA has established a computer-aided diagnostic device working group. This working group is in the process of evaluating the agency's approach to review of

premarket submissions for these medical devices.

II. Purpose and Tentative Agenda of the Workshop

The purpose of the public workshop is to obtain suggestions that will help FDA develop reviewer guidance for device description and assessment methodologies in premarket submissions for CADx medical devices.

Presiding over the workshop will be: David G. Brown, Chief Scientist, and Mary P. Anderson, Chief of the Medical Imaging and Computer Applications Branch, Division of Electronics and Computer Systems, Office of Science and Technology, Center for Devices and Radiological Health, FDA. They will be assisted by other FDA officials.

FDA will open the workshop with a summary of the present status of FDA review of these devices. This presentation will provide information on the impetus, objectives, and scope of the FDA's activities in this area. Following FDA's presentation, a specific period of time will be provided for participants to make presentations. Interested persons who wish to participate in the public workshop may, on or before January 15, 1996, submit a written notice of participation to the Dockets Management Branch (address above) identified with the docket number found in brackets in the heading of this document, including name, address, telephone number, business affiliation, a brief summary of the presentation, and an estimate of the amount of the time required for comments.

FDA requests that individuals or groups having similar interests consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. A schedule of the allotted times will be available at the workshop. Each participant will be notified before the workshop of the approximate time of their presentation. The schedule will be placed on file in the Dockets Management Branch under the docket number found in brackets in the heading of this document. The workshop will also include an opportunity for interested persons who did not submit a notice of participation to make brief statements or comments, if time permits. The workshop will then proceed to a panel discussion of specific issues to be considered in developing FDA's approach to the review of premarket submissions for CADx medical devices. The workshop is informal, and the rules of evidence will

not apply. No participant may interrupt the presentation of another participant.

Dated: November 28, 1995.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-30333 Filed 12-12-95; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

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.

1. Type of Information Collection

Request: Reinstatement, with change, of a previously approved collection for which approval has expired.

Title of Information Collection: Request for Medicare Payment-Ambulance.

Form No.: HCFA-1491.

Use: This form is completed on an "occasional" basis by beneficiaries and/or ambulance services. It is also submitted to a Medicare carrier to request payment for ambulance services.

Frequency: On occasion.

Affected Public: Individuals or households, business or other for-profit, not-for-profit institutions.

Number of Respondents: 8,513,300.

Total Annual Hours Requested:

1,418,883.

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: December 5, 1995.

Kathleen B. Larson,

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

[FR Doc. 95-30393 Filed 12-12-95; 8:45 am]

BILLING CODE 4120-03-P

Public Information Collection Requirements Submitted for Public Comment and Recommendations

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 proposals for the collection of information. Interested persons are invited to send comments regarding this 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 Request:* Revision of a currently approved collection.

Title of Information Collection: Annual Report on Home and Community-Based Waivers.

Form No.: HCFA-372, HCFA-372(S).

Use: States with an approved waiver under section 1915© of the Social Security Act are required to submit the HCFA-372 or HCFA-372(S) annually in order for HCFA to: (1) verify that State assurances regarding waiver cost neutrality are met, and (2) determine the waiver's impact on the type, amount, and cost of services provided under the State plan and health and welfare of recipients.

Frequency: Annually.

Affected Public: State, local, or tribal government.

Number of Respondents: 49.

Total Annual Hours: 18,000.

To request copies of the proposed paperwork collection 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: December 4, 1995.

Kathleen B. Larson,

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

[FR Doc. 95-30290 Filed 12-12-95; 8:45 am]

BILLING CODE 4120-03-P

Health Resources and Services Administration

Request for Nominations to the National Advisory Committee on Rural Health; Extension of Closing Date

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Extension of Closing Date.

SUMMARY: The Health Resources and Services Administration is requesting nominations to fill five vacancies on the Secretary's National Advisory Committee on Rural Health. The closing date is extended to February 2, 1996. All other aspects of the November 7, 1995 Federal Register Notice (60 FR 62254) remain the same.

ADDRESSES: Nominations and curricula vitae of nominees should be sent to Dena S. Puskin, SC.D., Executive Secretary to the National Advisory Committee on Rural Health, Room 9-05, 5600 Fishers Lane, Rockville, MD 20857.

Dated: December 7, 1995.

Ciro V. Sumaya,

Administrator.

[FR Doc. 95-30338 Filed 12-12-95; 8:45 am]

BILLING CODE 4160-15-P

Funding Notice for Grant Programs Funded Under Title VIII of the Public Health Service Act for Fiscal Year 1996; Notice of Extension of Application Due Date

This notice extends the application due date for fiscal year (FY) 1996 grant program for Nursing Education Opportunities for Individuals from

Disadvantaged Backgrounds (section 827). The application due date is extended to January 12, 1996. All applications must be received in the Parklawn Building by close of business on January 12, 1996. This change is necessary because of difficulties experienced with electronically accessing the program materials and unexpected delays in mailing. All other aspects of the October 20, 1995 Federal Register Notice (60 FR 54243) remain the same.

Dated: December 7, 1995.

Ciro V. Sumaya,

Administrator.

[FR Doc. 95-30337 Filed 12-12-95; 8:45 am]

BILLING CODE 4160-15-M

Public Health Service

National Institutes of Health; Proposed Data Collection Available for Public Comment

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects. To request more information on the proposed project, call Ruth A. Kleinerman, M.P.H., Epidemiologist, at (301) 496-6600.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Ruth A. Kleinerman, M.P.H., National Cancer Institute, EPN 408, 6130 Executive Boulevard, Rockville, MD 20892-7364. Written comments should be received by [Federal Register insert the date 60 days following the date of publication].

Proposed Project: Cancer Risk in X-ray Technologists: Second Survey for Incidence—renewal—A cohort study will be conducted to quantify the risk of radiation-induced cancer among 135,000 registered x-ray technologists. X-ray technologists will be asked to respond to a mail questionnaire which collects information about incident