

## § 425.800

limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the statutory and regulatory requirements of the Shared Savings Program.

(2) If the ACO misuses or discloses data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the DUA, it will no longer be eligible to receive data under subpart H of this part, may be terminated from the Shared Savings Program under § 425.218, and may be subject to additional sanctions and penalties available under the law.

(b) [Reserved]

### Subpart I—Reconsideration Review Process

#### § 425.800 Preclusion of administrative and judicial review.

(a) There is no reconsideration, appeal, or other administrative or judicial review of the following determinations under this part:

(1) The specification of quality and performance standards under §§ 425.500, 425.502, 425.510, and 425.512.

(2) The assessment of the quality of care furnished by an ACO under the performance standards established in § 425.502 or § 425.512, as applicable.

(3) The assignment of Medicare fee-for-service beneficiaries under Subpart E of this part.

(4) The initial determination or revised initial determination of whether an ACO is eligible for shared savings, and the amount of such shared savings, including the initial determination or revised initial determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO in accordance with section 1899(d) of the Act, as implemented under §§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, 425.610, and 425.652.

(5) The percent of shared savings specified by the Secretary and the limit on the total amount of shared savings established under §§ 425.604, 425.605, 425.606, and 425.610.

(6) The termination of an ACO for failure to meet the quality perform-

#### 42 CFR Ch. IV (10-1-24 Edition)

ance standards established under § 425.502 or § 425.512, as applicable.

(7) The termination of a beneficiary incentive program established under § 425.304(c).

(b) [Reserved]

[76 FR 67973, Nov. 2, 2011, as amended at 81 FR 38017, June 10, 2016; 83 FR 68082, Dec. 31, 2018; 85 FR 85044, Dec. 28, 2020; 87 FR 70249, Nov. 18, 2022]

#### § 425.802 Request for review.

(a) An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under § 425.800 by requesting a reconsideration review by a CMS reconsideration official.

(1) An ACO that wants to request reconsideration review by a CMS reconsideration official must submit a written request by an authorized official for receipt by CMS within 15 days of the notice of the initial determination.

(i) If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(ii) Failure to submit a request for reconsideration within 15 days will result in denial of the request for reconsideration.

(2) The reconsideration review must be held on the record (review of submitted documentation).

(b) An ACO that requests a reconsideration review for termination will remain operational throughout the review process.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32845, June 9, 2015]

#### § 425.804 Reconsideration review process.

(a) *Acknowledgement of reconsideration review request.* The reconsideration official sends an acknowledgement of the reconsideration review request to the ACO and CMS that includes the following:

(1) Review procedures.

(2) Procedures for submission of evidence including format and timelines.

(3) A briefing schedule that permits each party to submit only one written brief, including any evidence, for consideration by the reconsideration official in support of the party's position. The submission of any additional briefs

or supplemental evidence will be at the sole discretion of the reconsideration official.

(b) *Burden of proof, standard of proof, and standards of review.* The burden of proof is on the ACO to demonstrate to the reconsideration official with convincing evidence that the initial determination is not consistent with the requirements of this part or applicable statutory authority.

(c) *Reconsideration official.* The reconsideration official is an independent CMS official who did not participate in the initial determination that is being reviewed.

(d) *Evidence.* (1) The reconsideration official's review will be based only on evidence submitted by the reconsideration official's requested deadline, unless otherwise requested by the reconsideration official.

(2) Documentation submitted for the record as evidence cannot be documentation that was not previously submitted to CMS by the applicable deadline and in the requested format.

(3) All evidence submitted by the ACO and CMS, in preparation for the reconsideration review will be shared with the other party to the hearing.

(e) The reconsideration official will notify CMS and the ACO of his or her recommendation.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32845, June 9, 2015]

**§ 425.806 On-the-record review of reconsideration official's recommendation by independent CMS official.**

(a)(1) If CMS or the ACO disagrees with the recommendation of the reconsideration official, it may request an on the record review of the initial determination and recommendation by an independent CMS official who was not involved in the initial determination or the reconsideration review process.

