Improvements Act of 1994, Pub. L. 103–296, was enacted, establishing SSA as an independent agency. As a result, the Secretary of Health and Human Services has decided to delegate to the Chair of the Departmental Appeals Board the authority to review ALJ decisions concerning claims for payment under Medicare Part A and B as well as ALJ decisions concerning entitlement to Medicare coverage. The delegation will be effective October 1, 1995. All Medicare cases pending before SSA's Appeals Council on September 30, 1995, will thereafter be the responsibility of the Departmental Appeals Board (DAB). Request for ALJ hearings on claims for payment under Parts A and B and requests for ALJ hearings on entitlement to Medicare coverage will continue to be decided by the ALJs in SSA's Office of Hearings and Appeals.

Until the procedures are modified, the DAB will conduct its review of ALJ decisions under the existing regulations governing appeals of Part A and B claims. Therefore, in conducting its review, the DAB will use the procedures provided in the following authorities, as applicable: 20 CFR Part 404, Subparts J and R, 42 CFR Part 405, Subparts G and H, 42 CFR Part 473, Subpart B (concerning review of decisions on Part A and B determinations made by peer review organizations) and regulations in 42 CFR part 417 governing review of decisions concerning Part A and B claims submitted by enrollees of health maintenance organizations, competitive health plans and health care prepayment plans. For the cases covered by this delegation, where ever the term ''Appeals Council'' is used, the term ''Departmental Appeals Board'' should be inserted.

The DAB, in cooperation with the Health Care Financing Administration, will review current procedures for appropriate changes and improvements. Interested parties may send comments and suggestions to the DAB at the following address: Departmental Appeals Board, Department of Health & Human Services, 200 Independence Avenue, S.W., Room 637D, Washington, DC 20201, or at the following e-mail address: gbm@ospahb.ssw.dhhs.gov.

On October 13, 1993, I delegated to the Departmental Appeals Board my authority to make final decisions on review of, or to decline to review, decisions of Administrative Law Judges involving, *inter alia,* provider participation and termination under section 1866(b)(2) of the Social Security Act and the other authorities enumerated in that delegation. See 58 Fed. Reg. 58171 (October 29, 1993). The delegation to the Departmental Appeals Board dated October 13, 1993, superseded all previous delegations of authority to review decisions by Administrative Law Judges on the referenced authorities, except that the delegation provided that the Social Security Administration, Office of Hearings and Appeals, Appeals Council continued to have the authority to review, or to decline to review, decisions in cases pending before it. There are still five of those cases pending; they are assigned to the same specialized personnel who are transferring to DAB to process the other Medicare appeals being delegated in this notice. Thus, notice is hereby given that any case pending before SSA's Appeals Council on September 30, 1995 that concerns the authorities referenced in the October 13, 1993 delegation will be transferred to the Departmental Appeals Board effective October 1, 1995.

Delegation of Authority

Notice is hereby given that I have delegated to the Chair of the Departmental Appeals Board my authority to make final decisions on review of, or to decline to review, decisions of Administrative Law Judges of the Office of Hearings and Appeals of the Social Security Administration involving Title XVIII, Parts A and B of the Social Security Act, as provided below:

1. The authority to make final decisions on review of, or to decline to review, decisions of Administrative Law Judges involving determinations made under section 1869 of the Social Security Act concerning whether an individual is entitled to benefits under Part A or Part B, and concerning claims for benefits under Parts A or B.

2. The authority to make final decisions on review of, or to decline to review, decisions of Administrative Law Judges involving determinations made under section 1876(c)(5) of the Social Security Act, which affect an individual's right to receive items and services, without additional cost, from a health maintenance organization.

3. The authority to make final decisions on review of, or to decline to review, decisions of Administrative law Judges involving determinations made under section 1155 of the Social Security Act.

I have also delegated to the Chair of the Departmental Appeals Board the authority to make final decisions on review of, or to decline to review, decisions of Administrative Law Judges of the Office of Hearings and Appeals of the Social Security Administration involving, *inter alia,* provider participation and termination under section 1866(b)(2) of the Social Security Act and the other authorities enumerated in that delegation for any cases pending before SSA's Appeals Council on September 30, 1995 that concern the authorities referenced in my October 13, 1993 delegation. See 58 Fed. Reg. 58171 (October 29, 1993).

These delegations include, but are not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, and to make findings of fact and conclusions of law. These delegations, which supersede all previous delegations of authority to make final decisions on review of, or to decline to review, decisions by Administrative Law Judges on the above-referenced authorities, are effective October 1, 1995. Accordingly, all cases decided pursuant to the above-referenced authorities that are pending with the Appeals Council of the Office of Hearing and Appeals, Social Security Administration on September 30, 1995, will thereafter be the responsibility of the Chair of the Departmental Appeals Board.

Dated: October 24, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–30282 Filed 12–12–95; 8:45 am]

BILLING CODE 4120–03–M

Food and Drug Administration

[Docket No. 95N–0363]

Medical Devices; Review of Computer-Aided Diagnostic Software Devices; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss the appropriate approach to the review of premarket submissions for computer-aided diagnostic (CADx) medical devices. Because there is increasing interest in and development of CADx medical devices, the agency is holding this workshop to obtain public comments and suggestions that may help FDA develop device description and assessment methodologies for reviewer guidance for premarket submissions for these CADx medical devices.

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