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(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.

(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.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(v) MCAC transcripts.

(3) Public comments received during the notice and comment period.

(4) Coverage decision memoranda.

(5) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the NCD record not furnished to the aggrieved party.* The NCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.519 NCD record furnished to the Board.

The NCD record furnished to the Board includes—

(a) Documents included in § 426.518(a); and

(b) Privileged information and proprietary data considered that must be filed with the Board under seal.

§ 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.

(a) CMS may withdraw an NCD or NCD provision under review before the date the Board issues a decision regarding that NCD. Withdrawing an NCD or NCD provision under review has the same effect as a decision under § 426.560(b).

(b) CMS may revise an NCD under review to remove or amend the NCD provision listed in the complaint through the reconsideration process before the date the Board issues a decision regarding that NCD. Revising an NCD under review to remove the NCD provision in question has the same effect as a decision under § 426.560(b).

(c) CMS must notify the Board within 48 hours of—

(1) Withdrawing an NCD or NCD provision that is under review; or

(2) Issuing a revised or reconsidered version of the NCD that is under review.

(d) If CMS issues a revised or reconsidered NCD, CMS forwards a copy of the revised/reconsidered NCD to the Board.

(e) The Board must take the following actions upon receiving a notice that CMS has withdrawn or revised/reconsidered an NCD under review:

(1) If, before the Board issues a decision, the Board receives notice that CMS has withdrawn the NCD or revised the NCD to completely remove the provision in question, the Board must dismiss the complaint and inform the aggrieved party (ies) who sought the review that he or she or they will receive individual claim review without the retired/withdrawn provisions.

(2) If, before the Board issues a decision, the Board receives notice that CMS has revised the NCD provision in question but has not removed it altogether, the Board must continue the review based on the revised NCD. In this case, CMS must send a copy of the supplemental record to the Board and all parties. In that circumstance, the Board permits the aggrieved party to respond to the revised NCD and the supplemental record.

§ 426.523 Withdrawing a complaint regarding an NCD under review.

(a) *Circumstance under which an aggrieved party withdraws a complaint regarding an NCD.* An aggrieved party who filed a complaint regarding an NCD may withdraw the complaint before the Board issues a decision regarding that NCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an NCD.* To withdraw a complaint regarding an NCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the Board (see § 426.500) and CMS. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.503.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw a complaint regarding an NCD*—(1) *NCD reviews involving one aggrieved party.* If the Board receives a withdrawal notice regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing the complaint under § 426.544 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *NCD reviews involving joint complaints.* If the Board receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an NCD before the