(2) In order to request an on-the-record review, CMS or the ACO must submit an explanation of why it disagrees with the recommendation by the timeframe and in the format indicated in the reconsideration official's recommendation letter.

(b) The on-the-record review process is based only on evidence presented during the reconsideration review.

(c) The independent CMS official considers the recommendation of the reconsideration official and makes a final agency determination.

**§ 425.808 Effect of independent CMS official's decision.**

(a) The decision of the independent CMS official is final and binding.

(b) The reconsideration review process under this subpart must not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

**§ 425.810 Effective date of decision.**

(a) If the initial determination denying an ACO's application to participate in the Shared Savings Program is upheld, the application will remain denied based on the effective date of the original notice of denial.

(b) If the initial determination to terminate an agreement with an ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

(c) If the initial determination to terminate an ACO is reversed, the ACO is reinstated into the Shared Savings Program, retroactively back to the original date of termination.

**PART 426—REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS**

**Subpart A—General Provisions**

Sec.

- 426.100 Basis and scope.
- 426.110 Definitions.
- 426.120 Calculation of deadlines.
- 426.130 Party submissions.

**Subpart B [Reserved]**

**Subpart C—General Provisions for the Review of LCDs and NCDs**

- 426.300 Review of LCDs, NCDs, and deemed NCDs.

**Pt. 426**

- 426.310 LCD and NCD reviews and individual claim appeals.
- 426.320 Who may challenge an LCD or NCD.
- 426.325 What may be challenged.
- 426.330 Burden of proof.
- 426.340 Procedures for review of new evidence.

**Subpart D—Review of an LCD**

- 426.400 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an LCD.
- 426.403 Submitting new evidence once an acceptable complaint is filed.
- 426.405 Authority of the ALJ.
- 426.406 *Ex parte* contacts.
- 426.410 Docketing and evaluating the acceptability of LCD complaints.
- 426.415 CMS' role in the LCD review.
- 426.416 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the LCD review.
- 426.417 Contractor's statement regarding new evidence.
- 426.418 LCD record furnished to the aggrieved party.
- 426.419 LCD record furnished to the ALJ.
- 426.420 Retiring or revising an LCD under review.
- 426.423 Withdrawing a complaint regarding an LCD under review.
- 426.425 LCD review.
- 426.431 ALJ's review of the LCD to apply the reasonableness standard.
- 426.432 Discovery.
- 426.435 Subpoenas.
- 426.440 Evidence.
- 426.444 Dismissals for cause.
- 426.445 Witness fees.
- 426.446 Record of hearing.
- 426.447 Issuance and notification of an ALJ's decision.
- 426.450 Mandatory provisions of an ALJ's decision.
- 426.455 Prohibited provisions of an ALJ's decision.
- 426.457 Optional provisions of an ALJ's decision.
- 426.458 ALJ's LCD review record.
- 426.460 Effect of an ALJ's decision.
- 426.462 Notice of an ALJ's decision.
- 426.463 Future new or revised LCDs.
- 426.465 Appealing part or all of an ALJ's decision.
- 426.468 Decision to not appeal an ALJ's decision.
- 426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions.
- 426.476 Board review of an ALJ's decision.
- 426.478 Retiring or revising an LCD during the Board's review of an ALJ's decision.
- 426.480 Withdrawing an appeal of an ALJ's decision.
- 426.482 Issuance and notification of a Board decision.

**42 CFR Ch. IV (10-1-24 Edition)**

- 426.484 Mandatory provisions of a Board decision.
- 426.486 Prohibited provisions of a Board decision.
- 426.487 Board's record on appeal of an ALJ's decision.
- 426.488 Effect of a Board decision.
- 426.489 Board remands.
- 426.490 Board decision.

