was promulgated, or the instruction issued, before January 1, 1981.

[62 FR 25854, May 12, 1997]

§ 405.860 Review of a national coverage determination (NCD).

(a) *General rule.* (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

(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 is applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, 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 is remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

[68 FR 63716, Nov. 7, 2003]

§ 405.870 Appointment of representative.

A party to an initial determination, informal review or hearing as provided in §§ 405.803 through 405.934, may appoint as his representative in any such proceeding any person qualified under § 405.871. Where the representative is an attorney, in the absence of information to the contrary, his representation that he has such authority shall be accepted as evidence of the attorney's authority to represent a party.

§ 405.871 Qualifications of representatives.

Any individual may be appointed to act as representative in accordance with § 405.870, unless he is disqualified or suspended from acting as a representative in proceedings before the SSA or the CMS or unless otherwise prohibited by law.

[39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.872 Authority of representatives.

A representative, appointed and qualified as provided in §§ 405.870 and 405.871, may make or give, on behalf of the party he represents, any request or notice relative to any proceeding before the carrier including review and hearing. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to the claim of such party to the same extent as such party. Notice to any party or any action, determination, or decision, or request to any party for the production of evidence, shall be sent to the representative of such party.

§ 405.874 Appeals of CMS or a CMS contractor.

A CMS contractor's (that is, a carrier, Fiscal Intermediary or Medicare Administrative Contractor (MAC)) determination that a provider or supplier fails to meet the requirements for Medicare billing privileges.

(a) *Denial of a provider or supplier enrollment application.* If CMS or a CMS contractor denies a provider's or supplier's enrollment application, CMS or the CMS contractor must notify the provider or supplier by certified mail. The notice must include the following:

(1) The reason for the denial in sufficient detail to allow the provider or supplier to understand the nature of its deficiencies.

(2) The right to appeal in accordance with part 498 of this chapter.

(3) The address to which the written appeal must be mailed.

(b) *Revocation of Medicare billing privileges*—(1) *Notice of revocation.* If CMS or a CMS contractor revokes a provider's or supplier's Medicare billing privileges, CMS or a CMS contractor must notify the supplier by certified mail. The notice must include the following:

(i) The reason for the revocation in sufficient detail for the provider or supplier to understand the nature of its deficiencies.

(ii) The right to appeal in accordance with part 498 of this chapter.

(iii) The address to which the written appeal must be mailed.

(2) *Effective date of revocation.* The revocation of a provider's or supplier's billing privileges is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational. When a revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

(3) *Payment after revocation.* Medicare does not pay and the CMS contractor rejects claims for services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

(c) *Appeal rights.* (1) A provider or supplier may appeal the initial determination to deny a provider or supplier's enrollment application, or if applicable, to revoke current billing privileges by following the procedures specified in part 498 of this chapter.

(2) The reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges will be handled by a CMS Regional Office or a contractor hearing officer not involved in the initial determination.

(3) Providers and suppliers have the opportunity to submit evidence related to the enrollment action. Providers and suppliers must, at the time of their request, submit all evidence that they want to be considered.

(4) If supporting evidence is not submitted with the appeal request, the contractor contacts the provider or supplier to try to obtain the evidence.

(5) If the provider or supplier fails to submit this evidence before the contractor issues its decision, the provider or supplier is precluded from introducing new evidence at higher levels of the appeals process.

(d) *Impact of reversal of contractor determinations on claims processing.* (1) Claims for services furnished to Medicare beneficiaries during a period in which the supplier billing privileges were not effective are rejected.

(2) If a supplier is determined not to have qualified for billing privileges in one period but qualified in another, Medicare contractors process claims for services furnished to beneficiaries during the period for which the supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for the recovery of overpayments.

(3) If a revocation of a supplier's billing privilege is reversed upon appeal, the supplier's billing privileges are reinstated back to the date that the revocation became effective.

(4) If the denial of a supplier's billing privileges is reversed upon appeal and becomes binding, then the appeal decision establishes the date that the supplier's billing privileges become effective.

(e) *Reinstatement of provider or supplier billing privileges following corrective action.* If a provider or supplier completes a corrective action plan and provides sufficient evidence to the CMS contractor that it has complied fully with the Medicare requirements, the CMS contractor may reinstate the provider's or supplier's billing privileges. The CMS contractor may pay for services furnished on or after the effective date of the reinstatement. The effective date is based on the date the provider or supplier is in compliance with

all Medicare requirements. A CMS contractor's refusal to reinstate a supplier's billing privileges based on a corrective action plan is not an initial determination under part 498 of this chapter.

(f) *Effective date for DMEPOS supplier's billing privileges.* If a CMS contractor, contractor hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in § 424.57 of this chapter and any other requirements that may apply, the determination establishes the effective date of the billing privileges as not earlier than the date the carrier made the determination to deny the DMEPOS supplier's enrollment application. Claims are rejected for services furnished before that effective date.

(g) *Submission of claims.* A provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed in a binding decision, or in having its billing privileges reinstated, may submit claims to the CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims. If the claims previously were filed timely but were rejected, they are considered filed timely upon resubmission. Previously denied claims for items or services rendered during a period of denial or revocation may be resubmitted to CMS within 1 year after the date of reinstatement or reversal.

(h) *Deadline for processing provider enrollment initial determinations.* Contractors approve or deny complete provider or supplier enrollment applications to approval or denial within the following timeframes:

(1) *Initial enrollments.* Contractors process new enrollment applications within 180 days of receipt.

(2) *Revalidation of existing enrollments.* Contractors process revalidations within 180 days of receipt.

(3) *Change-of-information and reassignment of payment request.* Contractors process change-of-information and reassignment of payment requests within 90 days of receipt.

[73 FR 36460, June 27, 2008, as amended at 73 FR 69932, Nov. 19, 2008]

§ 405.877 Appeal of a categorization of a device.

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the provisions of sections 1869 (a) through (e) and (g) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under Part A or Part B, including an initial determination made by a quality improvement organization under section 1154(a)(2) of the Act or by an entity under contract with the Secretary