

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

■ 5. Revise § 405.860 to read as follows:

§ 405.860 Review of a national coverage determination (NCD).

(a) *General rule.* (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD is applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case is remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

■ 6. Add part 426 to subchapter B to read as follows:

PART 426—REVIEWS OF LOCAL AND NATIONAL 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.
- 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.
- 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)