data to the pipeline's computer.[11] When the EBB requirement was first imposed in Order No. 636, the technology was to use direct telephone modem connections to dial-up a pipeline EBB. The dial-up system was non-standardized, with each pipeline requiring the use of different software packages and log-on procedures to access the pipelines' computers. As technology has changed, however, pipelines can now provide the same interactive service using more current and standardized technological methods that are consistent with the GISB standards, such as an Internet or Web-based system. Using an Internet-based system removes many of the idiosyncracies in log-on procedures that plagued the dial-up systems, since each user can access each pipeline's World Wide Web site using the same Internet connection and Web browser. Thus, pipelines are not prohibited by Commission regulations from using a Web-based EBB in place of a dial-up EBB.

However, even moving pipeline EBBs to the Internet may not necessarily create the open and standardized communication system that is required. For instance, standards may need to delineate the minimum Web browser and encryption levels that are needed to access pipeline Web sites, the basic organization of the Web site, and the format in which data will be presented. Moreover, as happened with the standardization of business transactions, communication efficiency may require that standards be developed to specify specific file formats for the exchange of business information.

GISB too has recognized that there is further need to standardize all EBB functions and information within a reasonable amount of time.[12] But, at the present time, the standardization effort is not complete. Standards still have not been developed to cover all the information the Commission requires to be posted on EBBs.[13] Although GISB has standardized much of these data, a few still remain. For instance, the GISB standards do not provide standards for submitting offers to release capacity and bids via the Internet, nor do they provide standards for downloading the Index of Customers in the specified format. Nor have standards been developed to cover the myriad other information and business transactions (not covered by the Commission regulations) that many pipelines provide using EBBs.[14] As GISB has recognized, until the standardization effort is complete, pipelines should not be forced to discontinue their proprietary EBB systems.[15]

Maintenance of existing systems during the transition to standardized communications should not result in significant added costs or burden. Pipelines, however, should not expend significant resources to expand or enhance the functionality of proprietary systems. These resources and efforts would be better spent on completing the process of developing standardized systems as quickly as possible.

Given the importance of developing standardized communications, the Commission expects GISB and the industry to move forward rapidly to complete the standardization process so that the Commission can substitute standardized communication modalities for the requirement for pipelines to maintain EBBs. The Commission requests a report by GISB, and by others who may wish to comment, by September 1, 1997 on the extent of their progress and the contemplated completion date.

In the meantime, as discussed above, the Commission regulations do not require pipelines to use EBBs to conduct the business transactions standardized in Order No. 587. Thus, pipelines can file tariff revisions under section 4 of the Natural Gas Act when they are ready to discontinue using EBBs to provide these services and, instead, rely upon the standardized methodologies.

In its waiver request, Ozark did not make clear whether it is intending to substitute GISB's Internet server model for its EBB to conduct the relevant business transactions or whether every one of the business transactions and communication now provided using its EBB will be provided using the Internet communications. As discussed above, the Commission's regulations do not require such transactions to be provided on an EBB, so no waiver of the regulations is needed. However, if Ozark previously provided such services on an EBB, it cannot dispense with those services through a filing to comply with Order No. 587, but will need to make a section 4 filing.

*The Commission orders:*

(A) The requests for rehearing are denied.

(B) Ozark's request for waiver is denied.

By the Commission.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–12398 Filed 5–9–97; 8:45 am]

BILLING CODE 6717–01–P

[11] *See* Standards For Electronic Bulletin Boards Required Under Part 284 Of The Commission's Regulations, Order No. 563, 59 FR 516 (Jan. 5, 1994) FERC Stats. & Regs. Regulation Preambles [Jan. 1991–June 1996], ¶ 30,988, at 31,001 n.10 (Dec. 23, 1993).

[12] Electronic Delivery Mechanism Standard 4.3.6.

[13] Commission regulations require the use of EBBs only for limited purposes: to provide equal and timely access to information relevant to the availability of transportation service, including the provision of a capacity release system involving a posting and bidding mechanism to facilitate capacity reallocations (Sections 284.8(b)(3) and 284.9(b)(3); Pipeline Service Obligations and Revisions to Regulations Governing Self-Implementing Transportation; and Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol, [Regs. Preambles Jan. 1991–June 1996] FERC Stats. & Regs. ¶ 30,939, at 30,415 (1992)); information about pipeline affiliate transactions (sections 161.3(h) and 250.16(c)); and an index of customers (section 284.106). Section 284.10 of the Commission's regulations establishes certain features that pipeline EBBs, whether required by the regulations or the pipeline's tariff, must support.

[14] This process was begun in Order Nos. 587, 587–B, and 587–C, in which the Commission approved GISB standards requiring pipelines to transact some of these business transactions (nominations, flowing gas, invoicing, and capacity release) using standardized file formats that would be exchanged according to the Internet protocols established by GISB. However, these standards do not cover all of the information and transactions currently performed on pipeline EBBs.

[15] Electronic Delivery Mechanism Standard 4.3.6.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### 42 CFR Parts 405, 417, 473

**[BPD–453–FC]**

**RIN 0938–AG18**

## Medicare Program; Medicare Appeals of Individual Claims

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Final rule with comment period.

**SUMMARY:** Under section 1869 of the Social Security Act, Medicare beneficiaries and, under certain circumstances, providers or suppliers of health care services may appeal adverse determinations regarding claims for benefits under Medicare Part A or Part B. This rule expands our regulations to recognize the right of Part B appellants to a hearing before an administrative law judge (ALJ) for claims if at least $500 remains in dispute and the right to judicial review of an adverse ALJ decision if at least $1,000 remains in controversy. Also, this rule codifies in regulations: Limitations on the review by ALJs and the courts of certain national coverage determinations, and the statutory authority for an expedited appeals process under Part A and Part B.

**DATES:** *Effective Date:* This final rule is effective June 11, 1997.

*Comment Date:* Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on July 11, 1997.

**ADDRESSES:** Mail written comments (an original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–453–FC, P.O. Box 26676, Baltimore, MD 21207–0476.

If you prefer, you may deliver your written comments (an original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments may also be submitted electronically to the following e-mail address: BPD453FC@hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address, below.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–453–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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**FOR FURTHER INFORMATION CONTACT:** Morton Marcus, (410) 786–4477.

**SUPPLEMENTARY INFORMATION:**

## I. Background

### *A. Appeals under Part A and Part B*

The Social Security Administration (SSA) makes determinations concerning basic entitlement to Medicare Part A and Part B. Other determinations concerning Medicare payment of individual claims are made initially by Medicare contractors. Fiscal intermediaries make most Part A and some Part B determinations; carriers make most Part B determinations. (For purposes of this preamble discussion and regulations set forth at 42 CFR part 405, subpart H, the term ''carrier'' also refers to intermediaries authorized to make determinations with respect to Part B benefits.)

Section 1869 of the Social Security Act (the Act) grants Medicare beneficiaries who are dissatisfied with certain Medicare determinations the right to a hearing before an administrative law judge (ALJ) and the right to judicial review under certain circumstances. In general, a hearing before an ALJ is available to resolve disputes concerning: (1) An individual's basic entitlement to benefits under Part A or Part B of Medicare, and (2) the amount of benefits due. Since the inception of the Medicare program, hearings on all Part A or Part B entitlement questions and Medicare Part A claims that have reached the ALJ hearing level have been conducted by ALJs employed by the SSA's Office of Hearings and Appeals (OHA). Our regulations generally address appeals of claims arising under Part A at 42 CFR part 405, subpart G and appeals of claims under Part B at 42 CFR part 405, subpart H.

Peer review organizations (PROs) also make certain types of Part A and Part B determinations. Section 1155 of the Act establishes beneficiary rights to ALJ hearings and judicial review of certain Medicare issues (mostly inpatient hospital service denials) adjudicated initially by PROs. In order for a PRO appellant to qualify for an ALJ hearing and judicial review, the amount in controversy must be at least $200 and $2,000, respectively. (However, appeals on PRO determinations involving limitation of liability follow the appeals provisions in subparts G and H of part 405, requiring an amount in controversy at the ALJ level of $100 for Part A claims and $500 for Part B claims, and an amount in controversy of $1,000 for judicial review.) Our regulations address this subject at 42 CFR part 473, subpart B.

