

(2) Sets a reasonable timeframe—

(i) For LCDs, of not more than 90 days, by which the contractor completes the reconsideration; or

(ii) For NCDs, in compliance with the timeframes specified in section 1862(1) of the Act, by which CMS completes the reconsideration.

(f) The ALJ or Board lifts the stay in proceedings and continues the review on the challenged provision(s) of the original LCD or NCD, including the new evidence in the review record, if the contractor or CMS—

(1) Informs the ALJ or Board that a reconsideration is not initiated; or

(2) Does not meet—

(i) For LCDs, the 90-day reconsideration timeframe; or

(ii) For NCDs, the reconsideration timeframe specified by the Board, in compliance with section 1862(1) of the Act.

(g) If an LCD or NCD is reconsidered and revised within the timeframe allotted by the ALJ or Board, then the revised LCD or NCD and any supplement to the LCD or NCD record is forwarded to the ALJ or the Board and all parties and the review proceeds on the LCD or NCD.

[68 FR 63716, Nov. 7, 2003, as amended at 70 FR 70335, Nov. 21, 2005; 71 FR 9461, Feb. 24, 2006]

Subpart D—Review of an LCD

§ 426.400 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an LCD.

(a) *The complaint.* An aggrieved party may initiate a review of an LCD by filing a written complaint with the office designated by CMS on the Medicare Web site, <http://www.medicare.gov/cov-erage/static/appeals.asp>.

(b) *Timeliness of a complaint.* An LCD complaint is not considered timely unless it is filed with the office designated by CMS within—

(1) 6 months of the issuance of a written statement from each aggrieved party's treating practitioner, in the case of aggrieved parties who choose to file an LCD 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 LCD 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) E-mail address, if applicable.

(2) *If the beneficiary has a representative,* the representative-identifying information must include the following:

(i) Name.

(ii) Mailing 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 LCD. 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) *LCD-identifying information:*

(i) Name of the contractor using the LCD.

(ii) Title of LCD being challenged.

(iii) The specific provision (or provisions) of the LCD 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 LCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that support the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the LCD 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 LCD by filing a single written complaint with the ALJ if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical 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 LCD.

(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 LCD-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 LCD—

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

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

§ 426.403 Submitting new evidence once an acceptable complaint is filed.

Once an acceptable complaint is filed, the aggrieved party may submit additional new evidence without with-

drawing the complaint until the ALJ closes the record.

§ 426.405 Authority of the ALJ.

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

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

(c) The ALJ 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 § 426.400.

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

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on his or her own motion concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceedings in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in § 426.340.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when

there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an LCD review for failure to comply with an ALJ order or procedural request without good cause shown.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The ALJ does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings on his or her own motion or on the motion of a non-aggrieved party.

(2) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(3) Review any decisions by contractors to develop a new or revised LCD.

(4) Conduct a review of any draft, retired, archived, template, or suggested LCDs.

(5) Conduct a review of any policy that is not an LCD, as defined in § 400.202 of this chapter.

(6) Conduct a review of any NCD according to section 1869(f)(1)(A)(i) of the Act.

(7) Conduct a review of the merits of an unacceptable LCD complaint as discussed in § 426.410.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his/her representative;

(ii) CMS and/or the contractor; and

(iii) Experts called by the parties or the ALJ.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel the contractor to conduct studies, surveys, or develop new information to support an LCD record.

(12) Deny a contractor the right to reconsider, revise or retire an LCD.

(13) Find invalid applicable Federal statutes, regulations, rulings, or NCDs.

(14) Enter a decision specifying terms to be included in an LCD.

§ 426.406 *Ex parte* contacts.

No party or person (except employees of the ALJ's office) communicates in any way with the ALJ on any substantive matter at issue in a case, unless on notice and 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.

§ 426.410 Docketing and evaluating the acceptability of LCD complaints.

(a) *Docketing the complaint.* The office designated by CMS does the following upon receiving a complaint regarding an LCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular LCD; or

(ii) Related to a pending LCD review.

(3) Forwards the complaint to the ALJ that conducts the review. In cases related to pending reviews, the complaint generally is forwarded to the ALJ who is conducting the review.

(b) *Evaluating the acceptability of the complaint.* The ALJ assigned to the LCD review 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 ALJ 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 § 426.400 and does not challenge one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the ALJ determines that the complaint is unacceptable, the ALJ 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 time-frame as determined by the ALJ, the ALJ must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined 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 ALJ determines that the complaint (or amended complaint) is acceptable, the ALJ 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 the contractor to produce the LCD 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 the applicable contractor and CMS.

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

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

(i) The complaints are in regard to the same provision(s) of the same LCD 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 ALJ's decision.

