

party's estate to file a complaint within 120 days of receipt of the denial notice.

In § 426.110 we define the following:

- “Board” to mean the Departmental Appeals Board.

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

- “Contractor” as a carrier (including a DMERC) or a fiscal intermediary (FI) (including an RHHI) that has jurisdiction for the LCD at issue.

- “Deemed NCD” as a determination that the Secretary makes in response to a request for an NCD by an aggrieved party 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. Section 1869(f)(4)(C) of the Act deems certain decisions of the Secretary to be NCDs for purposes of administrative review. Please see our proposed rule for further discussion of deemed NCDs (67 FR 5434).

- “New evidence” is clinical or scientific evidence that was not previously considered by the contractor or by us before the LCD or NCD was issued.

- “Party” as an aggrieved party, which is an individual or estate who has the right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS. In the case of an LCD review, we may choose whether to be a party in the review along with or instead of the contractor. These reviews involve challenges to important CMS policies that may impact many beneficiaries. We note that we are always a party to an NCD review and contractors would not participate in an NCD review.

- “Proprietary data” and “privileged information” are 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 pursuant to 45 CFR Part 164, under the Trade Secrets Act (18 U.S.C. 1905), or under Exemption 4 or 5 of the Freedom of Information Act (5 U.S.C. 552) as specifically interpreted in our Departmental regulations at 45 CFR 5.65, and (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 that information. Members of the public that send us proprietary data must mark these documents as such, and include the

legal basis for any such assertion. Any information received from the public that is not designated as “proprietary data” will not be considered “proprietary.”

- “Reasonableness standard” is 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/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 such submissions are not considered as supplementing the LCD/NCD record.

- “Treating physician” is 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.

In § 426.120, we explain how deadlines are calculated. In § 426.130, we explain that any documents submitted to the ALJ/Board after the initial challenge, excluding privileged or proprietary data, must also be served on all other parties simultaneously. These sections have been added to provide additional guidance in implementing the requirements of this final rule.

#### C. Subpart B (Reserved)

We are reserving subpart B.

#### D. Subpart C (General Provisions for the Review of LCDs and NCDs)

The general provisions common to both the review of LCDs and NCDs are established in subpart C. In § 426.300(a), we state that the review of a challenged provision (or provisions) of an LCD is conducted by an ALJ only upon the receipt of an acceptable complaint as described in § 426.400. We also state in § 426.300(b) that the review of a

challenged provision (or provisions) of an NCD is conducted by the Board only upon the receipt of an acceptable complaint as described in § 426.500. An acceptable complaint must be filed with the applicable adjudicator by an aggrieved party. Additionally, § 426.300(c) would allow for the review of deemed NCDs, a process that would parallel the review of NCDs.

In § 426.310(a), we explain that LCD and NCD reviews are largely independent of the claims appeal processes set forth in part 405, subparts F and G; part 417, subpart Q; and part 422, subpart M. In § 426.310(b), we require the aggrieved party to notify the ALJ/Board of any pending claim or appeal related to the LCD/NCD appeal.

In § 426.320(a), we explain that only an aggrieved party may initiate a review to challenge an LCD or NCD (including a deemed NCD), or an existing specific provision or provisions of an LCD or an NCD by filing an acceptable complaint. In § 426.320(b), we explain that neither an ALJ nor the Board will recognize as valid any attempt to assign rights under section 1869(f) of the Act.

In § 426.325, we describe the policies that are, and are not, subject to this review. Under this requirement, an aggrieved party would be allowed only to challenge an LCD or NCD. Conversely, an aggrieved party may not use this process to challenge anything that does not meet the definition of an LCD or an NCD (*see* § 426.325). For example, draft LCDs or NCDs, and coverage decision memos would be excluded from review as they are predecisional. LCD and NCD provisions that are no longer in effect are excluded from review. Other interpretive policies that are not LCDs or NCDs would also not be subject to review under this process. Provisions of contractor policies that are based on things other than the reasonable and necessary provision of section 1862(a)(1)(A) of the Act, such as benefit category determinations, statutory exclusion determinations, and HCPCS/Revenue Code coding determinations, would not be subject to review under this part. In addition, any M+C or other managed care plan policy, rule, or procedure is not subject to review under this process. Individual claim determinations by adjudicators are also not subject to review under this process.

In § 426.330, we state that the aggrieved party filing the complaint bears the burden of proof and the burden of persuasion for the issue or issues raised in the complaint. The burden of persuasion will be judged by a preponderance of the evidence.