

such as the ready availability of qualified medical professionals in one contractor's area, but not in another. Moreover, an ALJ or the Board may not determine that an LCD is unreasonable solely on the basis that another Medicare contractor has issued an LCD that permits coverage of the service at issue, under the clinical circumstances presented by the complaint.

For legal interpretations, the reasonableness standard would not be met if an interpretation is in direct conflict with the plain language of the statute or regulation being interpreted. Moreover, an interpretation in an LCD would not meet the reasonableness standard if it directly conflicts with an NCD or with a CMS Ruling. So long as an interpretation is one of the readings permitted by the plain language of the law and can be reconciled with relevant policy, however, it must be upheld, even if the ALJ or the Board might have reached a different result if interpreting the statute or regulation in the first instance.

#### *Authority of ALJs and the Board*

*Comment:* Some comments supported the limited authority granted to the ALJs/Board in issuing decisions, and many comments requested that the ALJ/Board be granted greater authority in issuing decisions. A number of comments suggested that the proposed rule restricted ALJ/Board authority so that the main outcome of a decision of unreasonableness would be contractor/CMS reconsideration, and that a decision of unreasonableness should result in the policy being null and void. Furthermore, numerous comments suggested that authority is not granted to the ALJ or the Board in the way that the Congress intended, and that the contractor/CMS retains too much authority over the process.

*Response:* We have revised the final regulation to allow for greater authority for the adjudicators in several respects. In appropriate cases, the ALJ/Board may find a provision(s) of the LCD/NCD invalid and may limit that holding to a beneficiary's clinical indication (or similar condition). Furthermore, the contractor or CMS would effectuate the ALJ/Board decision within 30 days (if not sooner), by either retiring or withdrawing the policy or revising the policy that would be applied prospectively. This means that neither the contractor nor CMS will apply a policy that has been held invalid to a claim of the aggrieved party or to any other similar Medicare claim with date(s) of service beginning on or after 30 days of the adjudicatory decision. Even though we are giving broader

effect to the ALJ/Board decision by extending the decision to others on a prospective basis, we continue to believe that the Congress intended that CMS or its contractors would have the authority to develop clinical policies. Thus, we will maintain in the final rule the prohibition against adjudicators developing new language for LCDs and NCDs.

After a policy has been held invalid, it will not be applied to the beneficiary who raised the challenge or to others who receive services after the effective date of the invalidation. CMS or the contractor may issue a new or revised LCD/NCD that does not include the invalid provision(s). The new or revised LCD/NCD would be applied prospectively. The new/revised LCD/NCD would also be subject to challenge under this review process.

Please note that whenever we discuss claim relief or dates of service in the context of an ALJ or DAB decision holding invalid an LCD or NCD, the references should be read to include pre-service requests denied by an M+C organization and the dates of pre-service requests. The application of this regulation in the M+C context is discussed further below.

#### *Effective Dates*

*Comment:* Several commenters stated that timeframes should be set in this process to reflect the timeframes set in the NCD process notice.

*Response:* We agree with the concept of timeframes, but do not reference the "NCD process notice" since that notice does not speak to this issue, and we have added language to § 426.460 and § 426.560 requiring that contractors/CMS either—

1. Retire/withdraw the LCD/NCD in its entirety within 30 days of the ALJ/Board decision; or
2. Issue a revised LCD/NCD removing the invalid provisions, effective for claims with dates of service after the 30th day of the ALJ/Board decision.

If the Board issues a decision finding an NCD provision invalid and the NCD is revised to reflect the Board's decision, all contractors must review and appropriately revise any related LCDs so as not to be in conflict with the revised NCD. If we choose to withdraw the entire NCD, the contractors must review and appropriately revise any LCDs so as not to rely on the withdrawn NCD as the basis for the LCD.

#### *Precedential Value of ALJ/Board Decisions*

*Comment:* One commenter stated that previous ALJ/Board decisions should be controlling precedent. Another

commenter recommended that ALJs/Board be bound by previous ALJ decisions on local policies in other jurisdictions.

*Response:* We have revised the final rule at § 426.431(a) to require ALJs to treat as precedential Board LCD and NCD decisions, and to require the Board to follow its own applicable precedents. We believe this will improve the efficiency of the review process. Because of differences in the local practice of medicine, we do not believe it would be prudent for ALJs to treat as precedential other ALJ decisions on an LCD challenge.

#### *Appeals of Decisions Involving Joint Complaints and Consolidated Reviews*

*Comment:* One commenter requested that for joint appeals, aggrieved parties should be prohibited from appealing decisions to higher levels unless all parties to the initial appeal agree to appeal.

*Response:* We will not require in this final rule that all parties must agree to appeal an ALJ decision as a prerequisite for the appeal to continue. Even if some individuals decide not to pursue an appeal, other parties in the case may exercise their appeal rights. Section 426.470 of the regulation allows the Board to consolidate similar appeals.

#### *Appeal of ALJ Decision/Board Review of ALJ Decisions*

*Comment:* One commenter suggested that we should not be allowed to appeal ALJ decisions to the Board due to conflicts of interest. Another commenter objected to having the Board overturn ALJ decisions that were favorable to the aggrieved party due to potential burdens on the beneficiary. Another commenter felt that the regulation should not require the Board to affirm or reverse the ALJ decision in its entirety and suggested that the Board should have the discretion to reverse a decision in part. We received one comment suggesting the Board should not support a policy based on a rationale that is not stated in the supporting documents that were submitted. We also received three comments requesting that the Board not be limited to fundamental rules of procedures, and that it have broader discretion in reviewing ALJ decisions.

*Response:* Nothing in the statutory language of section 522 suggests that the Congress intended to bar the government from appealing an adverse decision of an ALJ. We believe that such an appeal is warranted as a mechanism to ensure that ALJs are applying the statute and regulations correctly, even if we rarely employ this strategy. Because the statute provides that ALJ decisions