For enrollees of health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans (HCPPs), the HMO/CMP/HCPP is responsible for making the organization determination, which is the equivalent of the initial determination made by the carriers and intermediaries. Section 1876(c)(5)(B) of the Act establishes beneficiary rights to ALJ hearings and judicial review of certain Part A and Part B claims submitted by or on behalf of enrollees of HMOs/CMPs/HCPPs. Limited appeal rights also exist for an HMO/CMP/HCPP. If the beneficiary requests, and is granted an ALJ hearing, the HMO/CMP/HCPP must be made a party to the hearing and the HMO/CMP/HCPP then has the same appeals rights as the beneficiary to further administrative or judicial review. In order for an HMO/CMP/HCPP appellant to qualify for an ALJ hearing and judicial review, the amount in controversy must be at least $100 and $1,000, respectively. Our regulations address this subject at 42 CFR 417.600 through 417.638.

For the following discussion, the term ''provider'' has the meaning given in sections 1861(u) and 1866(e) of the Act and in 42 CFR 400.202. That is, a provider is a hospital, rural primary care hospital, skilled nursing facility, home health agency, comprehensive outpatient rehabilitation facility, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a

rehabilitation agency, or a public health agency that has a similar agreement, but only to furnish outpatient physical therapy or speech pathology services.

The term ''supplier'' is defined in § 400.202 and means a physician or other practitioner, or an entity other than a ''provider,'' that furnishes health care services under Medicare. Although ''supplier'' encompasses physicians, our usual phraseology is ''physician or supplier.''

Under section 1879(d) of the Act, a provider, or a physician or supplier that accepts assignment has, under certain limited circumstances, the same appeal rights as that of an individual beneficiary when the issue in dispute involves a service that is excluded from coverage under section 1862(a)(1) of the Act, custodial care, home health denials involving the failure to meet homebound or intermittent skilled nursing care requirements, or certain supplier refunds required under section 1879(h) of the Act. Moreover, by regulation, we have always provided that a physician or supplier that has taken assignment of a Medicare claim under Part B has the same appeal rights as the beneficiary has on that claim. Additionally, we have been providing appeal rights for providers in cases decided under section 1879(e) of the Act.

Under section 1842(l) of the Act, a physician who does not accept assignment must refund to the beneficiary any amounts collected for services found to be not reasonable and necessary under section 1862(a)(1). A refund is not required if the physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the services or if the beneficiary was appropriately informed in advance that Medicare would not pay for the services and agreed in writing to pay for them. Our regulation at 42 CFR 411.408 provides that if payment is denied for unassigned claims because the services are found to be not reasonable and necessary, the physician who does not accept assignment has the same appeal rights as the physician who submits claims on an assignment-related basis, as described in subpart H of part 405 and subpart B of part 473.

Before the enactment of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86, Pub. L. 99–509) on October 21, 1986, section 1869 of the Act provided for ALJ hearings and judicial review of claims for entitlement to Medicare Parts A and B and of disputes over claims for benefits under Part A. There was no provision for ALJ hearings or judicial review for disputes over the amount of Part B benefits, except under section 1876 of the Act pertaining to HMO/CMP/HCPP denials, and except for certain PRO matters as authorized by section 1155 of the Act. Instead, as specified in section 1842(b)(3)(C) of the Act and our regulations at part 405, subpart H, Medicare carriers processed claims for Part B benefits and made an initial determination, either approving or denying the claim, in whole or in part. A beneficiary, or a physician, or a supplier that accepted assignment and, that disagreed with an initial determination, could obtain a review by the carrier that denied the claim. (Under certain circumstances, a provider could also obtain a Part B review or fair hearing with the same limited appeal rights for Part B initial determinations as they have for Part A.) Following the review determination, if the amount remaining in controversy was $100 or more, the final appeal under Part B was a hearing before a hearing officer appointed by the carrier.

*B. Appeals Provisions of the Omnibus Budget Reconciliation Act of 1986*

Section 9341(a)(1) of OBRA '86 amended section 1869 of the Act to permit hearings before ALJs and judicial review of claims for benefits under Part B. The law provided that, for a Part B ALJ hearing, the amount in controversy must be at least $500, and for judicial review of a Part B dispute, the amount in controversy must be at least $1,000.

Section 9341(a)(2) of OBRA '86 amended section 1842(b)(3)(C) of the Act to provide for a hearing before a carrier hearing officer if the amount in controversy is at least $100, but not more than $500. (Prior to OBRA '86, a claimant qualified for a hearing before a carrier hearing officer by having at least $100 in controversy.)

A portion of section 9341(a)(1)(C) of OBRA '86 amended section 1869(b)(2) of the Act to provide for the aggregation of claims under certain specific circumstances to reach the threshold minimum amount in controversy needed for an ALJ hearing. This aggregation provision was implemented by regulations (including 42 CFR 405.815) published in the **Federal Register** on March 16, 1994 (59 FR 12172).

Section 9341(a)(1)(D) of OBRA '86 added section 1869(b)(3) to the Act placing several limitations on the review of national coverage determinations made under section 1862(a)(1) of the Act concerning whether a particular type or class of items or services is covered. Although the legislation uses the phrase ''national coverage determinations,'' Medicare national coverage determinations are referred to as ''national coverage decisions'' in our manuals and regulations. Consequently, in discussions below, we use the latter phrase. The first limitation is that an ALJ has no authority to review such a decision, except to determine whether the national coverage decision applies to a specific claim for benefits. The ALJ may also determine whether the national coverage decision has been applied correctly to the claim at issue. For example, when a national coverage decision permits coverage if certain criteria are met, the ALJ may reach a different factual conclusion (from lower level adjudicators) regarding whether those criteria were met for the claim at issue. Second, a national coverage decision may not be held unlawful or set aside solely on the grounds that the decision was not published in accordance with the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) or section 1871(b) of the Act. Third, in any case in which a court determines that the record is incomplete or otherwise lacks adequate information to support the validity of a national coverage decision, it must remand the matter to the Secretary for additional proceedings to supplement the record. The court may not determine that an item or service is covered except upon review of the supplemented record.

Section 9341(a)(1)(D) of OBRA '86 also added section 1869(b)(4) to the Act. This provision prohibits judicial review of regulations or instructions issued prior to January 1, 1981, that relate to a method for determining the amount of payment under Part B.

The appeals amendments contained in section 9341 of OBRA '86 apply to items and services furnished on or after January 1, 1987.

Section 9313(a)(1) of OBRA '86 amended section 1869(b)(1) of the Act to permit representation of beneficiaries in Medicare appeals by the individuals who have furnished items or services to those beneficiaries. (This statutory provision effectively invalidated certain HCFA manual instructions in effect at the time that barred providers from representing beneficiaries in Medicare Part A appeals.) Section 1869(b)(1) also limits representation under the limitation on liability provisions under section 1879 of the Act, which applies when the appeal involves: A service that is excluded from coverage under section 1862(a)(1) of the Act; custodial care; home health denials, if the individual is determined to be not homebound or does not or did not need skilled nursing care on an intermittent basis; certain

supplier refunds required under section 1879(h) of the Act; or cases decided under section 1879(e) of the Act. In any of the above situations, the provider, physician, or supplier cannot represent the beneficiary in an appeal unless the provider or other supplier of services waives in writing any rights for payment from the beneficiary with respect to those items or services, including the right to any deductible or coinsurance in connection with the service(s) at issue. The requirement that a provider or supplier representative must waive his or her right to payment is intended to ensure against a potential conflict of interest between the beneficiary and the person who furnished the items or services to the beneficiary. Further, a provider, physician, or supplier representative is not entitled to charge the beneficiary a fee for services furnished in connection with representation. The representation rules contained in section 9313(a)(1) of OBRA '86 were effective on October 21, 1986, and only affect appeals arising under section 1869 of the Act. They are the subject of a separate regulation document under development.