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

(i) Provides notification that the LCD 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 LCD complaint as introduced in the consolidated review.

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

[68 FR 63716, Nov. 7, 2003; 68 FR 65346, Nov. 19, 2003]

§ 426.415 CMS' role in the LCD review.

CMS may provide to the ALJ, and all parties to the LCD review, information identifying the person who represents the contractor or CMS, if necessary, in the LCD review process.

§ 426.416 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the LCD review.

Medicare MCOs and Medicaid State agencies have no role in the LCD review process. However, once the ALJ has issued its decision, the decision is made available to all Medicare MCOs and State agencies.

§ 426.417 Contractor's statement regarding new evidence.

(a) The contractor may review any new evidence that is submitted, regardless of whether the ALJ has stayed the proceedings, including but not limited to—

(1) New evidence submitted with the initial complaint;

(2) New evidence submitted with an amended complaint;

(3) New evidence produced during discovery;

(4) New evidence produced when the ALJ consults with scientific and clinical experts; and

(5) New evidence presented during any hearing.

(b) The contractor may submit a statement regarding whether the new evidence is significant under § 426.340, within such deadline as the ALJ may set.

§ 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

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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

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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

specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.447.

(b) *Optional steps.* The ALJ may do the following to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint:

(1) Consult with appropriate scientific or clinical experts concerning evidence.

(2) Consider any previous ALJ decision made under § 426.447 regarding the same provision(s) of the LCD under review and for the same clinical conditions.

(c) *Authority for ALJs in LCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an LCD, the ALJ must follow all applicable laws, regulations, rulings, and NCDs.

§ 426.432 Discovery.

(a) *General rule.* If the ALJ orders discovery, the ALJ must establish a reasonable timeframe for discovery.

(b) *Protective order—(1) Request for a protective order.* Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The ALJ granting of a protective order.* The ALJ may grant a motion for a protective order if (s)he finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;
(ii) Is unduly costly or burdensome;
or

(iii) Unduly delays the proceeding.

(c) *Types of discovery available.* A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific LCD.

(d) *Types of documents.* For the purpose of this section, the term “documents” includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section is interpreted to require the creation of a document.

(e) *Types of discovery not available.* Requests for admissions, depositions, or any other forms of discovery, other

than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information and proprietary data.* The ALJ must not, under any circumstance, order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification.* The ALJ notifies all parties in writing when the discovery period closes.

§ 426.435 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.440 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the ALJ not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by the witnesses or documents and whether other evidence may establish without the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The ALJ may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the ALJ grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the ALJ.

(2) Include the docket number and title of the LCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

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(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the “Commissioner of Social Security” shall be considered a reference to the “Secretary.”

§ 426.440 Evidence.

(a) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The ALJ must exclude evidence that (s)he determines is clearly irrelevant, immaterial, or unduly repetitive.

(c) The ALJ may accept privileged information or proprietary data, but must maintain it under seal.

(d) The ALJ may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The ALJ may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the ALJ or a party to the proceeding, or the reports will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the ALJ for good cause shown, all documents and other evi-

dence offered or taken for the record are open to examination by all parties.

§ 426.444 Dismissals for cause.

(a) The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a pre-hearing conference (the pre-hearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the ALJ without good cause shown.

(b) The ALJ must dismiss any complaint concerning LCD provision(s) if the following conditions exist:

(1) The ALJ does not have the authority to rule on that provision under § 426.405(d).

(2) The complaint is not timely. (See § 426.400(b).)

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an NCD. (See § 426.405, regarding the authority of the ALJ.)

(6) The contractor notifies the ALJ that the LCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (See § 426.423 for requirements related to withdrawing a complaint regarding an LCD under review.)

§ 426.445 Witness fees.

(a) A witness testifying at a hearing before an ALJ receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If an ALJ requests expert testimony, the appropriate office overseeing the ALJ is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.446 Record of hearing.

The ALJ must ensure that all hearings are open to the public and are

electronically, mechanically or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the ALJ relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.447 Issuance and notification of an ALJ's decision.

An ALJ must issue to all parties to the LCD review, within 90 days of closing the LCD review record to the taking of evidence, one of the following:

- (a) A written decision, including a description of appeal rights.
- (b) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

§ 426.450 Mandatory provisions of an ALJ's decision.

(a) *Findings.* An ALJ's decision must include one of the following:

- (1) A determination that the provision of the LCD is valid under the reasonableness standard.
- (2) A determination that the provision of the LCD is not valid under the reasonableness standard.
- (3) A statement dismissing the complaint regarding the LCD and a rationale for the dismissal.
- (4) A determination that the LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard.

