

§ 426.488

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—

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(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 subject of the NCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *NCD-identifying information:*

- (i) Title of NCD being challenged.
- (ii) The specific provision or provisions of the NCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the NCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that supports the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the NCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked "proprietary data," and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints—(1) Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an NCD by filing a single written complaint with the Board if all of the following conditions are met:

- (i) Each aggrieved party named in the joint complaint has a similar med-

ical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same NCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The NCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an NCD—

(i) Before receiving the service, must file with the Board a joint complaint within 6 months of the written statement from each aggrieved party's treating physician; or

(ii) After receiving the service, must file with the Board a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.503 Submitting new evidence once an acceptable complaint has been filed.

Once an acceptable complaint has been filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the Board closes the record.

§ 426.505 Authority of the Board.

(a) The Board conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) The Board defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The Board has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.500.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.