*C. Appeals Provisions of the Omnibus Budget Reconciliation Act of 1987*

Section 4082(b) of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87, Pub. L. 100–203) enacted on December 22, 1987, added subparagraph (b)(5) to section 1869 of the Act to provide for the expedited review of a case by an ALJ when the appellant alleges that there are no material issues of fact in dispute. The provision is intended to bring disputes that are beyond the authority of the ALJ (and which thus need court intervention) to a quicker settlement. The provision was effective with requests for ALJ hearings filed as of February 20, 1988.

Section 4085(i)(5) of OBRA '87 amended section 1842(b)(3)(C) of the Act by substituting the phrase ''less than $500'' for ''not more than $500,'' thereby clarifying the amount in controversy requirement for a carrier hearing. This provision is discussed further in section II.B. of this preamble.

*D. Implementation of OBRA Appeals Amendments Prior to the Promulgation of Regulations*

With the additional review rights granted by OBRA '86 and OBRA '87, appellants under Part B have essentially the same appeal rights as appellants under Part A. To implement the appeals provisions prior to the publication of regulations, HCFA and SSA (the agency responsible for conducting ALJ hearings) published a joint notice on June 1, 1988, at 52 FR 20023, stating that ALJ hearings (and Appeals Council review) under Part B would be governed to the extent possible by existing SSA regulations at 20 CFR part 404, subparts J and R, and existing Part A regulations at 42 CFR part 405, subpart G. The notice provided that, prior to having an ALJ hearing under Part B, an appellant must complete the carrier administrative review process set forth in 42 CFR part 405, subpart H. This process calls for a carrier review and a carrier hearing officer hearing. The notice also stated that ALJ hearings will be held for Medicare Part B claims that meet the amount in controversy requirement established by section 9341 of OBRA '86.

To date, Part B appeals are being processed under the provisions of the June 1, 1988, general notice and the implementing instructions we issued to Medicare contractors (Medicare Carriers Manual (HCFA Pub. 14–3), section 12000ff and Medicare Intermediary Manual (HCFA Pub. 13–3), section 3700ff).

**II. Revisions to the Rules**

*A. Overview*

It is our intention to develop a rule establishing in title 42 all Medicare hearings and appeals procedures, including the relevant procedures currently found in SSA's regulations in title 20. As an interim measure to ensure uniform application of the Part A and Part B appeals regulations, this rule, for the most part, amends subparts G and H of part 405 to incorporate the various appeals provisions found in section 9341(a) of OBRA '86 and section 4082(b) of OBRA '87. (As noted earlier, we do not address section 9313(a)(1) of OBRA' 86 regarding representation of beneficiaries or the portion of section 9341(a) that deals with the aggregation of claims to establish amount in controversy requirements for ALJ hearings.) We also make clarifying changes to subparts G and H of part 405 and to parts 417 and 473.

*B. Specific Revisions*

Carrier Fair Hearing—Prior to OBRA '86, an individual could request a carrier fair hearing (hereinafter, carrier hearing) following the carrier's review determination if there was at least $100 in controversy. The hearing provided by the carrier represented the final level of appeal of a Part B determination. In 1982, the U.S. Supreme Court, in the case of *Schweiker* v. *McClure,* 456 U.S. 188 (1982), upheld the constitutionality of the carrier hearing process.

Section 9341(a)(2) of OBRA '86 amended section 1842(b)(3)(C) of the Act to provide an individual with the opportunity for a carrier hearing when the amount in controversy was ''at least $100, but not more than $500.'' In 1987, we amended our Medicare Carriers Manual (§ 12005) to require that a carrier hearing precede an ALJ hearing regardless of the amount in controversy. HCFA and SSA restated this requirement in their 1988 joint notice, referenced above.

The Secretary's authority to require that appellants whose claims exceed $500 complete the carrier hearing process before obtaining an ALJ hearing was affirmed by a decision of the U.S. Court of Appeals for the Second Circuit in *Isaacs* v. *Bowen,* 865 F.2d 468 (2d Cir. 1989). The Court noted that following our 1987 revision to the Medicare Carriers Manual, Congress held hearings concerning the Medicare appeals process, in which it heard testimony concerning our decision to require carrier hearings in all circumstances. Congress subsequently enacted OBRA '87, which addressed the carrier hearing procedures in two respects. First, the language of section 1842(b)(3)(C) describing the monetary amount for a carrier hearing was changed by substituting the phrase ''less than $500'' for the phrase ''not more than $500.'' Second, Congress authorized the General Accounting Office (GAO) to conduct a cost-effectiveness study of the Secretary's requirement for carrier hearings prior to an ALJ hearing. In light of these provisions, the U.S. Court of Appeals in the Second Circuit found that Congress by its actions had ratified the Secretary's decision to require carrier hearings in cases exceeding $500.

Accordingly, we are specifying, in § 405.801(a), that a carrier hearing always precede an ALJ hearing, including cases in which the amount in controversy at the carrier hearing level exceeds $500. We believe that the continuation of the current carrier hearing process serves a valuable function by assembling evidence, defining issues, and identifying cases of carrier error or determinations that should be changed due to the presentation of new evidence, or for other reasons. Therefore, those cases that reach the ALJ hearing level will involve actual disputes of fact or law and the issues before the ALJ are clearly defined. By ensuring the development of a complete record, the carrier hearing reduces the need for time-consuming and costly development at the ALJ level. Retention of the carrier hearing process results in a substantial reduction in the

number of cases that would otherwise have been appealed to the ALJ level, and more expeditious processing of cases at the ALJ level. Beneficiaries, providers, and suppliers, and the Federal government all benefit from this process. Finally, we would like to note that in its Report dated July 16, 1990 (HRD–90–57), GAO stated that:

> The congressional intent in establishing a $500 threshold for ALJ appeals is unclear. Court opinions initially differed on whether the Congress intended such claims to bypass carrier fair hearings. However, a recent federal district court appeal decision (*Isaacs* v. *Bowen*) concluded that HCFA's instructions requiring claimants with disputed amounts of at least $500 to go through a carrier fair hearing before proceeding to the ALJ were valid.

National Coverage Decisions—The term ''national coverage decision'' (NCD) refers to a statement regarding the coverage status of specific medical services or items that HCFA makes and issues as national policy as provided for in section 1871(a)(2) of the Act. We publish national coverage decisions in the Medicare Coverage Issues Manual (HCFA Pub. 6) and may also publish them in other HCFA program manuals, including the Medicare Intermediary Manual and Medicare Carriers Manual, or in the **Federal Register** as a regulation, notice, or HCFA Ruling. All national coverage decisions are binding upon Medicare carriers, fiscal intermediaries, PROs, HMOs, CMPs, and HCPPs. Prior to OBRA '86, however, national coverage decisions, except those published as HCFA Rulings, were not binding upon ALJs. (ALJs are bound by the provisions of the Medicare law, Departmental regulations and SSA regulations incorporated by Departmental regulations, and other issuances as provided for by law or regulation (such as HCFA Rulings described in 42 CFR 401.108(c), SSA Rulings in 20 CFR 422.406(b)(1), and national coverage decisions based on section 1862(a)(1) of the Act)).

On August 21, 1989, we published a notice in the **Federal Register** (54 FR 34555) listing those current national coverage decisions that had been issued in the Medicare Coverage Issues Manual. In that notice, we explained that unless another statutory basis applies, national coverage decisions are made under the authority of section 1862(a)(1) of the Act which, among other things, prohibits payment under the Medicare program for expenses incurred for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. If a determination to exclude or limit a service is made under another statutory authority—for example, the dental exclusion under section 1862(a)(12) or the cosmetic surgery exclusion under section 1862(a)(10)—that statutory authority for exclusion or limitation constitutes the sole basis for that determination, unless otherwise specified. An exclusion under section 1862(a)(1) of the Act is applicable only if no other statutory basis for exclusion exists.

Section 9341(a)(1)(D) of OBRA '86 added section 1869(b)(3) to the Act to provide that ALJs may not review a national coverage decision (NCD) made under section 1862(a)(1) of the Act concerning whether a particular type or class of items or services is covered under Medicare. This provision was effective for services furnished beginning January 1, 1987.

