

for the aggrieved party to review the record, particularly for an individual pursuing a complaint with minimal outside assistance. The commenter recommended a 45-to-60-day timeframe for the aggrieved party to respond.

Response: We accept the commenter's suggestion to increase the time for review of the record. While we have maintained the 30-day timeframe, we have added an exception for good cause shown, for review and response to the relevant LCD or NCD record, if additional time is required.

No Evidence To Support an LCD/NCD

Comment: We received several comments stating that where no record exists to support an LCD/NCD, the beneficiary should not have to introduce new evidence.

Response: We expect it would be a rare event that no record exists. In that rare event, we agree with the commenter. We have made changes to clarify that, in the rare event that no evidence exists to support an LCD or NCD, we will either voluntarily retire/withdraw the policy, or request the ALJ/Board to strike down the applicable provision(s) of the policy, whichever is the more expeditious option.

New Evidence

Comment: Approximately half of the commenters made comments on the issue of new evidence. Most of the comments stated that allowing us to have an automatic stay, coupled with the absence of specific deadlines, would unduly delay the review process. Other commenters suggested that the stay should be a matter of ALJ/Board discretion. Numerous comments specifically requested that the ALJ or Board review all evidence, including new evidence, to allow for a more efficient process.

Response: We agree that a more efficient and time-sensitive adjudicatory process is important, and we have addressed several aspects of these comments in the final rule. We have taken considerable steps to create an efficient adjudicatory process that still preserves the important role of the clinical and scientific experts in making LCDs and NCDs.

We have eliminated the proposed automatic stay when new evidence is submitted. Instead, our final rule will require that, if new evidence has been received by the ALJ/Board that would otherwise be admissible, the ALJ/Board will review the new evidence after the period for discovery and the taking of evidence is complete, and decide if it has the potential to significantly affect the LCD/NCD provision in question. If

not, the review will continue. If the ALJ/Board determines that the new evidence has the potential to significantly affect the validity of the LCD/NCD, the ALJ/Board will stay the proceedings and forward the material to the contractor or to us for a brief review. The contractor/CMS will have 10 days to provide a statement indicating whether or not: (1) A reconsideration will be initiated, or (2) the policy will be revised or retired/withdrawn. If the Agency undertakes a reconsideration, it must be completed within a period set by the ALJ/Board that is not more than 90 days. We believe this 90-day timeframe is reasonable due to the potentially large body of evidence that must be reviewed. Following a reconsideration, the contractor/CMS will prepare and submit the new LCD/NCD record, and the ALJ/Board proceedings will continue on the revised LCD/NCD. If the contractor/CMS chooses not to initiate a reconsideration, the ALJ/Board proceedings will continue on the original LCD/NCD as supplemented with the new evidence. The aggrieved party will have an opportunity to submit a statement about whether the record still fails to support the validity of the LCD/NCD. The contractor/CMS will have an opportunity to respond. No further evidence will be taken at this stage, and the ALJ/Board will proceed to make a determination on the merits.

We have also made changes to the definition of "new evidence" to clarify that new evidence means evidence that was not considered by the contractor or CMS.

When Does the Review Stop?

Comments: In the proposed rule, we specifically asked for comments on alternatives for structuring the review process. We proposed to divide the decision making process for cases at the ALJ/Board level into two stages and thereby establish the prerequisites for discovery under the statutory framework set forth at section 1869(f)(1)(A)(iii)(I) and section 1869(f)(2)(A)(i)(I) of the Act. Under the proposed regulation, in order to obtain discovery, a challenger was required to first file a motion with the Board or ALJ alleging that the record was incomplete or lacked adequate information to support the validity of the determination. Only if the record was incomplete or otherwise inadequate would an aggrieved party be able to pursue discovery. Even if the challenger did not file such a discovery motion, however, a beneficiary could seek a decision on whether the determination was based on reasonable findings of fact, reasonable interpretations of law,

and reasonable applications of fact to law.

We outlined another possible approach in our proposed rule at 67 FR 54542. That approach would require a party to file a statement regarding whether that party considers the record complete and adequate, and an "offer of proof" supporting factual allegations about incompleteness. The adjudicator would then decide whether the record is complete and adequate to support the decision and would prepare a written decision. If the adjudicator found that the record was complete and adequate, this decision would be a final Agency action appealable to the court.

There were two public comments on this issue. One commenter suggested that, if the adjudicator found that the record was incomplete or inadequate, the Board would be legally required to determine that the "NCD is not reasonable." This commenter believed that the Board would be precluded from allowing discovery or any other new evidence at this point, but must automatically rule against CMS. A commenter appeared to prefer the following approach: "If, upon review of the record, the aggrieved party does not have objections to the completeness or adequacy of the LCD or NCD record, then what is the basis of the aggrieved parties complaint? Presumably the coverage policy would be challenged on the basis that it is inconsistent with current clinical or scientific evidence. In such case, a motion by the aggrieved party would appear to be a necessary part of the complaint process and an appropriate step given the limited time and resources of adjudicators, CMS and contractors." The commenter "believed that the aggrieved party should challenge the completeness or adequacy of the record before an adjudicator should make a determination with respect thereto."

Response: We have re-examined our proposed procedures in light of the public comments and the unique statutory language in section 1869(f)(1)(A)(iii)(I) and section 1869(f)(2)(A)(i)(I) of the Act. In this final rule, we clarify at § 426.400 and § 426.500, the procedural and substantive steps involved in the appeal. The revised procedures incorporate approaches from both alternatives discussed in the proposed rule. We believe that the revised procedures are fair, consistent with the statutory framework, and will enable the ALJs and Board to fairly resolve challenges to LCDs and NCDs in an expeditious manner.

The administrative review provisions in BIPA section 522 are unique. While