

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.