All national coverage decisions made under section 1862(a)(1) of the Act are subject to the review limitations of section 1869(b)(3). Thus, an ALJ may not disregard, set aside, or otherwise review any national coverage decision (that grants or limits coverage, or excludes an item or service from coverage) made under section 1862(a)(1). Section 1869(b)(3), however, does not apply to cases involving national coverage decisions made under a statutory authority other than 1862(a)(1), such as the exclusion of an item of durable medical equipment because it does not meet the requirements of section 1861(n) of the Act. However, an ALJ will be bound by a national coverage decision made under such other statutory authority when contained in a regulation or in a HCFA Ruling. Moreover, while an ALJ may not disregard, set aside, or otherwise review a national coverage decision based upon section 1862(a)(1), an ALJ remains free to review the facts of a particular case to determine whether the national coverage decision applies to a specific claim for benefits and, if so, to determine whether the national coverage decision has been applied correctly to the claim at issue.

In OBRA '86, Congress also limited judicial review of national coverage decisions in two significant ways. First, in section 1869(b)(3)(B), Congress provided that a court may not hold unlawful or set aside a national coverage decision on the ground that it was not issued in accordance with the notice and comment procedures of the Administrative Procedure Act or section 1871(b) of the Social Security Act. Second, Congress expressly prescribed the extent to which a Federal court may review a challenge to a national coverage decision. Under section 1869(b)(3)(C) of the Act, if, upon a court's initial review of a national coverage decision, the court determines that ''the record is incomplete or otherwise lacks adequate information to support the validity'' of the decision, then the court must remand the matter to the Secretary for additional proceedings to supplement the record and the court may not determine that an item or service is covered except upon review of the supplemented record. If a court remands a national coverage decision to the Secretary because the record is incomplete or inadequate, the Secretary will remand the case to HCFA for further development. On remand from the Secretary, we have the opportunity to supplement the record to include new, updated evidence, and issue a revised decision, if necessary. We then are able to defend the initial national coverage decision or a revised decision based on state-of-the-art technology and evidence. Because ALJs have no role in making agency policy, remand to an ALJ is not appropriate for additional proceedings to supplement the record that was used by us to promulgate the national coverage decision NCD). When on remand, we decide not to revise the NCD, the supplemented record is returned to the court that issued the remand order. When on remand, we decide to revise the NCD, an ALJ will issue a new decision applying the revised NCD to the facts of the claim(s) under consideration. The ALJ's decision will then be subject to a Departmental Appeals Board (DAB) review and, ultimately, judicial review. When an individual case is on court remand, the proceedings must be conducted on an expedited basis.

This final rule amends subpart G, by adding a new § 405.732, and Subpart H, by adding a new § 405.860, to incorporate the review limitations on national coverage decisions described above.

*Review of Payment Methodologies*—Section 9341(a)(1)(D) of OBRA '86 also added section 1869(b)(4) to the Act to prohibit the Federal courts from reviewing certain payment methodologies established by the Secretary. Specifically, a court is not permitted to review a regulation or instruction that relates to a method for determining the amount of payment under Part B if the regulation was promulgated, or the instruction issued, prior to January 1, 1981. We are adding § 405.857(b) to codify the statutory amendment barring judicial review of pre-1981 Part B payment methodologies.

*Departmental Appeals Board*—The level of administrative review between the ALJ hearing and judicial review is now known as Departmental Appeals Board (DAB) review. The review of ALJ decisions in Medicare cases had been performed by the SSA Appeals Council, along with the review of all other SSA cases. However with the establishment of an independent SSA, it was decided that the Medicare functions of the Appeals Council should be exercised within the Department of Health and Human Services (DHHS). That appellate function was assigned to the DAB, which has experience in conducting hearings and appeals for DHHS. We are specifying that the regulations currently in place regarding SSA Appeals Council review, beginning at 20 CFR 404.967, apply to Medicare appeals handled by the DAB. In appealing Part A claims under subpart G of the regulations, appellants must request the DAB to review an ALJ's decision before the case can be taken to court (§ 405.724). Although DAB review is not specifically referred to in the OBRA '86 expansion of the Part B appeals process, we believe this level of review should also apply to the appeal of Part B claims. Therefore, we are adding a new § 405.856 to provide DAB review as the intermediate level of appeal between the ALJ hearing and judicial review for the appeal of Part B claims. If dissatisfied with the ALJ hearing decision or dismissal, an appellant may request that the DAB review that action or the DAB may initiate a review at its discretion. The DAB may deny, dismiss, or grant the appellant's request for review. If the DAB grants the request for review, or elects to review the ALJ decision at its own discretion, it may affirm, reverse, or modify a decision or dismissal made by an ALJ, and/or remand the case to an ALJ for further action. The DAB's authority includes, but is not limited to, the authority to take any action that the ALJ could have taken.

*Expedited Review*—Section 4082(b) of OBRA '87 added section 1869(b)(5) to the Act to provide for the expedited review of cases by ALJs when an appellant alleges that there are no material issues of fact in dispute. The ALJ must make an expedited determination as to whether such facts are in dispute and, if not, must then determine the case expeditiously so that the appellant is given an expedited opportunity to seek judicial review on the issue of law raised. The House Report accompanying OBRA '87 described the purpose of section 4082(b) as follows:

> ALJs may resolve factual disputes and resolve cases by applying the pertinent statutory and regulatory (standards). However, they do not have authority to declare statutes or regulations invalid. That is the responsibility of the Federal courts. If a claimant wishes to challenge the legality of a regulation or the constitutionality of a statute, and there are no factual issues in contention, the claimant should not have to expend the resources and endure the delay entailed in completing an ALJ review that will not resolve the case and will not contribute to its resolution. In that situation, the claimant should be able to present its case expeditiously to a Federal court. In order not to waste the time of the Federal court, however, there needs to be some assurance that there are no questions of fact in contention, since the resolution of the factual dispute might either resolve the case entirely or have an important influence on the proper framing of the legal issues. The Committee bill establishes a procedure for expediting judicial review in appropriate cases. It permits a claimant to allege that there are no factual disputes before the ALJ, and to request the ALJ to make an expedited determination to that effect. If the ALJ made such a determination, he would close the case quickly and permit the claimant to go immediately to Federal court.

H.R. Report No. 391, 100th Cong., 1st Sess. 429 (October 26, 1987).

In light of the above legislative history, we believe that the Congress intended section 1869(b)(5) to provide an expedited review process for all cases in which the ALJ has no authority to grant the relief requested by the appellant, that is, when the only material issue is the constitutionality of a statute or the validity of a regulation, HCFA Ruling, or national coverage decision based on section 1862(a)(1) of the Act that the ALJ is bound to apply to the case. However, the expedited review process would not apply to a challenge to a manual instruction or a policy statement. (ALJs are, among other things, required to apply the Department's regulations, HCFA Rulings, and national coverage decisions based on section 1862(a)(1) of the Act, but are not bound by HCFA manuals or other operating guidelines—see 20 CFR 422.406(b)(1)).

