

and is an efficient method to bring new evidence to the contractor's attention.

*Making NCD Complaints and Documentation Available and Announcing the Proceedings*

*Comments:* A number of commenters suggested that all interested parties should have notice of an LCD/NCD complaint and have the opportunity to participate in the proceedings. One commenter recommended the use of an on-line docketing system whereby the public could learn of LCD/NCD challenges and determinations made by the ALJs and Board in these cases.

*Response:* The statute does not require that we develop such a nationwide online docketing system. While the concept is interesting, an online docketing system is beyond the scope of this regulation. Currently, we are exploring options for the best way to docket and track challenges.

Changes in NCDs may determine the health care services, technologies, and treatments to which beneficiaries have access. The denial of coverage for a service that is allegedly reasonable and necessary may have an adverse impact on others across the nation. Hence, it is important that the review decisions are based on a comprehensive and well-developed record.

In addition, the general public may have a substantial interest in the outcome of some NCD reviews. NCD review decisions will constitute a legal precedent with respect to the outcome. Board decisions will clarify the extent of available Medicare coverage.

Therefore, under the final rule, the Board will make available to the public information about all NCD complaints by means of posting on the Internet. This method will provide the broadest possible public notice, without unreasonably delaying review of the complaint already filed. Any request to participate as an *amicus* must then generally be filed within the timeframes set by the Board.

Although LCDs are also important, LCDs are regional in nature. Because LCD reviews generally impact only a limited geographic area, we will not require the ALJs to make public all LCD complaints.

*Notice to Managed Care Organizations (MCOs) and State Agencies*

*Comment:* Several commenters suggested that Medicare managed care organizations (MCOs) and State agencies receive timely notification when a challenge is filed at each stage of review, when an ALJ/Board decision is made, and when a revised LCD/NCD is effective. One commenter suggested that

the regulation be revised to require the ALJ or the Board to notify MCOs when an enrollee challenges an LCD/NCD.

*Response:* We will work with the ALJs and the Board to make available to MCOs and State agencies, relevant information about complaints and decisions.

*Mediation*

*Comment:* We received one comment for and one comment against using mediation in an evidence-based review process.

*Response:* We have added a provision authorizing the Board to stay the review proceedings for a reasonable time when all parties voluntarily engage in settlement negotiations, with or without the assistance of an impartial mediator. In general, we do not consider it appropriate to negotiate about clinical issues that affect the health or safety of Medicare beneficiaries. In some instances, however, it may be worthwhile to explore alternative and less costly means of resolving a dispute. Mediation may be useful to narrow the issues in dispute in order to make the review process more efficient. Using alternative means of resolving disputes is consistent with the Federal Administrative Dispute Resolution Act and HHS policy. Under this final rule, the ALJ or the Board could not compel mediation. Where the parties consent to mediation, the ALJ or the Board may provide an impartial mediator or assist the parties in finding an impartial mediator acceptable to them.

*Automatic Dismissal When a Contractor Retires an LCD or CMS Withdraws an NCD*

*Comments:* One commenter agreed that, if an NCD is withdrawn, the purpose for the review has been eliminated and the claims can be adjudicated without consideration of the repealed NCD, but objected to the statement that the repeal will have the same effect as a decision under § 426.560(b). The commenter, however, interpreted section § 426.560(b) as permitting a contractor to continue to rely on a withdrawn NCD.

*Response:* Retiring an LCD or withdrawing an NCD would result in the retired/withdrawn policy no longer applying in the claims adjudication process for services rendered on or after the date that the policy is retired/withdrawn. Moreover, the aggrieved party would be granted individual claim review. Since a claimant would receive the same relief that would have been available had the adjudicator found that the relevant LCD or NCD was not valid,

there would be no reason to continue the appeal.

*Comment:* One commenter recommended against automatic dismissal if a policy were retired or withdrawn. As an alternative, the commenter suggested giving the adjudicator discretion to dismiss "where the decision normally occurs" and opined that since a retired or withdrawn policy may be reconsidered or reaffirmed, the automatic dismissal provision effectively nullifies the entire policy appeal process.

*Response:* When we retire/withdraw an LCD/NCD we will not apply those policies for services furnished after the retirement/withdrawal date and we will reprocess the aggrieved party's affected claims without applying the retired/withdrawn policy. If, in the future, the contractor or CMS issues a new LCD/NCD on that subject the change would be adopted after an opportunity for public comment. Any such change would be prospective in nature, and a new LCD/NCD would be subject to challenge under this final rule.

*Comment:* Two commenters indicated that automatic dismissal would not permit an ALJ's or the Board's findings to be used in the appeal of claims decisions based upon the invalidated policy.

*Response:* Because the ALJ or the Board would not be required to make a decision in a case where the contractor/CMS retired/withdrew the LCD/NCD, there would be no Board decision with precedential effect. However, we believe our approach conserves resources for all parties and adjudicators.

*Timeline for Beneficiary Getting the LCD/NCD Record*

*Comment:* We received one comment on the timing of the LCD/NCD record production requirement. That commenter suggested that we should create a 45-day response timeframe to ensure that the review process proceeds without inordinate delays.

*Response:* We agree that the establishment of timeframes will promote the efficiency of the BIPA 522 process. However, we believe that the time required will vary with the size and scope of the record requested. Therefore, we have revised the final rule at § 426.410(d) and § 426.510(d) to state that the contractor or CMS must generally produce the record within 30 days, subject to extension for good cause shown.

*Timeline for an Aggrieved Party to Review the LCD or NCD Record*

*Comment:* One commenter suggested that 30 days might not be enough time