

adjudicator finds that the provision(s) named in the complaint was (were) valid under the reasonableness standard, the aggrieved party or parties (in the case of an LCD review) could appeal that decision to the Board or (in the case of NCD review) may challenge the final Departmental action in Federal court.

If the adjudicator found that the provision(s) listed in the complaint was (were) invalid under the reasonableness standard and the contractor or we do not appeal this decision to the Board in a timely manner, the contractor must or we will do several things. First, there would be individual claim review for the aggrieved party or parties named in the complaint(s).

- If the aggrieved party received a (fee-for-service or managed care) service that was the subject of the challenged coverage determination, then the contractor (if applicable) or Medicare managed care organization will not use the provision(s) of the coverage determination that was (were) found invalid in the adjudication of that claim.

- If the aggrieved party has not received the service, the individual may obtain the service and file a claim, which could be reviewed by the contractor, without using the provision that has been found invalid.

Neither the first level appeal reviewer nor the hearing officer is bound by the invalid provision. Specifically, we will instruct the contractor to make a claim determination without using the LCD or NCD provision(s) that has been found invalid in each of the following situations: (1) The claim has not been adjudicated or; (2) the claim was denied. It is important to note that individual claim review can only be provided to an aggrieved party if his or her individual claim or appeal has not been paid during the individual claims adjudication process. Furthermore, the contractor/CMS will not use the invalid provision as guidance to deny claims.

Second, there would be coverage policy relief. Within 30 days of the issuance of an ALJ or the Board decision, the contractor or CMS must either retire/withdraw the LCD/NCD or revise the LCD/NCD to remove the provisions found to be invalid by the ALJ or the Board. The effective date of the retirement/withdrawal or revision must be for dates of service no later than the 30th day following issuance of the ALJ or Board decision. As discussed earlier, the retirement of a coverage determination or removal of a provision of a coverage determination means that it can no longer be used in the adjudication of claims with dates of

service after the effective date of the ALJ/Board decision.

Under § 426.462 and § 426.562, “Notice of an ALJ’s decision,” and “Notice of the Board’s decision,” we require that, after the ALJ or the Board, respectively, has made a decision regarding an LCD or NCD complaint, the ALJ or the Board send a written notice of the decision to each party. The notice must state the outcome of the review and inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

Under § 426.463 and § 426.563, “Future New/Revised LCDs/NCDs,” we state that the contractor and CMS may not reinstitute an LCD/NCD provision found to be unreasonable by an ALJ/Board unless the contractor/CMS has a different basis (such as additional evidence). However, nothing in this regulation shall be construed to prevent contractors or CMS from developing new or revised/reconsidered LCD/NCD provisions, as long as these provisions are developed using a different basis and evidence.

In the remainder of the sections proposed in subpart D, we set forth the procedure for appealing an ALJ’s decision regarding an LCD review. In § 426.465(a), we state that an aggrieved party may appeal part or all of an ALJ’s decision that states that a provision of the LCD listed in the complaint is valid under the reasonableness standard or that dismisses a complaint (with certain exceptions). We also allow an aggrieved party who was part of a joint complaint or a consolidated LCD review to appeal an ALJ’s decision either independently or as a group.

In § 426.465(b), we state that a contractor or CMS may appeal to the Board an ALJ decision that an LCD was unreasonable. Because we allow Board consolidation of similar appeals, we believe that it is not necessary to prohibit aggrieved parties from appealing to higher levels if one or more parties to a joint complaint withdraw from that complaint.

In § 426.465(c), we require that the implementation of the ALJ decision will be stayed pending review by the Board.

In § 426.465(d), we establish that we do not allow an aggrieved party to appeal a dismissal in certain circumstances, namely, if the aggrieved party who filed the complaint withdraws the complaint, or because the contractor retired the LCD or revised the LCD to remove the provision in question.

Under § 426.465(e), we require that an appeal would have to be submitted to the Board within 30 days of the date the ALJ’s decision was issued. We believe this is a reasonable timeframe to allow a party to make a decision on whether to appeal and to prepare the necessary documents, but we permit the Board to consider a late appeal if good cause is shown by the party.

Section 426.465(f) lists the necessary components of an appeal to identify the relevant parties and issues.

In § 426.565, “Board’s role in making an LCD or NCD review record available,” we require that upon a request from a Federal Court, the Board must provide to the Federal Court, a copy of the Board’s LCD or NCD review record (as described in § 426.567).

In § 426.566, we state that a Board decision is subject to judicial review.

In § 426.468, we explain that an aggrieved party who initiates an LCD review, but does not appeal any part or parts of an ALJ’s decision to the Board in a timely manner, waives his or her right to any further review of that part or those parts.

In § 426.470, we state that the Board’s role in docketing and evaluating the acceptability of appeals of ALJ decisions is similar to the process that an ALJ would use in docketing and evaluating the acceptability of a complaint. The Board assigns a number to the appeal and determines if it meets all of the requirements of an acceptable appeal proposed in § 426.465. Unlike the evaluation of an initial complaint, however, we require, in § 426.470(c), that the Board issue a decision dismissing an unacceptable appeal, instead of allowing an opportunity to amend an unacceptable appeal.

Upon the request from the Board to provide copies of the LCD review record under § 426.470, we require that an ALJ send a copy of the LCD review record to the Board.

Once the Board has accepted an appeal to an ALJ’s decision and received the ALJ’s LCD review record, we describe in § 426.476 the steps that the Board will take in reviewing the ALJ’s decision. In addition to reviewing the ALJ’s LCD review record and the ALJ’s decision, the Board must allow the contractor or, if applicable, allow us, to submit a statement to the Board and the aggrieved party responding to the appeal. The final required step in the Board review of an ALJ’s decision is to issue a Board decision. We require that the Board must evaluate the ALJ’s application of the reasonableness standard to determine if the ALJ’s decision was erroneous.