

We believe that the Board review of an appeal of an ALJ's decision should remain a paper review of existing materials. Accordingly, we establish, in § 426.476(b), that the Board will determine whether the ALJ decision contains any material error, and prohibit the Board from considering any evidence that is not a part of the ALJ's LCD review record. We establish that the Board will remand the case for discovery and the taking of evidence if the ALJ erroneously determined that the contractor's record was complete, or if the ALJ permitted a prejudicial procedural error. In § 426.476(c), we establish the Board's scope of review and that the Board is bound by applicable laws, regulations, and NCDs when reviewing appeals of ALJ decisions. These include the applicable provisions of the Act, our regulations and rulings, and NCDs.

In § 426.476(d), we require the Board to dismiss an appeal of an ALJ's decision if the contractor retired the LCD or revised the LCD to remove the provision(s) in question during the appeal.

In § 426.478, we allow the contractor to retire an LCD or revise the LCD to remove the provision(s) in question during the Board's review of the ALJ's decision. As stated in the previous paragraph, this would lead to the Board dismissing the appeal.

In § 426.480, we allow a party to withdraw an appeal of an ALJ's decision. The provisions proposed in this section, for a party acting alone or as part of a joint or consolidated appeal, would be the same as the provisions for withdrawing a complaint in § 426.423.

In § 426.482, we require the issuance and notification of a Board decision regarding an appealed ALJ decision. These provisions are the same as the provisions we described for the issuance and notification of an ALJ decision.

In § 426.484, we set forth the mandatory provisions of a Board decision regarding an appealed ALJ decision. We require the Board to either dismiss the appeal or, for each part of the ALJ's decision named in the appeal, to uphold, modify or reverse that part or all of the ALJ's decision. Because the Board is conducting a review of the ALJ's decision using the ALJ's LCD review record, and is not conducting a *de novo* review of the LCD itself, a Board decision upholding, modifying or reversing each part, or all of the ALJ's decision is the proper outcome. The Board's decision must include the information necessary to identify the appeal, and the rationale for the Board's decision.

In § 426.486, we prohibit the Board's decision from including those provisions that we exclude from the ALJ's decision, for the reasons discussed earlier in this preamble. In § 426.487, "Board's Record on Appeal of an ALJ Decision," we state in paragraph (a) that except as provided in paragraph (b) of this section, the Board's LCD review record furnished to the public consists of any document or material that the Board compiled or considered during an LCD review.

Paragraph (b) states that the LCD review record furnished to the Court under appeal includes, under seal, material that is privileged or proprietary.

Paragraph (c) states that in any instance where proprietary data or privileged information is contained in the LCD record and the information goes to court, CMS or the Department will seek to have a protective order issued for that information, as appropriate.

In § 426.587, "Record for Appeal of a Board/NCD decision," we set forth in paragraph (a) that, except as provided in paragraph (b) of this section, the Board's NCD review record furnished to the court consists of any document or material that the Board compiled or considered during an NCD review. CMS or the Department may seek to have a protective order issued with respect to proprietary data or privileged information.

We describe in paragraph (b) that the NCD review record furnished the court maintain the seal on material that is privileged or proprietary. CMS or the Department may seek to have a protective order issued with respect to those documents.

In § 426.488, we set forth the effect of a Board decision. Section 426.488(a) explains the relief that is provided to a successful challenger. Moreover, there may be coverage relief for the aggrieved party. We also describe the effect of the Board reversing an ALJ decision.

We permit the Board to remand cases to the ALJ in a limited number of circumstances. In § 426.489(a), we explain the process the Board must follow to remand a case to the ALJ. In § 426.489(b), we explain required action by an ALJ upon a Board remand. In § 426.490, a decision by the Board would constitute a final Agency action and would be subject to judicial review. Neither the contractor nor we may appeal a Board decision.

## V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and

solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 required that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We have solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

### *Sections 426.400 and 426.500*

Sections 426.400, Procedure for filing an acceptable complaint to a provision (or provisions) of an LCD, and 426.500, Procedure for filing an acceptable complaint to a provision or provisions of an NCD, state that an aggrieved party may initiate a review of an LCD or NCD, respectively, by filing a written complaint. These sections also identify the information required in the complaint to qualify as an aggrieved party as defined in § 426.110, as well as the process and information needed for an aggrieved party to withdraw a complaint. The required documentation includes a copy of the written authorization to represent the beneficiary, if the beneficiary has a representative, and a copy of a written statement from the treating physician that the beneficiary needs a service that is the subject of the LCD.

Based on the lack of public comments, we continue to estimate that there will be 1,000 LCD complaints per year and that it will take the aggrieved party 4 hours to draft the complaint and gather the information to send to us. The national burden would be 4,000 hours annually. We estimate that there will be 15 to 20 NCD complaints per year. It will take 4 hours, maximum, to gather the information and to write each complaint. Thus, we estimate a total of 80 hours per year to comply with the requirement.

The estimate of 4 hours is based on previous experience in both the local and national coverage development processes, and the estimated time to submit beneficiary and policy-specific information (for example, name,