

*Response:* We believe that both options should be available to aggrieved parties, in order to allow for the parties to seek a decision in the most appropriate way possible, and to allow the most flexibility to these parties.

#### *Expedited Judicial Review*

*Comment:* Several commenters suggested that the final regulations should address section 1869(f)(3) of the Act, which relates to circumstances where a challenger may seek expedited judicial review when there are no material issues of fact in dispute.

*Response:* We are not adopting these comments. This section of the statute does not require regulatory action by CMS because it is related to the jurisdiction of the judicial branch of the government. The statute is self-implementing and does not require additional rulemaking by the Secretary.

### **IV. Provisions of the Final Rule**

#### *A. Overview*

We are establishing that a Medicare beneficiary who qualifies as an aggrieved party may challenge an LCD or an NCD (or specific provisions therein) by filing a complaint concerning an LCD with the office designated by CMS on the Medicare Web site, <http://www.medicare.gov/coverage/static/appeals.asp> (information on the designated office will be available by calling 1-800-Medicare) or by filing a complaint concerning an NCD with the Board of HHS. After a complaint is filed, the adjudicator determines whether the complaint is acceptable.

In this final rule, we are adding in § 400.202 a definition of “Local coverage determination (LCD)” and revising the definition of “National coverage determination (NCD).” The definitions are specific to Medicare and reflect the definitions for these terms found in section 522 of BIPA. With one exception described below, this final rule makes clear that a determination of the code assigned to a service, if any, or a determination with respect to the amount of payment to be made for the service is not included in the definition of an LCD or an NCD. We have clarified that diagnosis codes used in an LMRP to describe when a service is considered medically necessary are also part of the LCD. We use the term “Services” as defined in § 400.202 to include both “items and services.”

In § 405.732, “Review of a national coverage decision (NCD),” we revise paragraph (a) regarding appeals of Part A cases, to state that an NCD is a determination by the Secretary with

respect to whether or not a particular item or service is covered nationally under title XVIII. An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination with respect to the amount of payment made for a particular item or service. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act. An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

This final rule revises § 405.732(b) to specify that an ALJ may not disregard, set aside, or otherwise review an NCD. An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

We are revising § 405.732(c) to specify that for initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court’s review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. In such cases, the court may not invalidate an NCD except upon review of the supplemental record. For Part B appeals, we are making similar changes.

In § 405.860, “Review of a national coverage decision (NCD),” we revise paragraph (a) regarding appeals of Part B cases to specify that an NCD is a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII. An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination with respect to the amount of payment made for a particular item or service. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act. An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, Medicare Appeals Council, and ALJs.

We are revising § 405.860(b) to specify that an ALJ may not disregard, set aside, or otherwise review an NCD. An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

In § 405.860(c), we specify that for initial determinations and NCD challenges under section 1862(a)(1) of

the Act, arising before October 1, 2002, a court’s review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. The court may not determine that an item or service is covered except upon review of the supplemental record.

We are also adding a new part 426, titled “Reviews of Local and National Coverage Determinations,” to title 42 of the CFR to include the following subparts:

- Subpart A contains general provisions applicable to the entire part.
- Subpart B is reserved.
- Subpart C contains the general provisions applicable to the review of LCDs and NCDs.
- Subpart D contains the provisions specific to the review of LCDs
- Subpart E contains the provisions specific to the review of NCDs.

#### *B. Subpart A (General Provisions)*

Subpart A of part 426 specifies the general provisions applicable to the entire part. Section 426.100, “Basis and scope,” sets forth the basis (under sections 1869(f)(1) and (f)(2) of the Act), and the scope specifies the requirements and procedures for the review of LCDs and NCDs. In § 426.110, we define the terms used in part 426 whose definitions may not otherwise be implicit.

Under section 522 of BIPA, only an “aggrieved party” may file a complaint to initiate the review of an LCD or an NCD. In this final rule, we define “aggrieved party” as a Medicare beneficiary who is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan), and is in need of coverage for a service that is the subject of an applicable LCD (in the relevant jurisdiction) or an NCD as documented by the beneficiary’s treating physician. We revised the final rule to include also as an aggrieved party a beneficiary who has already received the service and is in need of coverage, or the estate of a deceased beneficiary in need of coverage.

Based on comments on our proposed rule, in this final rule we allow an aggrieved party’s estate to pursue an LCD/NCD challenge if the aggrieved party died after filing a proper complaint and the aggrieved party received the service for which coverage is sought. We also allow the aggrieved