

claims adjudication process if it is determined that the policy was invalid. Furthermore, although this adjudicatory process is not available to a State directly, a State may always request reconsideration of an LCD or NCD.

Dismissal of Complaint Upon Death of Beneficiary

Comments: We received comments about the proposed policy that would have dismissed complaints if the beneficiary died after initiating a section 522 challenge. Approximately one third of the commenters were opposed to this policy, and only one supported it. That commenter concluded that since the deceased would no longer be considered "in need," it would be appropriate to dismiss the claim. The majority of those who commented objected to permitting an estate to appeal a claim without permitting the estate to continue a challenge to the policy that could determine the outcome of the appeal, thereby denying meaningful relief. One commenter indicated that the policy of automatic dismissal of a complaint upon death runs contrary to Federal common law that allows for the survival of remedial, as distinguished from penal or punitive, claims. In describing the burdens created by an automatic dismissal, the commenters referred to the potential for delay, the requirement to seek meaningful redress in Federal court rather than through the administrative appeals process, wasted resources expended prior to the death of the beneficiary in LCD/NCD challenges, and the potential for devastating financial burdens on the estates of deceased beneficiaries.

Response: We have revised the final rule to permit the estate of a beneficiary, as a successor in interest, to continue a challenge in those cases where the aggrieved party received the service and filed a timely complaint prior to death. In addition, we will allow an estate to initiate a challenge within 120 days of the issuance of a denial notice.

Acceptability of Complaints

Comments: Some commenters stated their belief that the complaint filing process in the proposed rule was overly complex. One commenter suggested that complaints should be deemed acceptable if sent to the ALJ, the local Social Security office, carrier or fiscal intermediary (FI), or the Board.

Response: We have revised the final rule to simplify and clarify the complaint filing procedures and to make them more beneficiary-friendly. We have eliminated a number of requirements that we believe are unnecessary. However, it is the duty of

the beneficiary to file the complaint correctly under these regulations. Nevertheless, we will issue instructions advising our contractors of procedures for a misdirected LCD/NCD complaint. These instructions will inform the contractor that it should forward the complaint to the proper location and notify the beneficiary.

Physician Certification

Comment: Some commenters stated that physician documentation of medical need is a reasonable way of determining whether beneficiaries have a basis for challenging LCDs/NCDs. However, other commenters felt that the physician certification requirements imposed unnecessary new paperwork burdens on physicians. Some commenters argued that it was unrealistic to require physicians to be certain of the intricacies of Medicare policies. Others felt these requirements would prove to be a significant impediment to the process and suggested that the original physician order for the service suffice as certification that the beneficiary needed the service. Finally, a number of commenters suggested that non-physician practitioners should be allowed to document the beneficiary's need.

Response: We have revised the certification requirements at § 426.400(c) and § 426.500(c) in this final regulation by clarifying that the certification of need can be in the form of a written order for the service in question or other documentation in the medical record, thus significantly simplifying the certification requirements. We have also removed the requirement that the practitioner predict that payment would be denied. However, we continue to believe that the beneficiary's treating physician—not any treating practitioner—is best situated to determine "in need" status, both because he or she is the primary caregiver and also is responsible for the beneficiary's overall care.

Joint Complaints

Comments: We proposed permitting multiple parties to file a single complaint. We received one comment in support of the joint complaint option noting that it permits more effective resource utilization in addressing complaints. One commenter recommended that the criterion for joint complaints should not require "a similar medical condition," rather that the adverse impact created by the LCD or NCD should create standing. Another commenter asserted that requiring a similar medical condition was

unnecessary and inconsistent with the Federal Rules of Civil Procedure and that requiring a challenge to the same provisions of the same policy should be sufficient.

Response: In response to the comments concerning the requirement of a "similar medical condition" for the filing of a joint complaint, we believe that this requirement is reasonable, given the specific focus of these adjudications. Moreover, the Federal Rules of Civil Procedure are not controlling on our administrative proceedings. We believe that these procedures appropriately fit the specific requirements for LCD and NCD adjudications and are consistent with the Secretary's authority (42 U.S.C. 405(a)). Moreover, we do not eliminate the possibility of combining actions based upon different medical conditions if a party believes, and the ALJ/Board finds, that there are other bases for consolidating complaints.

Adjudicator Consolidation of Complaints

Comment: We received three comments on adjudicator authority to consolidate complaints. One commenter recommended merging the provisions for joint and consolidated complaints or, alternatively, having the provisions cross-reference one another. Another commenter objected to the consolidation of complaints without the aggrieved party having reviewed the other complaint(s) to determine whether or not the consolidation might negatively impact the individual's specific issue with the LCD or NCD. Another commenter questioned whether the consolidation might result in lengthening the process if an adjudicator combined a later complaint with an earlier one.

Response: We believe that preserving the procedures for aggrieved parties to file joint complaints and for adjudicators to consolidate complaints promotes efficiency in adjudicating challenges to LCDs and NCDs. While we recognize that the two procedures support a common goal, we note that they are separate and distinct and therefore should remain in their respective sections. With respect to the comments concerning the possibility that a party might find consolidation adverse or burdensome, we believe it is appropriate for the adjudicator to determine whether consolidation is appropriate under the specific circumstances. We will allow any aggrieved party who feels disadvantaged by consolidation to raise these issues to the ALJ/Board. We have added language to § 426.410(e) and § 426.510(e) to