

#### **§ 426.545**

(b) The Board must dismiss any complaint concerning NCD provision(s) if the following conditions exist:

(1) The Board does not have the authority to rule on that provision under § 426.505(d).

(2) The complaint is not timely. (See § 426.500(b)).

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an LCD except as provided in § 426.476, regarding the Board's review of an ALJ decision. (See § 426.505, regarding the authority of the Board.)

(6) CMS notifies the Board that the NCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (See § 426.523, for requirements for withdrawing a complaint regarding an NCD under review.)

#### **§ 426.545 Witness fees.**

(a) A witness testifying at a hearing before the Board receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If the Board requests expert testimony, the Board is responsible for paying all applicable fees and mileage, unless the expert waives payment.

#### **§ 426.546 Record of hearing.**

The Board must ensure that all hearings are open to the public and are electronically, mechanically, or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the Board relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

#### **42 CFR Ch. IV (10–1–23 Edition)**

#### **§ 426.547 Issuance, notification, and posting of a Board's decision.**

The Board must do the following:

(a) Issue to all parties to the NCD review, within 90 days of closing the NCD review record to the taking of evidence, one of the following:

(1) A written decision, including a description of appeal rights.

(2) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

(b) Make the decision available at the HHS Medicare Internet site. The posted decision does not include any information that identifies any individual, provider of service, or supplier.

#### **§ 426.550 Mandatory provisions of the Board's decision.**

(a) *Findings.* The Board's decision must include one of the following:

(1) A determination that the provision of the NCD is valid under the reasonableness standard.

(2) A determination that the provision of the NCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the NCD, and a rationale for the dismissal.

(4) A determination that the LCD or NCD record is complete and adequate to support the validity of the LCD or NCD provisions under the reasonableness standard.

(b) *Other information.* The Board's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the NCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the NCD was or was not valid based on the application of the reasonableness standard to the record before the Board, including CMS':

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. Where proprietary or privileged data were submitted under seal,

the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the Board's treatment of the sealed evidence must be prepared and kept under seal itself. If the Board decision is appealed to the court, this statement must be provided to the court, under seal.

(6) A statement regarding the right to judicial review.

**§ 426.555 Prohibited provisions of the Board's decision.**

The Board's decision may not do any of the following:

- (a) Order CMS to add any language to a provision or provisions of an NCD.
- (b) Order CMS or its contractors to pay a specific claim.
- (c) Set a time limit for CMS to establish a new or revised NCD.
- (d) Review or evaluate an NCD other than the NCD under review.
- (e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an NCD, or deadlines for implementing these types of changes.
- (f) Order or address how CMS implements an NCD.

**§ 426.557 Optional provisions of the Board's decision.**

When appropriate, the Board may limit a decision holding invalid a specific provision(s) of an NCD to specific clinical indications and for similar conditions.

**§ 426.560 Effect of the Board's decision.**

(a) *Valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party may challenge the final agency action in Federal court.

(b) *Not valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) invalid under the reasonableness standard, then CMS instructs its contractor, M + C organization, or other Medicare man-

aged care organization to provide the following—

(1) *Individual claim review.* (i) If the aggrieved party's claim/appeal(s) was previously denied, the contractor, an M + C organization, or another Medicare managed care organization must re-open the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(ii) If a revised NCD is issued, contractors, M + C organizations, and other Medicare managed care organizations must use the revised NCD in reviewing claim/appeal submissions or request for services delivered or services performed on or after the effective date of the revised NCD.

(iii) If the aggrieved party who sought review has not yet submitted a claim, the contractor must adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances, must be adjudicated without using the NCD provision(s) found invalid.

(2) *Coverage determination relief.* Within 30 days, CMS implements the Board decision. Any change in policy is applied prospectively to requests for service or claims filed with dates of service after the implementation of the Board decision.

**§ 426.562 Notice of the Board's decision.**

After the Board has made a decision regarding an NCD complaint, the Board sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

**§ 426.563 Future new or revised or reconsidered NCDs.**

CMS may not reinstate an NCD provision(s) found to be unreasonable unless CMS has a different basis (such as