

the reviews are, at the outset, based on the medical and scientific evidence that the contractor/CMS considered in issuing the LCD/NCD, and the statute requires that the adjudicator “shall review the record,” it does permit discovery in some limited circumstances and also permits that adjudicator to consult with “appropriate scientific and clinical experts.” Obviously, new evidence obtained through discovery or testimony could not have been considered by the agency when the policy predates the new evidence. Thus, the procedures are not entirely based on the record, but new evidence and testimony may influence the ALJ’s/Board’s decision in some cases.

It is possible that an aggrieved party would attempt to challenge an LCD/NCD for several reasons. For instance, a challenger may believe that a policy that was correct when it was issued has become outdated and is no longer valid in light of advances in medicine. Those challengers may be most interested in presenting new medical evidence in support of changing the policy rather than challenging the original factual basis for the policy. As noted previously, we are modifying our procedures to allow a party to submit new evidence to the ALJ/Board. We have modified the procedures at § 426.340 to allow the ALJ/Board to make a preliminary determination on whether the new evidence submitted would have a significant bearing on the validity of the LCD/NCD. If the evidence is found significant, it would be sent to the contractor/CMS to determine whether the contractor/CMS agrees that the evidence warrants a formal reconsideration. As mentioned earlier, the reconsideration process would be time limited but would allow the public to submit medical and scientific evidence and allow the agency to fully develop the record in light of advances in medical science. Following the time-limited reconsideration, a supplemental record would be filed and the adjudication could continue, if necessary.

This approach will provide the contractor/CMS the initial opportunity to permit medical and scientific experts to examine the new evidence and to make findings of fact concerning the new evidence. Among other things, the statute requires that the ALJ/Board “shall defer only to the reasonable findings of fact” and it was impossible for the agency to have made findings on evidence that did not yet exist or that had not been furnished to the agency for consideration. We believe this approach is necessary to ensure that the medical

and scientific opinions of the agency experts illuminate the record, since these appeals could involve very technical medical and scientific material related to the new evidence.

While it is possible that the challenger may submit credible medical and scientific studies that warrant a formal reconsideration, it is also possible that the evidence submitted would not be either relevant or persuasive, or that a challenger may seek to challenge the policy on other grounds. Because the public comments have highlighted the different types of disputes that may be presented, we have modified our procedures in attempt to fairly, yet expeditiously, resolve any type of challenge that may be presented. Our revised approach would allow the ALJ or the Board to resolve some cases without need for a reconsideration and would also allow the review proceedings to be resolved in a more expeditious manner. To resolve any confusion, we will describe the significant procedural and substantive steps of the review.

Under the revised procedures at § 426.425 and § 426.525, all aggrieved parties, after reviewing the LCD or NCD record, will be able to file a statement that includes the challenger’s arguments as to why the record is not complete, or not adequate to support the validity of the LCD/NCD under the reasonableness standard. This may be the most important step in the review process from the aggrieved party’s perspective because this is the opportunity to present any arguments for the LCD/NCD being held invalid. (See § 426.425(a), § 426.525(a)). CMS or the contractor will have 30 days to submit a response to this statement. (See § 426.425(b), § 426.525(b)).

After evaluating the materials and the record, our revised procedures will permit the ALJ/Board to make a prompt decision in the nature of a summary judgment if the case warrants this approach. For instance, if applying the reasonableness standard, the adjudicator finds that record is complete and has adequate information to support the validity of the LCD or NCD, the ALJ or the Board may issue a decision that “the record is complete and adequate” to support the policy. (See § 426.425(c)(1), and § 426.525(c)(1)). For cases involving an NCD, the aggrieved party would have the right to challenge this final agency action in Federal court. (Section 1869(f)(1)(A)(v) of the Act). For cases involving an LCD, the aggrieved party would have the right to challenge the ALJ’s decision at the Board, and potentially in Federal Court. (§ 426.465).

If, on the other hand, after evaluating the materials submitted by the parties and the record, the ALJ/Board determines that the record is not complete or not adequate to support the validity of the LCD/NCD, the adjudicator will permit discovery and the taking of evidence. Following discovery and the taking of evidence as set forth in these final rules, the ALJ/Board will issue a final decision. (See § 426.447, § 426.547). Those final decisions may also be appealed in appropriate circumstances.

Although we recognize that one commenter suggested that the ALJ or the Board would be legally required to hold invalid the LCD/NCD rather than allowing the agency to supplement the record, the case cited is not relevant given the unique language and history of BIPA section 522. The ALJs and the Board are not acting as a Federal court reviewing final agency action. The case relied on by the commenter concerned the scope of review under the judicial review provisions of the Administrative Procedure Act, 5 U.S.C. 706. Moreover, under prior provisions for court review of NCDs, even courts were required to permit us to supplement the record before declaring an NCD invalid. We believe our approach is consistent with the specific requirements of the statute.

#### *Scope and Weight of Evidence*

*Comment:* One commenter believed that the proposed rule would have the effect of excluding highly relevant information such as physicians’ standards of practice and their professional opinions from the review process. Another commenter believed that we should define the hierarchy of evidence strength to assure proper weighting by the ALJ or Board when considering scientific and clinical information.

*Response:* We are not accepting the recommendation to include a hierarchy of evidence in order to allow flexibility in analyzing evidence. We recognize that many types of evidence have value, and will consider clinical experience, as well as other forms of medical, technical, and scientific evidence in making LCDs and NCDs. We note that the ALJ/Board may seek input from clinical and scientific experts at their discretion. There is no prohibition against the ALJ or the Board seeking the input of practicing physicians or considering standards of practice.

#### *Discovery*

*Comment:* We received several comments on the nature and scope of discovery. One commenter supported the limitation upon discovery that