We are amending subparts G and H of part 405 of the regulations to include expedited review of cases in which the appellant challenges the constitutionality of a statute or the validity of a regulation, HCFA Ruling, or national coverage decision based on section 1862(a)(1) of the Act, and there are no material issues of fact in dispute. An expedited appeals process is already in place for part A appellants under § 405.718. That provision was issued in November 1975 in response to the U.S. Supreme Court's decision in *Weinberger* v. *Salfi*, 422 U.S. 749 (1975), which indicated that the Secretary had the authority to determine in particular cases that full exhaustion of administrative remedies was not necessary for a decision to be ''final'' within the meaning of the Act. The Court's decision left it to the Secretary to determine when and how the expedited review might be initiated. Although the § 405.718 review procedures are a reasonable exercise of the Secretary's authority, they are inconsistent in some respects with the expedited review process that the Secretary is required to provide under section 1869(b)(5) of the Act. The current regulation (§ 405.718) allows a Part A appellant to request expedited review after a reconsideration determination has been issued, but does not specifically require that the appellant must first file a request for an ALJ hearing. This is inconsistent with section 1869(b)(5) of the Act, which clearly contemplates that the expedited review process will be initiated as part of the ALJ hearing process and that, for cases pending at the ALJ level, the ALJ will make the expedited determination as to whether there are any material issues of fact in dispute. Accordingly, subpart G and subpart H need to be revised. We are revising the regulations to conform to section 1869(b)(5) of the Act and to specify that, in order for an appellant to qualify for expedited review, a request for an ALJ hearing must be filed and the amount in controversy for court review must be met. Thus, in cases in which a reconsideration determination or a carrier hearing decision has been made, an expedited appeals process may be used in lieu of an ALJ hearing and DAB review (expedited review may also be initiated at the DAB level) if the appellant asserts, and the ALJ or DAB, as appropriate, agrees that the only issue in controversy in the matter is the constitutionality of a statutory provision or the validity of a regulatory provision, HCFA Ruling, or a national coverage decision based on section 1862(a)(1) of the Act. The ALJ's or DAB's determination to this effect exhausts the appellant's administrative remedies. The appellant may then file a civil action in a Federal district court.

*Clarifying Revisions*—We are making other clarifying changes to part 405, subparts G and H; part 417, subpart Q, and part 473, as identified below:

- We define ''after receipt of the notice'', to mean that an appellant is presumed to have received a notice from the carrier, the ALJ, or the DAB 5 days after the date on the notice, unless it is shown that the notice was received

earlier or later (§ 405.802). The purpose of this addition is to provide a definition that is consistent with the terminology used in subpart G.

- We add the word ''carrier'' to various provisions in subpart H to clearly distinguish between carrier hearings and ALJ hearings.
- For consistency with the Part A appeals provisions in subpart G (§ 405.701(c)), § 405.801(c) is revised to indicate that subparts J and R of 20 CFR part 404 are also applicable to ALJ, DAB, and judicial review conducted under subpart H, except to the extent that specific provisions are contained in subpart H.
- One concern arising from a decision of the Supreme Court in *Darby* v. *Cisneros*, 113 S.Ct. 2539 (1993), is that where regulations deem agency action to be ''final,'' a court could find that action to be immediately reviewable even if the agency action is an initial determination or an intermediate appeal step. Therefore, because the term ''final'' decision has been construed to mean that an administrative decision may be subject to immediate judicial review, we have removed in subparts G and H of part 405, subpart Q of part 417, and part 473 all references to ''final'' decisions (except for those decisions made at the DAB level, which are final and immediately reviewable by the courts). The regulations state that non-final administrative decisions (for example, initial determinations, review/reconsideration determinations and carrier hearing decisions) are ''binding'' on the appellants, unless appealed in a timely fashion.
- We replace the terms ''Social Security Administration'' and ''Health Care Financing Administration'' with ''SSA'' or ''HCFA'', as appropriate.

We also make a number of technical revisions for consistency and clarification, as included in the following summary.

### III. Summary of Revisions

Current regulations concerning appeals of Part A claims determinations are at 42 CFR part 405, subpart G, ''Reconsiderations and Appeals Under Medicare Part A.'' Regulations concerning appeals of Part B claims determinations are at 42 CFR part 405, subpart H, ''Appeals under the Medicare Part B Program.'' We revised these two subparts to incorporate the OBRA '86 and OBRA '87 appeals provisions and to make additional clarifying changes. Corresponding clarifying changes are made to regulations at 42 CFR part 417, subpart Q, ''Beneficiary Appeals'' (for enrollees of HMOs/CMPs/HCPPs) and 42 CFR part 473, subpart B, ''Utilization and Quality Control Peer Review Organizations (PRO) Reconsiderations and Appeals.''

We redesignated and revised §§ 405.718 and 405.718a through 405.718e to modify the procedures for using an expedited review process in accordance with section 1869(b)(5) of the Act, and to improve readability.

We revised § 405.724 to specify that the SSA regulations governing Appeals Council review, apply to Medicare appeals handled by the DAB, the level of appeal between the ALJ hearing and judicial review.

We revised § 405.730 to update a statutory reference and to make minor editorial changes.

We added a new § 405.732 to implement the OBRA '86 provision regarding the limitations imposed on ALJs and courts in their review of national coverage decisions issued by HCFA under section 1862(a)(1) of the Act.

We revised § 405.801(a) to reference the statutory provisions allowing Part B claimants to seek an ALJ hearing if the amount remaining in controversy after the carrier hearing is at least $500 and to seek judicial review if the amount remaining in controversy after the ALJ hearing is at least $1,000. This revision conforms the regulations to current carrier manual instructions that require an appellant to complete the carrier fair hearing process before proceeding to an ALJ hearing.

In § 405.801(b), we moved the definition of ''with reasonable promptness'' to the section on definitions at § 405.802 and replaced it with a section stating our longstanding policy on appeal rights for physicians and suppliers who accept assignment and the appeal rights for non-participating physicians who meet the refund provisions under section 1842(l)(1)(A) of the Act.

We revised § 405.801(c) to improve readability and to indicate that subparts J and R of 20 CFR part 404 are applicable to ALJ, DAB, and judicial review conducted under subpart H, except to the extent that specific provisions are contained in subpart H.

We revised § 405.802 to define ''after receipt of the notice'' as being 5 days after the date on the notice, unless it is shown that the notice was received earlier or later. Also, we moved the definition of ''with reasonable promptness'' from § 405.801(b) to this section.

We revised § 405.803 to update the cross-references, and to reorganize the material in list form to improve readability.

In § 405.806 we removed the reference to a ''final'' decision and made minor editorial changes to improve readability.

In § 405.821, we removed an incorrect cross-reference.

In § 405.831, we revised the heading by adding the words ''at carrier hearing''.

In § 405.832, we revised paragraph (c)(1) to correct a statutory reference.

We revised § 405.833 to make minor editorial changes.

We amended § 405.834 by reorganizing the material in list form and, in accordance with the requirements of section 1869(b)(2)(B) of the Act, we added a requirement that the carrier hearing officer's decision includes notification to the parties of their right to an ALJ hearing if at least $500 remains in controversy following the carrier hearing.

We revised § 405.835 to state that a carrier hearing officer's decision is not binding if a request for an ALJ hearing is made.

In § 405.841 we amended paragraph (b) to correct a regulatory cross reference.

We redesignated § 405.860 as § 405.836. We made minor editorial changes to the section.

We added a new § 405.853 titled ''Expedited review'' to explain the procedure under which a case may go to court using the expedited appeals process, in accordance with section 1869(b)(5) of the Act.

We added a new § 405.855 titled ''ALJ hearing'' to incorporate the provisions of section 9341 of OBRA '86 that amended section 1869(b) of the Act to provide Part B appellants with the right to an ALJ hearing. This section specifies the procedures for requesting an ALJ hearing.

We added a new § 405.856 to specify that the SSA regulations governing Appeals Council review, apply to Medicare appeals handled by the DAB, the level of appeal between the ALJ hearing and judicial review. (Corresponding changes are also made in §§ 417.634 and 473.46).

We added a new § 405.857 titled ''Court review'' that: (1) Specifies the general requirements for requesting judicial review; and (2) codifies section 1869(b)(4) of the Act prohibiting judicial review of regulations or instructions issued prior to January 1, 1981, that relate to a method for determining the amount of payment under Part B.

In a new § 405.860, we specify the provisions of section 1869(b)(3) of the Act limiting review by ALJs and the courts of national coverage decisions issued by us under section 1862(a)(1) of the Act.

We revised several sections in subparts G and H of part 405, and in parts 417 and 473 of the regulations to remove the references to ''final'' decisions. This change removes any implication that a lower administrative decision is immediately appealable to a court. The affected sections are: 405.708 (a) and (b), 405.717, 405.750, 405.806, 405.812, 405.832(a), 405.835, 405.842(b), 417.612, 417.626, 473.38, and 473.48.