**Subpart E—Review of an NCD**

- 426.500 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an NCD.
- 426.503 Submitting new evidence once an acceptable complaint is filed.
- 426.505 Authority of the Board.
- 426.506 *Ex parte* contacts.
- 426.510 Docketing and evaluating the acceptability of NCD complaints.
- 426.513 Participation as *amicus curiae*.
- 426.515 CMS' role in making the NCD record available.
- 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.
- 426.517 CMS' statement regarding new evidence.
- 426.518 NCD record furnished to the aggrieved party.
- 426.519 NCD record furnished to the Board.
- 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.
- 426.523 Withdrawing a complaint regarding an NCD under review.
- 426.525 NCD review.
- 426.531 Board's review of the NCD to apply the reasonableness standard.
- 426.532 Discovery.
- 426.535 Subpoenas.
- 426.540 Evidence.
- 426.544 Dismissals for cause.
- 426.545 Witness fees.
- 426.546 Record of hearing.
- 426.547 Issuance, notification, and posting of a Board's decision.
- 426.550 Mandatory provisions of the Board's decision.
- 426.555 Prohibited provisions of the Board's decision.
- 426.557 Optional provisions of the Board's decision.
- 426.560 Effect of the Board's decision.
- 426.562 Notice of the Board's decision.
- 426.563 Future new or revised or reconsidered NCDs.
- 426.565 Board's role in making an LCD or NCD review record available.
- 426.566 Board decision.
- 426.587 Record for appeal of a Board NCD decision.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

SOURCE: 68 FR 63716, Nov. 7, 2003, unless otherwise noted.

**Subpart A—General Provisions****§ 426.100 Basis and scope.**

(a) *Basis.* This part implements sections 1869(f)(1) and (f)(2) of the Act, which provide for the review of LCDs, NCDs, and certain determinations that are deemed to be NCDs by statute.

(b) *Scope.* This subpart establishes the requirements and procedures for the review of LCDs and NCDs.

**§ 426.110 Definitions.**

For the purposes of this part, the following definitions apply:

*Aggrieved party* means a Medicare beneficiary, or the estate of a Medicare beneficiary, who—

(1) Is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare + Choice plan, or in another Medicare managed care plan);

(2) Is in need of coverage for a service that is denied based on an applicable LCD (in the relevant jurisdiction) or an NCD, regardless of whether the service was received; and

(3) Has obtained documentation of the need by the beneficiary's treating physician.

*Board* means the Departmental Appeals Board.

*Clinical and scientific experts* mean experts that are consulted by the ALJ or Board as independent and impartial individuals, with significant experience and/or published work, pertaining to the subject of the review.

*Contractor* means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue.

*Deemed NCD* means a determination that the Secretary makes, in response to a request for an NCD under section 1869(f)(4)(B) and (C) of the Act, that no national coverage or noncoverage determination is appropriate, or the Secretary's failure to meet the deadline under section 1869(f)(4)(A)(iv) of the Act.

*New evidence* means clinical or scientific evidence that was not previously considered by the contractor or

CMS before the LCD or NCD was issued.

*Party* means an aggrieved party, which is an individual, or estate who has a right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS.

*Proprietary data* and *Privileged information* means information from a source external to CMS or a contractor, or protected health information, that meets the following criteria:

(1) It is ordinarily protected from disclosure in accordance with 45 CFR part 164, under the Trade Secrets Act (18 U.S.C. 1905) or under Exemptions 4 or 5 of the Freedom of Information Act (5 U.S.C. 552) as specified in 45 CFR 5.31(d) and (e).

(2) The party who possesses the right to protection of the information from public release or disclosure has not provided its consent to the public release or disclosure of the information. Any information submitted by the public that is not marked proprietary is not considered proprietary.

*Reasonableness standard* means the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

*Supplemental LCD/NCD record* is a record that the contractor/CMS provides to the ALJ/Board and any aggrieved party and consists of all materials received and considered during a reconsideration. Materials that are already in the record before the ALJ/Board (for example, new evidence presented in the taking of evidence or hearing) need not be provided but may be incorporated by reference in the supplement to the LCD/NCD record. The contractor/CMS may provide statements, evidence, or other submissions to the ALJ/Board during the proceedings, as provided elsewhere in these regulations, but these submissions are not considered as supplementing the LCD/NCD record.

