

complaints that fail to meet the requirements for acceptable complaints, including complaints regarding inapplicable policies or determinations. We also require the adjudicator to dismiss a complaint if the aggrieved party withdraws the complaint, or if the complaint seeks review of a matter beyond the adjudicator's authority.

Under § 426.444(b)(6), we also require an ALJ to dismiss a complaint if the applicable contractor notifies the ALJ that the LCD is being retired or revised to remove the provision in question. Similarly, in § 426.544(b)(6), the complaint must be dismissed when we notify the Board that the NCD (or provision of the NCD) is no longer in effect.

In § 426.445 and § 426.545, we require that witness fees, for appearances during a hearing, be paid by the party seeking to present the witness.

Under § 426.446 and § 426.546, we require that an ALJ and the Board, respectively, ensure that any hearing conducted regarding a LCD or NCD review is open to the public and electronically, mechanically, or stenographically recorded. These sections require that, except for privileged information and proprietary data, all evidence upon which the adjudicator relies for a decision be contained in the public record, and that any pertinent document or record be incorporated into the record of the LCD/NCD hearing.

Under § 426.447 and § 426.547, we set forth the procedures for the issuance and notification of ALJ and Board decisions, respectively. Within 90 days from closing the review record to the taking of evidence, the applicable adjudicator is required either to issue a decision, including a description of appeal rights, or to provide notice that the decision is pending, and an approximate date a decision will be issued. In § 426.547(b), we explain that Board decisions regarding NCDs will be available on the Medicare Web site of the Department of Health and Human Services and that steps will be taken to ensure the privacy of the parties to the review.

Under § 426.450, we describe the required elements of an ALJ's decision regarding an LCD. In § 426.550, we describe the required elements of the Board's decision regarding an NCD. Since Board decisions will be published, identifying information about beneficiaries may be placed in an accompanying cover letter giving notice of the decision. This cover letter, however, will not be published, in order to preserve beneficiaries' privacy. As discussed earlier in this section of the

preamble, a decision may include the dismissal of a complaint or a finding that the LCD/NCD record is complete and adequate to support the validity of the LCD/NCD under the reasonableness standard. If the ALJ/Board decision neither dismisses the complaint nor finds that record complete and adequate, the decision must contain a statement pertaining to each provision listed in the complaint and state whether the provision is valid or invalid under the reasonableness standard. We also require that the decision include the information in § 426.450(b) and § 426.550(b), which include LCD review or NCD review identifying information, claim information (if known), the basis for the decision (including findings of fact, interpretations of laws, and application of facts to the law), a summary of the evidence reviewed during the review, and a statement about appeal rights. We provide that the materiality of any proprietary data or privileged information in the validity determination should be discussed in the decision without disclosing the substance or contents of the sealed evidence. In addition, a separate statement prepared and maintained under seal will explain the rationale for the treatment of the proprietary data or privileged information, including any necessary discussion of the data themselves. This statement will accompany the proprietary data or privileged information under seal if the decision is appealed to the next level of review.

In § 426.455 and § 426.555, we require that an ALJ or the Board decision be prohibited from doing any of the following:

- Ordering us or our contractors to add any language to an LCD or NCD or to pay a specific claim.
- Establishing a time limit for the creation of a new or revised LCD or NCD.
- Reviewing or evaluating an LCD or NCD other than the LCD or NCD under review.
- Including a requirement for us or our contractors that specifies payment, coding, or systems changes for an LCD or NCD, or deadlines for implementing these changes.
- Ordering or addressing how we or our contractors should implement an LCD or NCD.

As a result of comments we received on our proposed rule, we revised the requirements concerning ALJ or the Board decisions to allow such a decision to direct us or our contractors to delete language from a provision of an LCD or NCD, when the adjudicator finds provision(s) unreasonable with

respect to the aggrieved party's clinical indications, and for same or similar conditions. While we have revised the rule accordingly, we continue to believe that ALJs or the Board should be prohibited from ordering us or our contractors to add language to a LCD or NCD provision and have maintained the prohibition in this final rule. The ALJ/Board decision requiring a contractor or CMS to strike an LCD/NCD provision may be written narrowly. In one example, an aggrieved party with condition X challenges an LCD stating that a particular service is covered for conditions Y and Z and contains the following sentence: "This procedure is considered not reasonable or necessary for all other conditions." The ALJ may find that this sentence is invalid for condition X. The contractor would have several options for effectuating this decision. First, the contractor could remove the sentence altogether leaving coverage of all conditions other than Y and Z to individual consideration. Second, the contractor could add condition X to the list of covered conditions. Third, the contractor could revise the LCD to state that the service is covered for conditions Y and Z, individual consideration will determine coverage for condition X, and that the service is not covered for all other conditions.

In § 426.457 and § 426.557, we explain that ALJ or the Board decisions may be written narrowly to hold specific provision(s) invalid as applied to specific clinical indications and for similar conditions.

In § 426.458, we describe the ALJ's review record furnished to the public, and to the Board, and specify that proprietary data or privileged information must be under seal.

In § 426.460 and § 426.560, we describe the effect of ALJ or the Board decisions issued under § 426.447 and § 426.547. Although an ALJ or the Board will now be allowed to order us or our contractors to strike down a LCD or NCD provision, we continue to believe that the exact wording of a new coverage determination should be made by the contractor or by us. These policies affect other beneficiaries and, thus, these determinations must be made by clinicians and scientific experts who have the necessary specialized training. Thus, we and the contractor will remain the entities responsible for ensuring that the clinical and scientific policies are sound, in order to ensure the best quality of care for beneficiaries.

The effect of an ALJ or Board decision will depend on the outcome of the coverage determination review. If the