

may be reviewed by the Board, we have retained the language allowing either the contractor or CMS to seek Board review of ALJ decisions. Furthermore, our final rule provides flexibility in the Board's review of ALJ decisions.

We have modified the final rule at § 426.476(b) to provide that the Board will review an ALJ decision on appeal to determine whether it contains any material error, including any failure to properly apply the reasonableness standard. The Board will not reverse a decision for harmless error, but may remand if a prejudicial procedural error was made. Further, if the ALJ erred in determining that the LCD record was complete and adequate to support the validity of the LCD, the Board will reverse and remand the case to the ALJ to complete discovery and the taking of evidence. We believe that this standard of review provides appropriate discretion for Board review of ALJ decisions.

Impact on Medicare+Choice (M+C)

Comment: One commenter suggested that we should clarify an M+C organization's obligations when a complaint is under review by both the section 522 process and the M+C organization's existing appeals process.

Response: If an M+C enrollee files both an LCD/NCD review request and a request for reconsideration of an adverse organization determination for the same item or service, the M+C organization should adjudicate the reconsideration using the coverage policies in place on the date the service or item was requested (in the case of a pre-service determination) or provided (in the case of a payment determination). If the LCD/NCD under review is subsequently found to be unreasonable, then the aggrieved party who sought review of the LCD/NCD is entitled to have the previously adjudicated organization determinations or reconsidered determinations reopened and adjudicated without consideration of the invalid LCD/NCD provision(s). M+C organizations would be responsible for reopening and adjudicating organization determinations, and the independent review entity (IRE) would be responsible for reopening and adjudicating reconsidered determinations.

Comment: One commenter requested that we clarify the obligations of M+C organizations when an enrollee has an appeal pending at the time the revised LCD/NCD becomes effective.

Response: The type of organization determination being reconsidered (payment or pre-service) will determine an M+C organization's obligations when

an enrollee has a reconsideration pending at the time a revised LCD/NCD becomes effective. Consistent with original Medicare, LCD/NCD changes may only be applied prospectively to requests for payment. Therefore, when an enrollee requests reconsideration of a payment determination and the reconsideration is pending at the time a revised LCD/NCD becomes effective, the M+C organization should apply the LCD/NCD in place at the time the item or service was provided. In responding to a request for reconsideration of a pre-service determination that would be affected by a revised LCD/NCD, an M+C organization should dismiss the appeal and reopen the adverse organization determination on the basis of new and material evidence. The M+C organization should then apply the revised LCD/NCD in effect and issue a revised organization determination.

We recognize the importance of ensuring timely transmission of ALJ/Board decisions and intend to work closely with the Medicare managed care industry to make certain that an effective method of communicating LCD/NCD changes is in place.

Comment: Another M+C-related comment stated that claims that were adjudicated using the invalidated LCD/NCD should be eligible for a new decision (so long as the appeals timeframes have not passed).

Response: As noted in the comment above, LCD/NCD changes can only be applied prospectively to requests for payment, as was the case under original Medicare. Therefore, regardless of subsequent policy changes, for purposes of reconsidering a payment determination, the relevant LCD/NCD is the policy in effect at the time the item or service was provided.

Comment: One commenter requested that we clarify whether a decision made under individual claim review is considered an "organization determination," as defined under parts 417 and 422, giving rise to appeal rights.

Response: When an M+C organization reopens and adjudicates an organization determination under § 426.460(b)(1), the M+C organization must issue a revised organization determination, which gives rise to appeal rights under parts 417 and 422. An enrollee could benefit from a revised LCD/NCD by filing a new request for an organization determination.

Comment: One commenter requested clarification as to whether our statutory obligation, under section 1852(a)(5) of the Act, to make fee-for-service payments for a significant cost, midyear change in benefits would apply if a significant cost threshold for an NCD is

met as a result of a decision by the Board to revise an NCD.

Response: Section 1852(a)(5) of the Act provides that if an NCD or legislative change in benefits effective in the middle of an M+C contract year generates a significant change in the costs to a M+C organization of providing benefits that are the subject of the NCD, and if this significant change in costs was not incorporated into the M+C payment rates at the time the NCD becomes effective, the NCD does not apply to the M+C contracts until the first contract year after new M+C rates are published. Moreover, section 1853(c)(7) of the Act provides that, if there is a change in benefits resulting in a significant increase in costs to the M+C organization, we will adjust appropriately the M+C payment rates to reflect this change. The M+C organization must provide coverage of the NCD or legislative change in benefits by furnishing or arranging for the NCD service or legislative change in benefits. However, the M+C organization is not required to pay or assume risk for the costs of that service or benefit until the contract year for which payments are adjusted to take into account the cost of the NCD service or legislative change in benefits. Section 422.109 has been revised to define "significant cost" thresholds, and notes that, if the costs for new coverage or a change in benefits is significant, CMS will pay on a fee-for-service basis on behalf of the M+C organization for the new benefit until the M+C rates are appropriately adjusted. (These provisions do not apply if the change in benefits does not meet either significant cost threshold described at § 422.109.)

Automatic Stay Upon Appeal

Comment: Three commenters disagreed with the automatic stay of an ALJ decision when the contractor/CMS appeals a decision to the Board.

Response: We disagree. We believe it would be disruptive to beneficiaries overall to have ALJ decisions implement policies only to have these policies reversed by the Board. This would create both an inefficient and confusing process. Furthermore, a contrary ruling would require the expenditure of significant resources to implement an ALJ decision only to have to change the decision if the Board reverses.

Dual Track Process

Comment: We received one comment for and one comment against allowing aggrieved parties the option to pursue both a reconsideration and a review under these rules.