## § 426.120

*Treating physician* means the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge.

[68 FR 63716, Nov. 7, 2003, as amended at 85 FR 72909, Nov. 16, 2020]

### § 426.120 Calculation of deadlines.

In counting days, Saturdays, Sundays, and Federal holidays are included. If a due date falls on a Saturday, Sunday, or Federal holiday, the due date is the next Federal working day.

### § 426.130 Party submissions.

Any party submitting material, except for material for which a privilege is asserted, or proprietary data, to the ALJ or the Board after that party's initial challenge must serve the material on all other parties at the same time.

### Subpart B [Reserved]

## Subpart C—General Provisions for the Review of LCDs and NCDs

### § 426.300 Review of LCDs, NCDs, and deemed NCDs.

(a) Upon the receipt of an acceptable LCD complaint as described in § 426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in § 426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

### § 426.310 LCD and NCD reviews and individual claim appeals.

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate,

## 42 CFR Ch. IV (10-1-24 Edition)

regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

### § 426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

### § 426.325 What may be challenged.

(a) Only LCDs or NCDs (including deemed NCDs) that are currently effective may be challenged.

(b) Some items are not reviewable under this part, including the following:

(1) Pre-decisional materials, including—

(i) Draft LCDs;  
(ii) Template LCDs or suggested LCDs; and

(iii) Draft NCDs, including national coverage decision memoranda.

(2) Retired LCDs or withdrawn NCDs.

(3) LCD or NCD provisions that are no longer in effect due to revisions or reconsiderations.

(4) Interpretive policies that are not an LCD or NCD.

(5) Contractor decisions that are not based on section 1862(a)(1)(A) of the Act.

(6) Contractor claims processing edits.

(7) Payment amounts or methodologies.

(8) Procedure coding issues, including determinations, methodologies, definitions, or provisions.

(9) Contractor bulletin articles, educational materials, or Web site frequently asked questions.

(10) Any M + C organization or managed care plan policy, rule, or procedure.

(11) An individual claim determination.

**Centers for Medicare & Medicaid Services, HHS****§ 426.400**

(12) Any other policy that is not an LCD or an NCD as set forth in § 400.202 of this chapter.

**§ 426.330 Burden of proof.**

During an LCD or NCD review, an aggrieved party bears the burden of proof and the burden of persuasion for the issue(s) raised in a complaint. The burden of persuasion is judged by a preponderance of the evidence.

**§ 426.340 Procedures for review of new evidence.**

(a) The process for review of new evidence is initiated once the ALJ/Board completes the taking of evidence.

(b) If an aggrieved party has submitted new evidence pertaining to the LCD/NCD provision(s) in question, and the ALJ or the Board finds that evidence admissible, the ALJ or the Board reviews the record as a whole and decide whether the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard.

(c) If the ALJ or the Board determines that the new evidence does not have the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard, this evidence is included in the review record, and the review goes forward to a decision on the merits.

(d) If the ALJ or the Board determines that the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD or NCD provision(s) in question under the reasonableness standard, then the ALJ or the Board—

(1) Stays the proceedings and ensures that the contractor or CMS, whichever is appropriate, has a copy of the new evidence for its examination; and

(2) Allows the contractor/CMS 10 days, generally, to examine the new evidence, and to decide whether the contractor or CMS initiates a reconsideration.

(e) If the contractor or CMS informs the ALJ or the Board by the end of the 10 days that a reconsideration is initiated, and then the ALJ or the Board—

(1) Continues the stay in proceedings; and

(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/coverage/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

## § 426.403

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 de-

## 42 CFR Ch. IV (10-1-24 Edition)

vice 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 withdrawing 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.

## § 426.406

(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.

