

clarify that the ALJ/Board may not consolidate complaints if doing so would unduly delay the ALJ/Board decision.

#### *Amending a Complaint*

*Comment:* Several commenters indicated that they were concerned that the proposed rule allowed a beneficiary to amend a complaint only once and then required the ALJ/Board to dismiss the challenge if the aggrieved party failed to submit an acceptable amended complaint.

*Response:* The statute requires that the section 522 challenge begin with the filing of a complaint. We believe that it would be inefficient if an aggrieved party had an unlimited number of attempts to file an acceptable complaint. A complaint is a significant document in identifying issues on appeal and leads to the production of the record. The final rule continues to allow the aggrieved party one opportunity to amend an unacceptable complaint before a time penalty is imposed.

#### *Withdrawal of Complaint—Six-Month Limit on Refiling*

*Comment:* We received two comments in support of our proposal to establish a six-month limitation if an aggrieved party withdraws a complaint. One commenter was opposed, stating that if the aggrieved party has new evidence, he or she should be allowed to file another complaint regardless of the timeframe. We received two additional comments suggesting that, if the aggrieved party has new evidence, he or she should be allowed to file another complaint without a time limitation.

*Response:* We continue to believe that the six-month time limit is necessary to ensure the efficient use of scarce resources. If the aggrieved party withdraws a complaint, that aggrieved party must still wait six months before filing a new complaint on the same LCD/NCD. However, we have clarified that, once an acceptable complaint has been filed, if the aggrieved party identifies new evidence that was not available at the filing of the original complaint, the aggrieved party may submit that new evidence at any time without withdrawing and resubmitting the complaint.

#### *Aggrieved Party Submitting a Brief*

*Comment:* We received one comment suggesting that an aggrieved party should have the opportunity to submit a brief after the aggrieved party has had the opportunity to review the record upon which the LCD or NCD was based.

*Response:* We agree that an aggrieved party should have an opportunity to

make his or her case. In seeking to make this process accessible to Medicare beneficiaries, who may or may not have legal representation, we did not want to mandate that parties submit legal briefs in support of their claims. However, in view of the changes we have made to the review process in this final rule, particularly for the introduction and use of new evidence, we are clarifying that, while briefs are not required in all cases, the adjudicator may request or permit the parties to submit written briefs and that the aggrieved party has the option to retain representation and to submit these written briefs.

#### *Educating Beneficiaries and Providers About the Process*

*Comment:* Many commenters stressed the importance of having a well-constructed and advertised educational campaign for providers and beneficiaries. Some commenters suggested that a template for an acceptable complaint, a physician's certification, and an acceptable appeal of an ALJ's decision be available on the CMS Web site to assist beneficiaries in filing an acceptable complaint. Another commenter suggested that beneficiaries should be informed of their rights in the LCD or NCD review process and that one means of providing this might be to include it with advanced beneficiary notice (ABN) forms. Another commenter encouraged us to inform beneficiaries clearly as to their financial obligations while the complaint is pending. Several other commenters suggested that we provide model language for use by Medicare managed care organizations to use in their evidence of coverage documents.

*Response:* In the proposed rule (67 FR 54547), we explained our intent to produce a user-friendly guide that beneficiaries may use in accessing the section 522 process. We will work with the ALJs and Board to develop educational materials to inform the public of—

(1) The elements of an acceptable complaint;

(2) The standards for treating physician certifications; and

(3) The elements of an acceptable appeal of an ALJ decision. We intend to prepare this educational material (including templates) and make it publicly available, but we will not delay implementation of the final rule to wait for these materials to be developed. We will work with ALJs and the Board to make available to Medicare managed care organizations and Medicaid State agencies, relevant information on complaints and decisions. We do not

intend to revise ABNs as part of this educational program.

#### *Allowing Participation by Interested Entities*

*Comment:* Several commenters believed that we should allow for more public participation of interested entities in the process, along with submission of evidence by those parties.

*Response:* The LCD and NCD reconsideration processes currently exist to give all interested entities the right to request and participate in reconsiderations of these policies. These processes will continue to exist to provide an avenue for all interested entities to submit evidence that they consider pertinent. In contrast, the adjudicatory process created by section 522 is initiated only by a beneficiary in need of coverage, and not by all interested individuals. We are concerned that allowing any member of the public to submit evidence would make these adjudicatory proceedings unwieldy. We are modifying this final rule at § 426.513, however, to permit participation as *amicus curiae*, in the NCD process. We recognize that NCD reviews may impact a large number of stakeholders apart from the aggrieved parties initiating the review. We believe that the nationwide effect of an NCD review decision requires public notice and opportunities for input in a way that LCD reviews do not. In addition, this impact may be significant, even where no change to existing policy results from the review, such as when the Board concludes that an NCD record is complete and contains adequate information to support the validity of the NCD.

Anyone who has information that can assist the Board in reviewing an NCD challenge is permitted to request participation as an *amicus curiae*. Given the nationwide effect of an NCD review decision, the process must strike a careful balance between providing reasonable opportunities for input by those who may ultimately be substantially affected by any decision, and creating a workable process to address the issues presented by the aggrieved party seeking review. Because of the regional nature and high number of LCDs, allowing the opportunity for *amicus curiae* participation in the review of LCDs would create an inefficient process. However, at any time, any party within the contractor's jurisdiction who wishes to bring forward new evidence relating to a policy may do so through the contractor's LCD reconsideration process. This process is frequently used