(b) *Other information.* An ALJ's decision must include all of the following:

- (1) The date of issuance.
- (2) The docket number of the LCD review.
- (3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.
- (4) A basis for concluding that the LCD was or was not valid based on the application of the reasonableness standard to the record before the ALJ, including the contractor's:

- (i) Findings of fact.
- (ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. If proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the ALJ's treatment of the sealed evidence must be prepared and kept under seal itself. If the ALJ decision is appealed to the Board, this statement must be provided to the Board under seal.

(6) A statement regarding appeal rights.

§ 426.455 Prohibited provisions of an ALJ's decision.

An ALJ's decision may 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 for CMS or its contractors to establish a new or revised LCD.
- (d) Review or evaluate an LCD other than the LCD under review.
- (e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an LCD, or deadlines for implementing these types of changes.
- (f) Order or address how a contractor(s) must implement an LCD.

§ 426.457 Optional provisions of an ALJ's decision.

When appropriate, the ALJ may limit a decision holding invalid a specific provision(s) of an LCD to specific clinical indications and for similar conditions.

§ 426.458 ALJ's LCD review record.

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

- (1) The LCD complaint.

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- (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.
- (b) *Elements of the ALJ's LCD review record furnished to the Board under seal.* The ALJ's review record must include, under seal, any proprietary data or privileged information maintained under seal, and such data or information must not be included in the review record furnished to the public.

§ 426.460 Effect of an ALJ's decision.

(a) *Valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party or parties may appeal that (those) part(s) of the ALJ decision to the Board under § 426.465.

(b) *Not valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor or CMS under § 426.465(b), the contractor, the M + C organization, or other Medicare managed care organization must provide the following—

(1) *Individual claim review.* (i) If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), and if the party's claim or appeal(s) was previously denied, the contractor, an M + C organization or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid.

(ii) If a revised LCD is issued, the contractor, the M + C organization, and any other Medicare managed care organization within the contractor's jurisdiction uses the revised LCD in reviewing claim or appeal submissions or request for services delivered or services performed on or after the effective date of the revised LCD.

(iii) If the aggrieved party who sought the review has not yet submitted a claim, the contractor adjudicates the claim without using the

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provision(s) of the LCD that the ALJ found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances is adjudicated without using the LCD provision(s) found invalid.

(2) *Coverage determination relief.* If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), the contractor implements the ALJ decision within 30 days. Any change in policy applies prospectively to requests for service or claims filed with dates of service after the implementation of the ALJ decision.

§ 426.462 Notice of an ALJ's decision.

After the ALJ has made a decision regarding an LCD complaint, the ALJ sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.463 Future new or revised LCDs.

The contractor may not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated.

§ 426.465 Appealing part or all of an ALJ's decision.

(a) *Circumstances under which an aggrieved party may appeal part or all of an ALJ's decision.* An aggrieved party (including one or more aggrieved parties named in a joint complaint and an aggrieved party who is part of a consolidated LCD review) may appeal to the Board any part of an ALJ's decision that does the following:

(1) States that a provision of an LCD is valid under the reasonableness standard; or

(2) Dismisses a complaint regarding an LCD (except as prohibited in paragraph (b) of this section).

(b) *Circumstance under which a contractor or CMS may appeal part or all of an ALJ's decision.* A contractor or CMS may appeal to the Board any part of an

ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable.

(c) *Stay of an implementation pending appeal.* (1) If an ALJ's decision finds a provision or provisions of an LCD unreasonable, an appeal by a contractor or CMS stays implementation as described under § 426.460(b) until the Board issues a final decision.

(2) The appeal request must be submitted to the Board in accordance with paragraph (e) of this section.

(d) *Circumstances under which an ALJ's decision may not be appealed.* An ALJ's decision dismissing a complaint is not subject to appeal in either of the following circumstances:

(1) The contractor has retired the LCD provision(s) under review.

(2) The aggrieved party who filed the complaint has withdrawn the complaint.

(e) *Receipt of the appeal by the Board.* Unless there is good cause shown, an appeal described in paragraphs (a) or (b) of this section must be filed with the Board within 30 days of the date the ALJ's decision was issued.

(f) *Filing an appeal.* (1) To file an appeal described in paragraph (a) of this section, an aggrieved party, who sought LCD review, a contractor, or CMS must send the following to the Board:

(i) The full names and addresses of the parties, including the name of the LCD.

(ii) The date of issuance of the ALJ's decision.

(iii) The docket number that appears on the ALJ's decision.

(iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.

(2) If an appeal described in paragraph (a) of this section is filed with the Board later than the date described in paragraph (c) of this section, it must include a rationale stating why the Board must accept the late appeal.