Additionally, we made several technical changes throughout the subpart and substituted ''SSA'' or ''HCFA'' where the words ''Social Security Administration'' or ''Health Care Financing Administration'' appeared in the affected sections. In a few sections, we inserted ''he or she'' instead of ''he'' to make those particular sections gender neutral. Other technical changes made reflect current nomenclature and conform with our style requirements.

## IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite prior public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed and either the terms and substances of the proposed rule or a description of the subjects and issues involved. The notice of proposed rulemaking can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Since this rule merely codifies provisions of the Social Security Act and existing agency practices that have been upheld by the U.S. Court of Appeals for the Second Circuit and makes various clarifying changes to existing regulations, we believe that it is unnecessary to publish a proposed rule.

Specifically, this rule codifies the various appeal provisions found in section 9341(a) of the Omnibus Reconciliation Act of 1986 and section 4082(b) of the Omnibus Reconciliation Act of 1987. These two provisions contain limitations on the review by ALJs and the courts of national coverage decisions and the statutory authority for an expedited appeals process under Part A and Part B. This rule also expands our regulations to require that appellants whose claims exceed $500 complete the carrier hearing process before obtaining an ALJ hearing, a long-standing agency practice upheld by the U.S. Court of Appeals for the Second Circuit in *Issacs* v. *Bowen,* 865 F.2d 468 (2d Cir. 1989). The rule also makes clarifying changes to subparts G and H of part 405 and to parts 417 and 473. In addition, these changes to the regulations have no impact on program costs. Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule with comment period.

We will consider comments we receive by the date and time specified in the **DATES** section of this preamble from anyone who believes that in making these changes we have deviated from the provisions of the statute or the existing agency practices referenced above. Although we cannot respond to comments individually, if we change these rules as a result of comments, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## V. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

The provisions of this rule codify statutory requirements regarding appeals rights for Part A and Part B appellants and limitations on the review of national coverage decisions by ALJs and the courts.

Because the appeals provisions of this final rule with comment period have been implemented through the 1988 **Federal Register** notice and manual instructions issued to the Medicare carriers, we do not believe that the publication of this rule will have any significant effect on the appeals process.

The provision in § 405.801(a) requiring a carrier hearing prior to an ALJ hearing regardless of the amount in controversy is not statutory, but a long-standing practice that has been affirmed by the U.S. Court of Appeals for the Second Circuit in *Issacs* v. *Bowen,* 865 F. 2d 468 (2d Cir. 1989). The carrier hearing has proven beneficial to appellants and the government by reducing the number of time-consuming and costly cases forwarded to the ALJs. Additionally, in order to provide Part B appellants with the same rights as Part A appellants, we propose to include DAB review as an additional level of review for Part B claims.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

## List of Subjects

*42 CFR Part 405*

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

*42 CFR Part 417*

Administrative practice and procedure, Grant programs-health, Health care, Health facilities, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

*42 CFR Part 473*

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

42 CFR Chapter IV is amended as follows:

## PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405, is amended as set forth below:

### Subpart G—Reconsiderations and Appeals Under Medicare Part A

1. The authority citation for subpart G continues to read as follows:

**Authority:** Secs. 1102, 1151, 1154, 1155, 1869(b), 1871, 1872 and 1879 of the Social Security Act (42 U.S.C. 1302, 1320, 1320c, 1320c-3, 1320c-4, 1395ff(b), 1395hh, 1395ii and 1395pp).

2. Section 405.717 is revised to read as follows:

**§ 405.717 Effect of a reconsidered determination.**

The reconsidered determination is binding upon all parties unless—

(a) A request for a hearing is filed with SSA or HCFA within 60 days after the date of receipt of notice of the reconsidered determination by the parties (for purposes of this section, the date of receipt of notice of the reconsidered determination is presumed to be 5 days after the date of the notice, unless it is shown that the notice was received earlier or later); or

(b) The reconsidered determination is revised in accordance with § 405.750; or

(c) The expedited appeals process is used in accordance with § 405.718.

**§§ 405.718a through 405.718e [Removed]**

3. Sections 405.718a through 405.718e are removed and § 405.718 is revised to read as follows:

**§ 405.718 Expedited appeals process.**

(a) *Conditions for use of expedited appeals process (EAP).* A party may use the EAP to request court review in place of an administrative law judge (ALJ) hearing or Departmental Appeals Board (DAB) review if the following conditions are met:

(1) HCFA has made a reconsideration determination; an ALJ has made a hearing decision; or DAB review has been requested, but a final decision has not been issued.

(2) The filing entity is a party referred to in § 405.718(d).

(3) The party has filed a request for an ALJ hearing in accordance with § 405.722, or DAB review in accordance with 20 CFR 404.968.

(4) The amount remaining in controversy is $1,000 or more.

(5) If there is more than one party to the reconsideration determination or hearing decision, each party concurs, in writing, with the request for the EAP.

(b) *Content of the request for EAP.* The request for the EAP:

(1) Alleges that there are no material issues of fact in dispute; and

(2) Asserts that the only factor precluding a decision favorable to the party is a statutory provision that is unconstitutional or a regulation, national coverage decision under section 1862(a)(1) of the Act, or HCFA Ruling that is invalid.

(c) *Place and time for requesting an EAP.*—(1) *Place for filing request.* The person must file a written request—

(i) At an office of SSA or HCFA; or

(ii) If the person is in the Philippines, at the Veterans Administration Regional Office or with an ALJ; or

(iii) If the person is a qualified railroad retirement beneficiary, at an office of the Railroad Retirement Board.

(2) *Time of filing request.* The party may file a request for the EAP—

(i) If the party has requested a hearing, at any time prior to receipt of the notice of the ALJ's decision;

(ii) Within 60 days after the date of receipt of notice of the ALJ's decision or dismissal, unless the time is extended in accordance with the standards set out in 20 CFR 404.925(c). For purposes of this section, the date of receipt of the notice is presumed to be 5 days after the date on the notice, unless it is shown that the notice was received later; or

(iii) If the party has requested DAB review, at any time prior to receipt of notice of the Board's decision.

(d) *Parties to the EAP.* The parties to the EAP are the persons who were parties to the reconsideration determination and, if appropriate, to the hearing.

(e) *Determination on request for EAP.* (1) For EAP requests initiated at the ALJ level, an ALJ determines whether all conditions of paragraphs (a) and (b) of this section are met.

(2) If a hearing decision has been issued, the DAB determines whether all conditions of paragraphs (a) and (b) of this section are met.

(f) *ALJ or DAB certification for the EAP.* If the party meets the requirements for the EAP, the ALJ or the DAB, as appropriate, certifies the case in writing stating that:

(1) The facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (f)(3) of this section, HCFA's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision or the validity of a regulation, HCFA Ruling, or national coverage decision based on section 1862(a)(1) of the Act.

(4) Except for the provision challenged, the right(s) of the party is established; and

(5) The determination or decision made by the ALJ or DAB is final for purposes of seeking judicial review.

(g) *Effect of ALJ or DAB certification.* (1) Following the issuance of the certification described in paragraph (f) of this section, the party waives completion of the remaining steps of the administrative appeals process.

(2) The 60-day period for filing a civil suit in a Federal district court begins on the date of receipt of the ALJ or DAB certification.

(h) *Effect of a request for EAP that does not result in certification.* If a request for the EAP does not meet all the conditions for use of the process, the ALJ or DAB so advises the party and treats the request as a request for hearing or DAB review, as appropriate.

4. Section 405.724 is revised to read as follows:

**§ 405.724 Departmental Appeals Board (DAB) Review.**

Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are also applicable to DAB review of matters addressed by this subpart.

5. Section 405.730 is revised to read as follows:

**§ 405.730 Court review.**

(a) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a Departmental Appeals Board (DAB) decision or an ALJ decision if the DAB does not review the ALJ decision, may obtain a court review if the amount remaining in controversy is $1,000 or more. A party may obtain court review by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act. The filing procedure is set forth at 20 CFR 422.210.

