

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

**§ 426.565**

additional evidence) than what the Board evaluated.

**§ 426.565 Board's role in making an LCD or NCD review record available.**

Upon a request from a Federal Court, the Board must provide to the Federal Court a copy of the Board's LCD or NCD review record (as described in § 426.587).

**§ 426.566 Board decision.**

A decision by the Board constitutes a final agency action and is subject to judicial review. CMS may not appeal a Board decision.

**§ 426.587 Record for appeal of a Board NCD decision.**

(a) *Elements of the Board's NCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's NCD review record consists of any document or material that the Board compiled or considered

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during an NCD review, including, but not limited to, the following:

- (1) The NCD complaint.
- (2) The NCD and NCD record.
- (3) The supplemental NCD record, if applicable.
- (4) Transcripts of record.
- (5) Any other evidence relevant gathered under § 426.540.
- (6) The Board's decision.
- (b) *Documents excluded from the NCD review record furnished to the court.* The NCD review record furnished to the court maintains the seal on privileged information or proprietary data that is maintained under seal by the Board. In the event a court seeks to obtain or requires disclosure of any documents excluded from the NCD record as privileged information or proprietary data, CMS or the Department seeks to have a protective order issued for those documents, as appropriate.

**PARTS 427–429 [RESERVED]**