(3) An appeal described in paragraph (a) of this section must include a statement explaining why the ALJ's decision should be reversed.

§ 426.468 Decision to not appeal an ALJ's decision.

(a) Failure to timely appeal without good cause shown waives the right to challenge any part(s) of the ALJ's decision under § 426.465.

(b) Unless the Board finds good cause shown for late filing, an untimely appeal is dismissed.

(c) If a party does not timely appeal any part(s) of the ALJ's decision on an LCD review to the Board, as provided in this subpart, then the ALJ's decision is final and not subject to further review.

§ 426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions.

(a) *Docketing the appeal.* The Board does the following upon receiving an appeal of part or all of an ALJ's decision:

(1) Dockets the appeal either separately or with similar appeals.

(2) Assigns a docket number.

(b) *Evaluating the acceptability of the appeal.* The Board determines if the appeal is acceptable by confirming that the appeal meets all of the criteria in § 426.465.

(c) *Unacceptable appeal.* If the Board determines that an appeal is unacceptable, the Board must dismiss the appeal.

(d) *Acceptable appeal.* If the Board determines that an appeal is acceptable, the Board does the following:

(1) Sends a letter to the appellant to acknowledge that the appeal is acceptable, and informs them of the docket number.

(2) Forwards a copy of the appeal and the letter described in paragraph (d)(1) of this section to all parties involved in the appeal.

(3) Requires the ALJ to send a copy of the ALJ's LCD review record (maintaining any sealed documents) to the Board and a copy of the public record to all parties involved in the appeal.

(e) *No participation as amicus curiae.* The Board may not allow participation by amicus participants in the review of an LCD.

§ 426.476

§ 426.476 Board review of an ALJ's decision.

(a) *Review steps.* If the Board determines that an appeal is acceptable, the Board—

(1) Permits the party that did not file the appeal an opportunity to respond to the appeal;

(2) Hears oral argument (which may be held by telephone) if the Board determines that oral argument would be helpful to the Board's review of the ALJ decision;

(3) Reviews the LCD review record and the parties' arguments; and

(4) Issues a written decision either upholding, modifying, or reversing the ALJ decision, or remanding the case to the ALJ for further proceedings.

(b) *Standard of review*—(1) *In general.* The Board determines whether the ALJ decision contains any material error, including any failure to properly apply the reasonableness standard.

(2) If the ALJ erred in determining that the contractor's record was complete and adequate to support the validity of the LCD, the Board remands the case to the ALJ for discovery and the taking of evidence.

(3) If a party alleges a prejudicial error of procedure, and the Board determines that such an error was made, the Board may remand the case to the ALJ for further proceedings consistent with the Board decision or may take other appropriate steps to correct the procedural error.

(4) Harmless error is not a basis for reversing an ALJ decision.

(c) *Scope of review.* In reaching its conclusions, the Board is bound by applicable laws, regulations, and NCDs.

(d) *Dismissal as moot.* The Board dismisses an appeal by an aggrieved party of an ALJ decision finding that an LCD was valid if the contractor notifies the Board that it has retired the LCD or revised the LCD to remove the LCD provision in question.

§ 426.478 Retiring or revising an LCD during the Board's review of an ALJ's decision.

A contractor may retire or revise an LCD during the Board's review of an ALJ's decision using the same process described in § 426.420. If an LCD is retired or revised to remove completely

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the challenged provision(s), the aggrieved party who sought the review is entitled to individual claim review provided at § 426.488(b).

§ 426.480 Withdrawing an appeal of an ALJ's decision.

(a) *Withdrawal of an appeal of an ALJ's decision.* A party who filed an appeal of an ALJ's decision may withdraw the appeal before the Board issues a decision regarding the ALJ's decision.

(b) *Process of withdrawing an appeal of an ALJ's decision.* To withdraw an appeal of an ALJ's decision, the party who filed the appeal must send a written notice announcing the intent to withdraw to the Board and to any other party.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw an appeal of an ALJ's decision*—(1) *Appeals involving one aggrieved party, or initiated by CMS or a contractor.* If the Board receives a notice withdrawing an appeal of an ALJ's decision before the Board has issued its decision, the Board must issue a decision dismissing the appeal.

(2) *Appeals involving joint complaints.* If the Board receives a notice withdrawing an appeal from an aggrieved party who is named in a joint appeal before the Board issues its decision, the Board must issue a decision dismissing only that aggrieved party from the appeal. The Board must continue its review of the ALJ's decision for the remaining aggrieved party or parties.

§ 426.482 Issuance and notification of a Board decision.

The Board must issue a written decision, including a description of appeal rights, to all parties to the review of the ALJ decision.

§ 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 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