

independent from the claims appeal process. This process will be different, because the nature of the challenge and the relevant evidence is different. The procedures used in this process will be different from the claims appeals process. Review of an LCD or NCD requires examination of an entire policy, or specific provisions contained therein, and not just one claim denial. Therefore, such reviews may lead to changes that impact other beneficiaries if the policies are found to be unreasonable. A beneficiary, thus, may elect to pursue a claims denial through the claims appeal process, seek review of an LCD or NCD using the process in this final rule, or both. In no way does filing a 522 challenge, or a decision on a 522 challenge, affect beneficiary appeal rights or other issues that may arise in the claims appeal process.

Complaints under section 522 of the BIPA are subject to standing rules. Namely, under section 1869(f)(5) of the Act “[a]n action under this subsection seeking review of a national coverage determination or local coverage determination may be initiated only by individuals entitled to benefits under part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination.” In this final rule, we are interpreting the standing provision to include individuals who have received the item or service and whose initial claim was denied based on an LCD or NCD and, thus, are in need of Medicare coverage. We will also permit the estates of certain individuals to have standing. Only individuals who have standing may bring a challenge under section 522 of the BIPA, and in this final rule, we refer to these individuals as “aggrieved parties.”

As discussed in the proposed rule, the aggrieved party may not assign the right to bring a challenge under section 522 of the BIPA to anyone else. However, the aggrieved party is permitted to obtain assistance from any individual in pursuing the challenge. (We discuss the difference between assigning rights and receiving assistance in section IV of this final rule.)

The definition of an “aggrieved party” will permit an individual to bring a challenge to an LCD or NCD in advance of receiving an item or service, or after the LCD or NCD is applied to a claim causing the claim to be denied. As we discuss in greater detail in section IV.E of this preamble, a successful challenge would permit the individual to have his or her specific claim reviewed without reference to the challenged policy. Claims that are otherwise payable can be paid. In addition, a successful

challenge to an LCD or NCD may result in the following:

- The policy being retired/withdrawn in its entirety, or
- The policy being revised to effectuate the Board decision, or the ALJ decision if it is not appealed to the Board.

3. The Reconsideration Process

We previously established a procedure by which individuals could seek reconsideration of policies established in an LCD or NCD. The procedures for NCDs were set forth in the September 26, 2003 notice (68 FR 55634, 55641). The procedures for LCDs were set forth in the Program Integrity Manual, Chapter 13, Section 11.

4. The Role of Other Interested Individuals or Entities

The section 522 review process is intended to be initiated only by aggrieved parties. However, consistent with several public comments, we are expanding § 426.510(f) to allow for limited participation in an NCD challenge by other individuals as *amicus curiae* when the individuals or entities meet the standards set forth in these regulations. Please note that the reconsideration process described in section I.I.3 of this preamble remains the appropriate process by which all other interested entities may submit new evidence pertaining to the review of current LCDs and NCDs.

5. Differences Between an LCD/NCD Review and an LCD/NCD Reconsideration

The main difference between an LCD/NCD review under section 522 of the BIPA and an LCD/NCD reconsideration is the avenue an individual chooses to take to initiate a change to a coverage policy and who may initiate the review. All interested parties, including an aggrieved party, may request a reconsideration of an LCD or NCD, rather than filing a complaint to initiate the review of an LCD or NCD. Conversely, only an aggrieved party may file a complaint to initiate the review of an LCD or NCD. If the aggrieved party believes that we, or the contractor, misinterpreted evidence or excluded available evidence in making the coverage determination or has new evidence to submit, then the aggrieved party has the option to file a request for a reconsideration by the contractor or us, respectively, or to file a complaint to seek review by an adjudicator.

In the reconsideration process, all interested parties, not just aggrieved parties, have the opportunity to submit new scientific and medical evidence for

review by individuals with medical and scientific expertise. The reconsideration process permits experts to make judgments about those policies, rather than using an adjudicatory proceeding.

II. Provisions of the Proposed Rule

For a discussion of the specific provisions of the proposed rule, please see 67 FR 54534–54563. The significant changes to the final rule, based on public comments, are reflected in section III, below.

III. Analysis of and Response to Public Comments

We received 31 comments from the public on the proposed rule. Summaries of the major comments received and our responses to those comments are set forth below.

Definition of an NCD

Comment: We received several comments on our interpretation of what qualifies as an NCD, and which policies are subject to review. Some public comments stated that we interpreted the statute too narrowly, and that additional policies should be subject to review; other public comments suggested that we interpreted the statute too broadly, and that benefit category determinations should not be defined as NCDs, and should not be subject to review before the Board.

Response: Our definition of an NCD is consistent with the statutory language, and we are not accepting the public comments that suggest the definition is either too broad or too narrow. We continue to believe that the statute is clear, and that the Congress has created a new definition of NCD to include benefit category determinations. The Congress's definition of an NCD is now broader than the prior statute at section 1869(b)(3) of the Act. Moreover, it is broader than the definition of LCD that is specifically limited to determinations made in accordance with section 1862(a)(1)(A) of the Act. We presume that the Congress acted intentionally and precisely in defining an NCD, and we are following that definition in this final rule.

Definition of LCD

Comment: One commenter suggested that an LCD should be synonymous with LMRP.

Response: Because the statutory definition of an LCD is limited to the reasonable and necessary provisions in section 1862(a)(1)(A) of the Act, we could not make the definition of an LCD synonymous with the definition of an LMRP. As discussed earlier in this preamble, an LMRP may contain coding,