

(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.

[62 FR 25854, May 12, 1997]

§ 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.

[62 FR 25854, May 12, 1997]

§ 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.

[62 FR 25854, May 12, 1997]

§ 405.860 Review of national coverage decisions (NCDs).

(a) *General.* (1) CMS 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, QIOs, HMOs, CMPs, and

HCPPs when published in CMS 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 CMS in order to supplement the record.

(2) *Remand to CMS.* CMS 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 CMS does not issue a revised NCD, it returns the supplemented record to the court for review.

(iii) When CMS 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.

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