

the Medicare program. If the claim is for an item or service that falls within a Medicare benefit category, is reasonable and necessary for the individual, and is not otherwise statutorily excluded, a government contractor (either a fiscal intermediary for claims under Part A or Part B, or a carrier for claims under Part B) would pay the claim. However, if the Medicare contractor determines that the medical care is not covered under the Medicare program, the Medicare contractor would deny the claim.

This final rule does not seek to significantly alter the existing claims appeal process. Nor does this rule significantly alter our existing regulations for M+C beneficiaries as established at § 422.560 through § 422.622. However, it does create an expanded definition of aggrieved party to include a beneficiary who received a service, but whose claim for the service was denied, extending an opportunity to that beneficiary to file a complaint under § 426.400 or § 426.500. For further discussion of the claims appeal process please consult the proposed rule.

D. National Coverage Determinations (NCDs)

Section 1869(f)(1) of the Act defines national coverage determination as “a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.” For the full discussion of NCDs please consult our proposed rule at 67 FR 54535 published on August 22, 2002.

E. Local Medical Review Policy (LMRP)

As explained in the preamble to the proposed rule, Local Medical Review Policies are contractor-specific policies that identify the circumstances under which particular items or services will be (or will not be) considered covered and correctly coded. An LMRP is not controlling authority for ALJs or the Board in the claims appeals process. These guidelines simply help to ensure that similar claims are processed in a consistent manner within those jurisdictions. LMRPs may not conflict with an NCD, but may be written in the absence of, or as an adjunct to, an NCD.

An LMRP may contain any or all of the following:

- Coding provisions.
- Benefit category provisions.
- Statutory exclusion provisions.

- Provisions related to the authority under section 1862(a)(1)(A) of the Act, which prohibits payment for any expenses incurred for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.

Some LMRPs contain only a single type of provision, while other LMRPs contain all four types. The provisions described in bullets two through four above constitute coverage provisions.

For further information on LMRPs please consult our proposed rule at 67 FR 54535.

F. Local Coverage Determinations

Section 522 of BIPA does not use the term “LMRP,” but uses the term “Local Coverage Determination” (LCD). Section 522 of BIPA amends section 1869(f)(2)(B) of the Act, to define LCD as “a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).”

An LMRP may contain four different types of provisions (coding, benefit category, statutory exclusion, and reasonable and necessary). Section 1869(f)(2)(B) of the Act limits an LCD as a determination only under section 1862(a)(1)(A) of the Act’s “reasonable and necessary provision.” For the purposes of this regulation, we will use the term “reasonable and necessary provision” to describe section 1862(a)(1)(A) of the Act. We intend to work with contractors to divide LMRPs into separate LCD and non-LCD documents; however, it is likely that LMRPs will continue to exist for the next several years. During this time, the term LCD will refer to both of the following:

- Separate, stand-alone documents entitled “LCDs” that contain only reasonable and necessary language; and
- The reasonable and necessary provisions of an LMRP.

G. Differences Between NCDs and LMRPs/LCDs

Under our claims appeals process, ALJs may consider, but are not bound by, LMRPs or LCDs. Thus, an ALJ may rule that Medicare payment is due on a particular item or service received by a beneficiary, based on the particular circumstances represented by the case, even if the contractor’s LMRP or LCD clearly prohibits payment for the particular service. (We note that a regulation which may impact ALJ consideration of LCDs in claims appeal

cases has been proposed. See 67 FR 69328, 69351.) On the other hand, contractors and ALJs are bound by NCDs. ALJs may not review an NCD.

H. Individual Claim Determinations

In addition to policy determinations, contractors may make individual claim determinations, even in the absence of an NCD, LMRP, or LCD. In circumstances when there is no published policy on a particular topic, decisions are made based on the individual’s particular factual situation. See *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication).

I. Impact of Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

1. Overview of the Legislation

Section 522 of the BIPA created a new review process that enables certain beneficiaries to challenge LCDs and NCDs. These appeal rights are distinct from the existing appeal rights for the adjudication of Medicare claims. This section also creates additional avenues for beneficiaries to seek judicial review. Before BIPA, the statute did not provide an administrative avenue to challenge the facial validity of LCDs or NCDs.

2. Differences Between the Claims Appeal Process and the LCD/NCD Review Processes

The existing claims appeal rights were not significantly changed by section 522 of the BIPA. Our claims appeal regulations will continue to provide detailed administrative appeal rights for beneficiaries whose claims are denied. These claims appeal procedures permit beneficiaries to challenge the initial claims denial and include *de novo* review by an independent ALJ. If still dissatisfied after exhausting all administrative remedies, a beneficiary has a right to seek judicial review in a Federal district court. This claim appeal system enables beneficiaries to submit any relevant information pertaining to an individual claim. Moreover, because LCDs are not controlling authorities for ALJs, when an ALJ does not find an LCD persuasive, an individual claim appeal could result in the claim being paid without the need to challenge the underlying LCD. We have proposed rules that would modify the claims appeals process at 67 FR 69312 (November 15, 2002).

Section 522 of the BIPA created a review process that is separate and