

Section 426.340 provides procedures to be followed after discovery and the taking of evidence are complete. If an aggrieved party has submitted new evidence pertaining to an LCD or NCD which the ALJ or the Board finds admissible, the ALJ/Board must review the new evidence and decide if the new evidence has the potential to significantly affect the evaluation of the LCD/NCD provision(s) in question under the reasonableness standard. 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 LCD/NCD provisions, the review shall go forward to a decision on the merits. If the ALJ or the Board decides that the new evidence has the potential to significantly affect the evaluation of the policy, the ALJ or the Board must stay the proceedings and send the new evidence to the contractor or CMS. The contractor or CMS has 10 days upon receiving the evidence from the ALJ or the Board to provide a statement indicating whether a revision/reconsideration will be initiated. If the contractor or CMS informs the ALJ or the Board that a revision/reconsideration has been or will be initiated, then the stay shall continue and the ALJ or the Board shall set appropriate timeframes (not more than 90 days) by which the revision/reconsideration will be completed. If the contractor or CMS chooses not to initiate a revision/reconsideration and does not retire/withdraw the LCD/NCD, the ALJ or the Board proceedings will continue on the original LCD/NCD.

*E. Subpart D (The Review of an LCD) and Subpart E (The Review of an NCD)*

In subparts D and E, we set forth the procedures for the review of LCDs and NCDs, respectively. The process for LCD and NCD reviews is largely the same with the exception of the following:

- LCDs are based on section 1862(a)(1)(A) of the Act; NCDs may also be based on other statutory provisions.
- LCD reviews are conducted by an ALJ; NCD reviews are conducted by the Board.
- ALJs and contractors participate in an LCD review; there is no role for ALJs or contractors in an NCD review.
- We are not always a party to an LCD review, but are always a party to an NCD review.
- Amicus participation is not allowed when reviewing an LCD, but may be allowed when reviewing an NCD.
- Board decisions regarding NCDs will be made available on the Medicare Internet site, without beneficiary-identifying information.

For the purpose of this preamble, we consolidate the discussion of the requirements and policy decisions when possible. Sections 426.400 and 426.500 contain the requirements for filing an acceptable complaint regarding a provision or provisions of an LCD and an NCD, respectively. In both cases, a complaint must be in writing and must be from an aggrieved party. In § 426.400(a), we require that complaints regarding LCDs be submitted to the office designated by CMS on the Medicare Web site, <http://www.medicare.gov/coverage/static/appeals.asp> (information on the designated office will be available by calling 1-800-Medicare) or by filing a complaint concerning an NCD with the Board of HHS (see § 426.500(a)). Should the appropriate office change in the future, this regulation shall be read to conform to that change, and the information will be made publicly available. We have simplified and clarified the complaint-filing procedures.

In § 426.400(b) and § 426.500(b), we explain the circumstances under which a complaint will be considered timely received. A complaint will not be considered timely unless it is received by the office designated by CMS/Board of HHS within—(1) 6 months of the written statement from each aggrieved party's treating physician for aggrieved parties who choose to file an LCD/NCD challenge before receiving the service; or (2) 120 days of the initial denial notice for aggrieved parties who choose to file an LCD/NCD challenge after receiving the service.

In § 426.400(c)(1) and § 426.500(c)(1), we require a valid complaint to contain beneficiary-identifying information and a written statement from the treating physician indicating that the beneficiary needs the service that is the subject of the LCD/NCD. We also require the information in § 426.400(c)(2) and (c)(3) and § 426.500(c)(2) and (c)(3), which is necessary to identify the LCD or NCD (or the specific provision or provisions of the LCD or NCD) that is (are) adversely affecting the aggrieved party. In addition, we require a statement from the aggrieved party that explains the rationale for the complaint.

In § 426.400(c)(4) and § 426.500(c)(4), we also allow the aggrieved party to submit copies of material clinical or scientific evidence that supports the complaint. We require that any proprietary data submitted be marked as "proprietary data" and include the legal basis for so identifying it. In addition, in § 426.400(c)(4) and § 426.500(c)(4), we require that, in order to be considered and given weight in LCD or NCD

reviews, any such proprietary data submitted by a manufacturer of a drug or device must include an affidavit that the data consists of true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device. In § 426.400(d), we state that two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the ALJ if the conditions in § 426.400(d)(1)(i) and (ii) are met. Similarly, in § 426.500(d), we state that two or more aggrieved parties may initiate the review of an NCD by filing a single complaint with the Board if the conditions in § 426.500(d)(1)(i) and (ii) are met.

Based on public comments, we have added § 426.403 and § 426.503 to allow the aggrieved party to submit new evidence without withdrawing the complaint.

Section 426.405 specifies the authority of the ALJ during an LCD review, including authority during a hearing, if applicable. Similarly, in § 426.505, we set forth the specific authority of the Board during an NCD review, if applicable.

Sections 426.406 and 426.506 prohibit *ex parte* contacts so that no party or person (except employees or consultants of the ALJ/Board's office) may communicate in any way with the ALJ/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.

In § 426.410, we establish the ALJ's role in docketing and evaluating the acceptability of LCD complaints. These procedures are very similar to the Board's role in docketing and evaluating the acceptability of NCD complaints in § 426.510. Under the procedures, the adjudicatory body receives and docketes the complaint, evaluates the acceptability of the complaint, and resolves any consolidation issues. The appeal will be docketed under the name of the LCD or NCD rather than the aggrieved party or parties to protect the privacy of the party/parties.

In § 426.410 and § 426.510, we establish the criteria that a complaint must meet to be considered as an acceptable complaint by an ALJ or the Board. An aggrieved party must file the complaint; the complaint must meet all of the requirements of a valid complaint regarding an LCD in § 426.400, or regarding an NCD in § 426.500, and may only challenge a policy that meets the definition of an LCD or an NCD.