

§ 426.484 Mandatory provisions of a Board decision.

(a) *Findings.* A Board decision must include at least one of the following:

- (1) A statement upholding the part(s) of the ALJ decision named in the appeal.
- (2) A statement reversing the part(s) of the ALJ decision named in the appeal.
- (3) A statement modifying the part(s) of the ALJ decision named in the appeal.
- (4) A statement dismissing the appeal of an ALJ decision and a rationale for the dismissal.

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

- (1) The date of issuance.
- (2) The docket number of the review of the ALJ decision.
- (3) A summary of the ALJ's decision.
- (4) A rationale for the basis of the Board's decision.

§ 426.486 Prohibited provisions of a Board decision.

A Board decision must not do any of the following:

- (a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.
- (b) Order CMS or its contractors to pay a specific claim.
- (c) Set a time limit to establish a new or revised LCD.
- (d) Review or evaluate an LCD other than the LCD named in the ALJ's decision.
- (e) Include a requirement for CMS or its contractors that specifies payment, coding, or system changes for an LCD or deadlines for implementing these changes.
- (f) Order CMS or its contractors to implement an LCD in a particular manner.

§ 426.487 Board's record on appeal of an ALJ's decision.

(a) *Elements of the Board's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's LCD review record consists of any document or material that the Board compiled or considered during an LCD review, including, but not limited to, the following:

- (1) The LCD complaint.
 - (2) The LCD and LCD record.
 - (3) The supplemental LCD record, if applicable.
 - (4) Transcripts of record.
 - (5) Any other relevant evidence gathered under § 426.440.
 - (6) The ALJ's decision.
 - (7) The Board's decision.
- (b) *Elements of the Board's LCD appeal record furnished to the court*

under seal. The Board's LCD review record must include, under seal, any proprietary data or privileged information submitted and reviewed in the LCD review process, and that data or information must not be included in the review record furnished to the public, but the information must be maintained, under seal, by the Board.

(c) *Protective order.* In any instance where proprietary data or privileged information is used in the LCD process and a court seeks to obtain or require disclosure of any proprietary data or privileged information contained in the LCD record, CMS or the Department will seek to have a protective order issued for that information, as appropriate.

§ 426.488 Effect of a Board decision.

(a) *The Board's decision upholds an ALJ decision that an LCD is valid or reverses an ALJ decision that an LCD is invalid.* If the Board's decision upholds the ALJ decision that an LCD is valid under the reasonableness standard or reverses an ALJ decision that an LCD is invalid, the contractor or CMS is not required to take any action.

(b) *The Board's decision upholds an ALJ determination that the LCD is invalid.* If the Board's decision upholds an ALJ determination that the LCD is invalid, then the contractor, the M+C organization, or other Medicare managed care organization implements the decision as described in § 426.460(b).

(c) *The Board's decision reverses a dismissal or an ALJ decision that the LCD is valid.* If the Board reverses an ALJ decision dismissing a complaint or holding that an LCD is valid without requiring discovery or the taking of evidence, the Board remands to the ALJ and the LCD review continues. If the Board reverses an ALJ decision holding that an LCD is valid that is reached after the ALJ has completed discovery and the taking of evidence, the Board may remand the case to the ALJ for further proceedings, or the Board may find that the provision(s) of the LCD named in the complaint is (are) invalid under the reasonableness standard, and the contractor, the M+C organization, or other Medicare managed care organization provides the relief in § 426.460(b).

§ 426.489 Board remands.

(a) *Notice when case is remanded to the ALJ.* If the Board remands a case to the ALJ, the Board—

- (1) Notifies each aggrieved party who sought the LCD review, through his or her representative or at his or her last

known address, the contractor, and CMS of the Board's remand decision; and

- (2) Explains why the case is being remanded and the specific actions ordered by the Board.

(b) *Action by an ALJ on remand.* An ALJ takes any action that is ordered by the Board and may take any additional action that is not inconsistent with the Board's remand order.

§ 426.490 Board decision.

A decision by the Board (other than a remand) constitutes a final agency action and is subject to judicial review. Neither the contractor nor CMS may appeal a Board decision.

Subpart E—Review of an NCD**§ 426.500 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an NCD.**

(a) *The complaint.* An aggrieved party may initiate a review of an NCD by filing a written complaint with the Department of Health and Human Services Departmental Appeals Board.

(b) *Timeliness of a complaint.* An NCD complaint is not considered timely unless it is filed with the Board within—

- (1) 6 months of the written statement from each aggrieved party's treating physician, in the case of aggrieved parties who choose to file an NCD challenge before receiving the service; or

- (2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an NCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

- (1) *Beneficiary-identifying information:*
 - (i) Name.
 - (ii) Mailing address.
 - (iii) State of residence, if different from mailing address.
 - (iv) Telephone number, if any.
 - (v) Health Insurance Claim number, if applicable.
 - (vi) Email address, if applicable.
- (2) *If the beneficiary has a representative,* the representative's identifying information must include the following:
 - (i) Name.
 - (ii) Address.
 - (iii) Telephone number.
 - (iv) E-mail address (if any)
 - (v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the