## 42 CFR Ch. IV (10-1-24 Edition)

(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

**Centers for Medicare & Medicaid Services, HHS****§ 426.420**

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

## § 426.423

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 complaint must send a written with-

## 42 CFR Ch. IV (10-1-24 Edition)

drawal 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 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.

## § 426.435

(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.

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

## 42 CFR Ch. IV (10-1-24 Edition)

(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 evidence 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

## § 426.455

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.
- (2) The LCD and LCD record.
- (3) The supplemental LCD record, if applicable.

## 42 CFR Ch. IV (10-1-24 Edition)

- (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 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 provi-

sion (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

## § 426.470

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 Board review of an ALJ's decision.

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

## 42 CFR Ch. IV (10-1-24 Edition)

(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 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

## § 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—

## 42 CFR Ch. IV (10-1-24 Edition)

(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.

## § 426.506

(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 its 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 proceeding 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 this regulation.

(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 NCD review for failure to comply with a Board order or procedural request without good cause.

(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 Board does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings, except as provided by § 426.465.

(2) Conduct an NCD review or conduct NCD hearings on its own motion or on the motion of a nonaggrieved party.

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

(4) Review any decisions by CMS to develop a new or revised NCD.

(5) Conduct a review of any draft NCDs, coverage decision memoranda, or withdrawn NCDs.

(6) Conduct a review of the merits of an unacceptable NCD complaint as discussed in § 426.510.

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

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

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

(ii) CMS and/or the contractor;

(iii) Experts called by the parties or Board; or

(iv) Third parties with a clearly identifiable and substantial interest in the outcome of the dispute who have petitioned for and been granted permission by the Board to participate in the proceedings as *amicus curiae*.

(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 CMS to conduct studies, surveys, or develop new information to support an NCD record.

(12) Deny CMS the right to reconsider, revise, or withdraw an NCD.

(13) Subject to the timely filing requirements, deny an aggrieved party, CMS, or its contractor the right to appeal an ALJ decision.

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

(15) Enter a decision specifying terms to be included in an NCD.

## 42 CFR Ch. IV (10-1-24 Edition)

### § 426.506 *Ex parte* contacts.

No party or person (except Board staff) communicates in any way with the Board 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.

**§ 426.510 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 time-frame 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 consolidation.* 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

## § 426.513

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.

## 42 CFR Ch. IV (10-1-24 Edition)

(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

## § 426.525

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 date the Board issued a decision regarding that NCD, the Board issues a decision dismissing only that aggrieved party from the complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated NCD reviews.* If the Board receives a notice from an aggrieved party who is part of a consolidated NCD review withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board removes that aggrieved party from the consolidated NCD review and issues a decision dismissing that aggrieved party's complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

### § 426.525 NCD review.

(a) *Opportunity for the aggrieved party after his or her review of the NCD record to state why the NCD is not valid.* Upon receipt of the NCD record, the aggrieved party files a statement explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard. This statement must be submitted to the Board and CMS, within 30 days (or within additional time as allowed by the Board for good cause shown) of the date the aggrieved party receives the NCD record.

(b) *CMS response.* CMS has 30 days, after receiving the aggrieved party's statement, to submit a response to the Board in order to defend the NCD.

(c) *Board evaluation.* (1) After the aggrieved party files a statement and CMS responds as described in § 426.525(a) and § 426.525(b), or the time for filing has expired, the Board applies the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD.

## 42 CFR Ch. IV (10-1-24 Edition)

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

(3) If the Board determines that the NCD record is not complete and adequate to support the validity of the NCD, the Board permits discovery and the taking of evidence in accordance with § 426.532 and § 426.540, and evaluate the NCD in accordance with § 426.531.

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

### § 426.531 Board's review of the NCD to apply the reasonableness standard.

(a) *Required steps.* The Board must do the following to review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard:

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

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

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

(4) Treat as precedential any previous Board decision made under § 426.547 that involves the same NCD provision(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.547.

(b) *Optional steps.* The Board may consult with appropriate scientific or clinical experts concerning clinical and scientific evidence to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint.

