

§ 426.418 LCD record furnished to aggrieved party.

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

- (1) The LCD being challenged.
- (2) Any medical evidence considered on or before the date the LCD 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.
- (3) Comment and Response Document (a summary of comments received by the contractor concerning the draft LCD).
- (4) An index of documents considered that are excluded under paragraph (b) of this section.

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

- (1) Proprietary data or privileged information.
- (2) Any new evidence.

§ 426.419 LCD record furnished to the ALJ.

The LCD record furnished to the ALJ includes the following:

- (a) Documents included in § 426.418(a).
- (b) Privileged information and proprietary data considered that must be filed with the ALJ under seal.

§ 426.420 Retiring or revising an LCD under review.

(a) A contractor may retire an LCD or LCD provision under review before the date the ALJ issues a decision regarding that LCD. Retiring an LCD or LCD provision under review has the same effect as a decision under § 426.460(b).

(b) A contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint

through the reconsideration process before the date the ALJ issues a decision regarding that LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under § 426.460(b).

(c) A contractor must notify the ALJ within 48 hours of—

- (1) Retiring an LCD or LCD provision that is under review; or
- (2) Issuing a revised version of the LCD that is under review.

(d) If the contractor issues a revised LCD, the contractor forwards a copy of the revised LCD to the ALJ.

(e) The ALJ must take the following actions upon receiving a notice that the contractor has retired or revised an LCD under review:

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

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

§ 426.423 Withdrawing a complaint regarding an LCD under review.

(a) *Circumstance under which an aggrieved party may withdraw a complaint regarding an LCD.* An aggrieved party who filed a complaint regarding an LCD may withdraw the complaint before the ALJ issues a decision regarding that LCD. 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 LCD.* To withdraw a complaint regarding an LCD, the aggrieved party who filed the

§ 426.425

complaint must send a written withdrawal notice to the ALJ (see § 426.400), CMS (if applicable), and the applicable contractor. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.403.

(c) *Actions the ALJ must take upon receiving a notice announcing the intent to withdraw a complaint regarding an LCD*—(1) *LCD reviews involving one aggrieved party.* If the ALJ receives a withdrawal notice regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing the complaint under § 426.444 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *LCD reviews involving joint complaints.* If the ALJ receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing only that aggrieved party from the complaint under § 426.444. The ALJ continues the LCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated LCD reviews.* If the ALJ receives a notice from an aggrieved party who is part of a consolidated LCD review withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ removes that aggrieved party from the consolidated LCD review and issues a decision dismissing that aggrieved party's complaint under § 426.444. The ALJ continues the LCD review if there are one or more aggrieved parties who does not withdraw from the joint complaint.

§ 426.425 LCD review.

(a) *Opportunity for the aggrieved party, after his or her review of the LCD record, to state why the LCD is not valid.* Upon receipt of the contractor's LCD record, the aggrieved party files a statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD under the reasonableness standard. This statement must be submitted to

42 CFR Ch. IV (10–1–23 Edition)

the ALJ and to the contractor, or CMS, as appropriate, within 30 days (or within the additional time as allowed by the ALJ for good cause shown) of the date the aggrieved party receives the contractor's LCD record.

(b) *Contractor response.* The contractor has 30 days after receiving the aggrieved party's statement to submit a response to the ALJ in order to defend the LCD.

(c) *ALJ evaluation.* (1) After the aggrieved party files a statement and the contractor responds, as described in § 426.425(a) and § 426.425(b), or the time for filing has expired, the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process.

(3) If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ permits discovery and the taking of evidence in accordance with §§ 426.432 and 426.440 and evaluates the LCD in accordance with § 426.431.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an LCD record has been supplemented, except that discovery and the taking of evidence are not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.431 ALJ's review of the LCD to apply the reasonableness standard.

(a) *Required steps.* To review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard, an ALJ must:

(1) Confine the LCD review to the provision(s) of the LCD raised in the aggrieved party's complaint.

(2) Conduct a hearing, unless the matter can be decided on the written record.

(3) Close the LCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision under § 426.482 that involves the same LCD provision(s), same