

opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

**§ 426.510 Docketing and evaluating the acceptability of NCD complaints.**

(a) *Docketing the complaint.* The Board does the following upon receiving a complaint regarding an NCD:

- (1) Dockets the complaint.
- (2) Determines whether the complaint is—
  - (i) The first challenge to a particular NCD; or
  - (ii) Related to a pending NCD review.
- (3) Forwards the complaint to the Board member who conducts the review.

(b) *Evaluating the acceptability of the complaint.* The Board determines if the complaint is acceptable by confirming all of the following:

- (1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the Board assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)
- (2) The complaint meets the requirements for a valid complaint in § 426.500 and is not one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the Board determines that the complaint is unacceptable, the Board must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the Board, the Board must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined to be unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the Board determines that the complaint (or

amended complaint) is acceptable, the Board does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for CMS to produce the NCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to CMS.

(3) Requires CMS to send a copy of the NCD record to the Board and all parties to the NCD review within 30 days of receiving the Board's letter, a copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an NCD—*(1) *Criteria for consideration.* If a review is pending regarding a particular NCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the Board consolidates the complaints and conducts a consolidated NCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same NCD, or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the Board's decision.

(2) *Decision to consolidate complaint.* If the Board decides to consolidate complaints, the Board does the following:

(i) Provides notification that the NCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each NCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If the Board decides not to consolidate complaints, the Board conducts separate NCD reviews for each complaint.

(f) *Public notice of complaint and opportunity for interested parties to participate.* (1) If an acceptable complaint is

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the first complaint the Board has received challenging the particular NCD or provision, then the Board posts notice on its Web site that it has received the complaint, specifying a time period for requests to participate in the review process.

(2) If an acceptable complaint challenges an NCD provision when review is pending and no decision has been issued ending the review, the Board may supplement the public notice on its Web site and extend the time for participation requests if indicated.

(3) The Board may allow participation, in the manner and by the deadlines established by the Board, when an NCD is being challenged and the Board decides that—

- (i) The *amicus* participant has a clearly identifiable and substantial interest in the outcome of the dispute;
- (ii) Participation would clarify the issues or otherwise be helpful in resolution of the dispute;
- (iii) Participation does not result in substantial delay; and
- (iv) The petition for participation meets the criteria in § 426.513.

#### § 426.513 Participation as *amicus curiae*.

(a) *Petition for participation.* Any person or organization that wishes to participate as *amicus curiae* must timely file with the Board a petition that concisely states—

- (1) The petitioner's interest in the hearing;
- (2) Who will represent the petitioner; and
- (3) The issues on which the petitioner intends to present argument.

(b) *The nature of the proposed amicus participation.* An *amicus curiae* is not a party to the hearing but may participate by—

- (1) Submitting a written statement of position to the Board before the beginning of the hearing;
- (2) Presenting a brief oral statement or other evidence at the hearing, at the point in the proceedings specified by the Board; and
- (3) Submitting a brief or a written statement when the parties submit briefs.

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(c) *Service by amicus curiae.* Serving copies of any briefs or written statements on all parties.

#### § 426.515 CMS' role in making the NCD record available.

CMS will provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review within 30 days of the receipt of the Board's order.

#### § 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.

Medicare MCOs and Medicaid State agencies may participate in the NCD review process only if they meet the *amicus* participant criteria listed in §§ 426.510(f)(3) and 426.513.

#### § 426.517 CMS' statement regarding new evidence.

(a) CMS may review any new evidence that is submitted, regardless of whether the Board has stayed the proceedings, including but not limited to new evidence:

- (1) Submitted with the initial complaint;
- (2) Submitted with an amended complaint;
- (3) Produced during discovery;
- (4) Produced when the Board consults with scientific and clinical experts; and
- (5) Presented during any hearing.

(b) CMS may submit a statement regarding whether the new evidence is significant under § 426.340, by a deadline set by the Board.

#### § 426.518 NCD record furnished to the aggrieved party.

(a) *Elements of the NCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the NCD record consists of any document or material that CMS considered during the development of the NCD, including, but not limited to, the following:

- (1) The NCD being challenged.
- (2) Any medical evidence considered on or before the date the NCD was issued, including, but not limited to, the following:
  - (i) Scientific articles.
  - (ii) Technology assessments.
  - (iii) Clinical guidelines.