(c) *Authority for the Board in NCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an NCD, the Board must follow all applicable laws and regulations, as well as NCDs other than the one under review.

**§ 426.532 Discovery.**

(a) *General rule.* If the Board orders discovery, the Board 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 Board granting of a protective order.* The Board may grant a motion for a protective order if it finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;  
 (ii) Is unduly costly or burdensome; or  
 (iii) Will unduly delay 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 NCD.

(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 will be 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 or proprietary data.* The Board must not under any circumstances 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 Board notifies all parties in writing when the discovery period will be closed.

**§ 426.535 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 § 426.540 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the Board 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 witnesses or documents and state whether those facts could be established by evidence other than by 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 Board 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 Board grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the presiding Board member.

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

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

(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 Board 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."

**§ 426.540****§ 426.540 Evidence.**

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

(b) The Board must exclude evidence that it determines is clearly irrelevant or immaterial, or unduly repetitive.

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

(d) The Board may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The Board 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 Board or a party to the proceeding, or the report will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the Board for good cause shown, all documents and other evidence offered or taken for the record is open to examination by all parties.

**§ 426.544 Dismissals for cause.**

(a) The Board may, at the request of any party, or on its 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 prehearing may be conducted by telephone) or hearing without good cause shown.

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

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

(1) The Board does not have the authority to rule on that provision under § 426.505(d).

(2) The complaint is not timely. (See § 426.500(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

**42 CFR Ch. IV (10-1-24 Edition)**

statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an LCD except as provided in § 426.476, regarding the Board's review of an ALJ decision. (See § 426.505, regarding the authority of the Board.)

(6) CMS notifies the Board that the NCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (See § 426.523, for requirements for withdrawing a complaint regarding an NCD under review.)

**§ 426.545 Witness fees.**

(a) A witness testifying at a hearing before the Board 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 the Board requests expert testimony, the Board is responsible for paying all applicable fees and mileage, unless the expert waives payment.

**§ 426.546 Record of hearing.**

The Board 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 Board 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.

**§ 426.547 Issuance, notification, and posting of a Board's decision.**

The Board must do the following:

(a) Issue to all parties to the NCD review, within 90 days of closing the NCD review record to the taking of evidence, one of the following:

(1) A written decision, including a description of appeal rights.

(2) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

**Centers for Medicare & Medicaid Services, HHS****§ 426.560**

(b) Make the decision available at the HHS Medicare Internet site. The posted decision does not include any information that identifies any individual, provider of service, or supplier.

**§ 426.550 Mandatory provisions of the Board's decision.**

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

(1) A determination that the provision of the NCD is valid under the reasonableness standard.

(2) A determination that the provision of the NCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the NCD, and a rationale for the dismissal.

(4) A determination that the LCD or NCD record is complete and adequate to support the validity of the LCD or NCD provisions under the reasonableness standard.

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

(1) The date of issuance.

(2) The docket number of the NCD 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 NCD was or was not valid based on the application of the reasonableness standard to the record before the Board, including CMS':

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. Where 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 Board's treatment of the sealed evidence must be prepared and kept under seal itself. If the Board decision is appealed to the court, this statement must be provided to the court, under seal.

(6) A statement regarding the right to judicial review.

**§ 426.555 Prohibited provisions of the Board's decision.**

The Board's decision may not do any of the following:

(a) Order CMS to add any language to a provision or provisions of an NCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS to establish a new or revised NCD.

(d) Review or evaluate an NCD other than the NCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an NCD, or deadlines for implementing these types of changes.

(f) Order or address how CMS implements an NCD.

**§ 426.557 Optional provisions of the Board's decision.**

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

**§ 426.560 Effect of the Board's decision.**

(a) *Valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party may challenge the final agency action in Federal court.

(b) *Not valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) invalid under the reasonableness standard, then CMS instructs its contractor, M + C organization, or other Medicare managed care organization to provide the following—

(1) *Individual claim review.* (i) If the aggrieved party's claim/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 NCD that the Board found invalid.