(b) A party to a reconsidered determination or an ALJ hearing decision may obtain a court review if the amount in controversy is $1,000 or more, and he or she requests and meets the conditions for the expedited appeals process set forth in § 405.718.

6. Section 405.732 is added to read as follows:

**§ 405.732 Review of national coverage decisions (NCDs).**

(a) *General.* (1) HCFA makes NCDs either granting, limiting, or excluding Medicare coverage for a specific medical service, procedure or device. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act. An NCD is binding on all Medicare carriers, fiscal intermediaries, PROs, HMOs, CMPs, and HCPPs when published in HCFA program manuals or the **Federal Register**.

(2) Under section 1869(b)(3) of the Act, only NCDs made under section 1862(a)(1) of the Act are subject to the conditions of paragraphs (b) through (d) of this section.

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

(c) *Review by Court.* (1) A court's review of an NCD is limited to whether the record is incomplete or otherwise

lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. The court may not invalidate an NCD except upon review of the supplemented record.

(2) A Federal court may not hold unlawful or set aside an NCD because it was not issued in accordance with the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) or section 1871(b) of the Act.

(d) *Remands*—(1) *Secretary's action.* When a court remands an NCD matter to the Secretary because the record in support of the NCD is incomplete or otherwise lacks adequate information, the Secretary remands the case to HCFA in order to supplement the record.

(2) *Remand to HCFA.* HCFA supplements the record with new or updated evidence, including additional information from other sources, and may issue a revised NCD.

(3) *Final Actions.* (i) The proceedings to supplement the record are expedited.

(ii) When HCFA does not issue a revised NCD, it returns the supplemented record to the court for review.

(iii) When HCFA issues a revised NCD, it forwards the case to an ALJ who issues a new decision applying the revised NCD to the facts of the claim(s) under consideration. The ALJ's decision is subject to DAB review and, ultimately, judicial review.

7. In § 405.750, the heading and paragraph(b) introductory text are revised to read as follows:

**§ 405.750 Time period for reopening initial, revised, or reconsidered determinations and decisions or revised decisions of an ALJ or the Departmental Appeals Board (DAB); binding effect of determination and decisions.**

* * * * *

(b) *Reopenings concerning a request for payment.* An initial, revised, or reconsidered determination of HCFA, or a decision or revised decision of an ALJ or of the DAB, with respect to an individual's right concerning a request for payment under Medicare Part A, which is otherwise binding under 20 CFR 404.955 or 404.981 and §§ 405.708 or 405.717 of this subpart may be reopened:

* * * * *

## Subpart H—Appeals Under the Medicare Part B Program

8. The authority citation for subpart H continues to read as follows:

**Authority**: Secs. 1102, 1842(b)(3)(C), and 1869(b) of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b)).

9. Section 405.801 is revised to read as follows:

**§ 405.801 Part B appeals—general description.**

(a) The Medicare carrier makes an initial determination when a request for payment for Part B benefits is submitted. If an individual beneficiary is dissatisfied with the initial determination, he or she may request, and the carrier will perform, a review of the claim. Following the carrier's review determination, the beneficiary may obtain a carrier hearing if the amount remaining in controversy is at least $100. The beneficiary is also entitled to a carrier hearing without the benefit of a review determination when the initial request for payment is not being acted upon with reasonable promptness (as defined in § 405.802). Following the carrier hearing, the beneficiary may obtain a hearing before an ALJ if the amount remaining in controversy is at least $500. If the beneficiary is dissatisfied with the decision of the ALJ, he or she may request the Departmental Appeals Board (DAB) to review the case. Following the action of the DAB, the beneficiary may file suit in Federal district court if the amount remaining in controversy is at least $1,000.

(b) The rights of a beneficiary under paragraph (a) of this section to appeal the carrier's initial determination are granted also to—

(1) A physician or supplier that furnishes services to a beneficiary and that accepts an assignment from the beneficiary, or

(2) A physician who meets the conditions of section 1842(l)(1)(A) of the Act pertaining to refund requirements for nonparticipating physicians who have not taken assignment on the claim(s) at issue.

(c) Procedures governing the determinations by SSA as to whether an individual has met basic Part B entitlement requirements are covered in subpart G of this part and 20 CFR part 404, subpart J. Subparts J and R of 20 CFR part 404 are also applicable to ALJ, DAB, and judicial review conducted under subpart H, except to the extent that specific provisions are contained in this subpart.

10. In § 405.802, the undesignated introductory text is republished and two new definitions are added, in alphabetical order, to read as follows:

**§ 405.802 Definitions.**

As used in subpart H of this part, the term—

*After receipt of the notice* means 5 days after the date on the notice, unless it is shown that the notice was received earlier or later.

* * * * *

*With reasonable promptness* means within a period of 60 consecutive days after the receipt by the carrier of a request for payment.

11. Section 405.803 is revised to read as follows:

**§ 405.803 Initial determination.**

(a) Carriers make initial determinations regarding claims for benefits under Medicare Part B.

(b) An initial determination for purposes of this subpart includes determinations such as the following:

(1) Whether services furnished are covered.

(2) Whether the deductible has been met.

(3) Whether the receipted bill or other evidence of payment is acceptable.

(4) Whether the charges for services furnished are reasonable.

(5) If the services furnished to a beneficiary by a physician or a supplier pursuant to an assignment under § 424.55 of this chapter are not covered because they are determined to be not reasonable and necessary under § 411.15(k) of this chapter, whether the beneficiary, physician or supplier, or a physician who meets the requirements of § 411.408, knew or could reasonably have been expected to know at the time the services were furnished that the services were not covered.

(c) The following are not initial determinations for purposes of this subpart:

(1) Any issue or factor for which SSA or HCFA has sole responsibility, for example, whether an independent laboratory meets the conditions for coverage of services; whether a Medicare overpayment claim should be compromised, or collection action terminated or suspended.

(2) Any issue or factor which relates to hospital insurance benefits under Medicare Part A.

12. Section 405.806 is revised to read as follows:

**§ 405.806 Effect of Initial Determination.**

The initial determination is binding upon all parties to the claim for benefits unless the determination is—

(a) Reviewed in accordance with §§ 405.810 through 405.812; or

(b) Revised as a result of a reopening in accordance with § 405.841.

13. Section 405.833 is revised to read as follows:

**§ 405.833 Record of carrier hearing.**

A complete record of the proceedings at the carrier hearing is made. The

testimony is transcribed and copies of other documentary evidence are reproduced in any case when directed by the hearing officer, the carrier, or HCFA. The record will also be transcribed and reproduced at the request of any party to the hearing provided the requesting party bears the cost.

14. Section 405.834 is revised to read as follows:

**§ 405.834 Carrier hearing officer's decision.**

(a) As soon as practicable after the close of a carrier hearing, the carrier hearing officer issues a decision in the case based upon the evidence presented at the hearing or otherwise included in the hearing record. The decision is issued as a written notice to the parties and contains—

(1) Findings of fact,

(2) A statement of reasons, and

(3) Notification to the parties of their right to an ALJ hearing when the amount remaining in controversy is at least $500.

(b) A copy of the decision is mailed to the parties to the hearing at their last known addresses.

15. Section 405.835 is revised to read as follows:

**§ 405.835 Effect of carrier hearing officer's decision.**

The carrier hearing officer's decision is binding upon all parties to the hearing unless—

(a) A request for an ALJ hearing is filed in accordance with § 405.855, or

(b) The decision is revised in accordance with § 405.841.

16. Section 405.860 is redesignated as § 405.836 and revised to read as follows:

**§ 405.836 Authority of the carrier hearing officer.**

The carrier hearing officer, in adjudicating Medicare Part B claims, complies with all of the provisions of, and regulations issued under, title XVIII of the Act, as well as with HCFA Rulings, national coverage decisions, and other policy statements, instructions, and guides issued by HCFA.

17. Section 405.853 is added to read as follows:

**§ 405.853 Expedited appeals process.**

(a) *Conditions for use of expedited appeals process (EAP).* A party may use the EAP set forth in § 405.718 of this chapter to request court review in place of the ALJ hearing or Departmental Appeals Board (DAB) review if the following conditions are met:

(1) The carrier hearing officer has made a decision; an ALJ has made a hearing decision; or DAB review has been requested, but a final decision has not been issued.

