

§ 426.100

- 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.

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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.

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,