(2) The filing entity is a party referred to in § 405.718(d) of this chapter.

(3) The party has filed a request for an ALJ hearing in accordance with § 405.855, or DAB review in accordance with 20 CFR 404.968.

(4) The amount remaining in controversy is $1,000 or more.

(5) If there is more than one party to the hearing decision, each party concurs, in writing, with the request for an EAP.

(b) *Content of the request for EAP.* The request for an EAP:

(1) Alleges that there are no material issues of fact in dispute; and

(2) Asserts that the only factor precluding a decision favorable to the party is a statutory provision that is unconstitutional or a regulation, national coverage decision under section 1862(a)(1) of the Act, or HCFA Ruling that is invalid.

18. Section 405.855 is added to read as follows:

**§ 405.855 ALJ hearing.**

(a) *Right to hearing.* A party to the carrier hearing has a right to a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 days after receipt of the notice of the carrier hearing decision; and

(2) The amount remaining in controversy is $500 or more.

(b) *Place of filing hearing request.* The request for an ALJ hearing must be made in writing and filed with the carrier that issued the decision, a Social Security office, or, in the case of a qualified railroad retirement beneficiary, an office of the Railroad Retirement Board.

(c) *Effect of ALJ hearing decision.* (1) An ALJ's decision is binding on all parties to the hearing unless—

(i) The DAB reviews the ALJ decision;

(ii) The DAB does not review the ALJ decision, and the party requests judicial review;

(iii) The decision is revised by the DAB or an ALJ in accordance with the provisions of § 405.750 of this chapter; or

(iv) The expedited appeals process is used.

19. Section 405.856 is added to read as follows:

**§ 405.856 Departmental Appeals Board (DAB) review.**

Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are applicable to DAB review of matters addressed by this subpart.

20. Section 405.857 is added to read as follows:

**§ 405.857 Court review.**

(a) *General rule.* To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a DAB decision, or an ALJ decision if the DAB does not review the ALJ's decision, may obtain a court review if the amount remaining in controversy is $1,000 or more. A party may obtain court review by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act. The filing procedure is set forth in 20 CFR 422.210.

(b) *Prohibition against court review of certain Part B regulations or instructions.* Under section 1869(b)(4) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Part B if the regulation was promulgated, or the instruction issued, before January 1, 1981.

21. Section 405.860 is added to read as follows:

**§ 405.860 Review of national coverage decisions (NCDs).**

(a) *General.* (1) HCFA makes NCDs either granting, limiting, or excluding Medicare coverage for a specific medical service, procedure or device. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act. An NCD is binding on all Medicare carriers, fiscal intermediaries, PROs, HMOs, CMPs, and HCPPs when published in HCFA program manuals or the **Federal Register**.

(2) Under section 1869(b)(3) of the Act, only NCDs made under section 1862(a)(1) of the Act are subject to the conditions of paragraphs (b) through (d) of this section.

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

(c) *Review by Court.* (1) A court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. The court may not invalidate an NCD except upon review of the supplemented record.

(2) A Federal court may not hold unlawful or set aside an NCD because it was not issued in accordance with the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) or section 1871(b) of the Act.

(d) *Remands*—(1) *Secretary's action.* When a court remands an NCD matter to the Secretary because the record in support of the NCD is incomplete or otherwise lacks adequate information, the Secretary remands the case to HCFA in order to supplement the record.

(2) *Remand to HCFA.* HCFA supplements the record with new or updated evidence, including additional information from other sources, and may issue a revised NCD.

(3) *Final Actions.* (i) The proceedings to supplement the record, are expedited.

(ii) When HCFA does not issue a revised NCD, it returns the supplemented record to the court for review.

(iii) When HCFA issues a revised NCD, it forwards the case to an ALJ who issues a new decision applying the revised NCD to the facts of the claim(s) under consideration. The ALJ's decision is subject to DAB review and, ultimately, judicial review.

## PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

B. Part 417 is amended as set forth below:

1. The authority citation for part 417 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9); and 31 U.S.C. 9701.

2. Section 417.634 is revised to read as follows:

### § 417.634 Departmental Appeals Board (DAB) review.

Any party to the hearing, including the HMO or CMP, who is dissatisfied with the hearing decision, may request the DAB to review the ALJ's decision or dismissal. Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are applicable to DAB review for matters addressed by this subpart.

## PART 473—RECONSIDERATIONS AND APPEALS

C. Part 473 is amended as set forth below:

1. The authority citation for part 473 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 473.46, paragraph (a) is revised to read as follows:

### § 473.46 Departmental Appeals Board (DAB) and judicial review.

(a) The circumstances under which the DAB will review an ALJ hearing decision or dismissal are the same as those set forth at 20 CFR 404.970, (''Cases the Appeals Council will review'').

* * * * *

D. Technical Amendments.

### §§ 405.711, 405.712, 405.714, 405.715, 405.716, 405.720, 405.722, 405.750, 405.807, 405.841, 405.871 [Amended]

1. In §§ 405.711, 405.712, 405.714, 405.715, 405.716, 405.720, 405.722, 405.750(a), 405.807(b), and 405.871, the following changes are made:

a. The words ''Social Security Administration'' are removed wherever they appear, and ''SSA'' is added in their place.

b. The words ''Health Care Financing Administration'' are removed wherever they appear, and ''HCFA'' is added in their place.

### § 405.708, 405.812, 405.832, 405.842, 417.612, 417.626 [Amended]

2. In §§ 405.708(a) and (b), 405.812, 405.832(a), 405.842(b), 417.612(a) and 417.626 the word ''final'' or the words ''final and'' are removed wherever they appear.

### §§ 405.722, 405.747, 417.632 [Amended]

3. Sections 405.722, 405.747, and 417.632(b) are amended by removing the term ''presiding officer'' wherever it appears and adding, in its place, ''ALJ''.

### § 405.821 [Amended]

4. In § 405.821, paragraph (c), is amended by removing the parenthetical phrase ''(see § 405.801)''.

### § 405.831 [Amended]

5. In § 405.831, the heading is amended by adding the words ''at carrier hearing'' before the word ''and''.

### § 405.832 [Amended]

6. In § 405.832, paragraph (c)(1) is amended by removing the reference to ''section 1842(b)(3)(c)'' and adding in its place, ''section 1842(b)(3)(C)''.

### § 405.841 [Amended]

7. In § 405.841, paragraph (b) is amended by removing the parenthetical reference ''(see 20 CFR 404.958)'' and adding in its place the parenthetical reference ''(see 20 CFR 404.988(b) and 404.989)''.

### § 473.38 [Amended]

8. In § 473.38 the following changes are made:

(a) The heading is amended by removing the word ''Finality'' and adding in its place ''Effect''.

(b) In paragraph (a), the words ''final and'' are removed.

### § 473.48 [Amended]

9. a. In § 473.48, in paragraphs (a)(1) and (a)(2), the word ''final'' is removed and ''binding'' is added in its place.

b. In paragraph (b), the word ''final'' is removed.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 7, 1997.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

[FR Doc. 97–12263 Filed 5–9–97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Health Care Financing Administration

## Centers for Disease Control and Prevention

## 42 CFR Part 493

**[HSQ–237–FC]**

**RIN 0938–AH84**

## Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Requirements—Extension of Certain Effective Dates for Clinical Laboratory Requirements Under CLIA

**AGENCY:** Centers for Disease Control and Prevention (CDC) and Health Care Financing Administration (HCFA), HHS.

**ACTION:** Final rule with comment period.

**SUMMARY:** This final rule extends certain effective dates for clinical laboratory requirements in regulations published on February 28, 1992, and subsequently revised December 6, 1994, that implemented provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This rule extends the phase-in date of the quality control requirements applicable to moderate and high complexity tests and extends the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing.

These effective dates are extended to allow the Department additional time to issue revised quality control requirements and to ensure laboratory directors are able to complete certification requirements. These effective date extensions do not reduce