CMS Rulings

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Ruling No. 01-01
Date: September 28, 2001

Centers for Medicare & Medicaid Services (CMS) Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

CMS Rulings are binding on all CMS components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and Administrative Law Judges (ALJs) of the Social Security Administration (SSA) who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the CMS policy regarding the appropriate actions upon receipt of a complaint seeking review of a national or local coverage determination under section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106-554.

MEDICARE PROGRAM

The National and Local Coverage Determination Review Process for an Individual with Standing as Defined in Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protections Act of 2000.

SUMMARY: Under section 1869(f)(5) of the Social Security Act (the Act), as added by section 522 of BIPA, effective October 1, 2001, certain individuals ("aggrieved parties") may file a complaint to initiate a review of a national or local coverage determination. Complaints filed under section 1869(f) of the Act concerning national coverage determinations are to be reviewed by the Departmental Appeals Board (DAB) of the Department of Health and Human Services; complaints filed under section 1869(f) of the Act concerning local coverage determinations are to be reviewed by ALJs of the Social Security Administration. The purpose of this Ruling is to establish the interim administrative procedures that CMS contractors, ALJs, and the DAB are to follow in processing such complaints until final regulations are published regarding the adjudication of the complaints and the effectuation of ALJ and DAB decisions with respect to complaints.

CITATIONS: Section 1869 of the Social Security Act (42 U.S.C. 1395ff), and section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106-554 (2000).

BACKGROUND

Section 522 of BIPA amends section 1869 of the Act to create a new administrative review process that enables certain beneficiaries to challenge CMS Medicare policies, commonly referred to as national coverage determinations (NCDs) and local coverage determinations (LCDs). These administrative challenges are distinct from the existing appeal rights for the adjudication of Medicare claims.

Prior to BIPA, there was no administrative mechanism for any party to challenge a coverage policy. Section 1869(b)(3) of the Act, however, provided a remedy for judicial review of NCDs based on section 1862(a)(1) of the Act, that is, determinations as to whether an item or service is reasonable and necessary. Section 1869(f) of the Act requires that CMS establish an administrative review process for NCDs and LCDs. Under the statute, beneficiaries who are in need of a service that is the subject of a coverage determination may challenge an NCD in an administrative proceeding before the Departmental Appeals Board (DAB). Similar provisions allow aggrieved parties to challenge LCDs before an ALJ. An aggrieved party dissatisfied with the ALJ's decision may seek review by the DAB. In this type of appeal, the DAB acts as an appellate body. The decision of the DAB relating to an LCD challenge or an NCD challenge becomes a final agency action and is subject to judicial review.

The effective date for these provisions is October 1, 2001. Section 521 of BIPA sets forth additional changes to our existing claim appeals process that are to take effect on October 1, 2002.

DELAY OF REVIEWS UNDER SECTION 1869(f)

Section 522(d) of BIPA establishes an effective date of October 1, 2001 for new section 1869(f) of the Act. Although the statute thus permits aggrieved parties to file complaints with respect to NCDs and LCDs beginning October 1, 2001, we believe it is clearly in the public interest to complete notice and comment rulemaking to develop the rules and procedures for adjudicating these policy challenges. Notice and comment rulemaking will ensure that the public has an opportunity to fully participate in the development of these rules. It also will ensure that the DAB and the ALJs have a uniform adjudicative process for resolving these issues in a fair and efficient manner.

It is essential that these complaints be handled in a uniform manner for several reasons. First, the coverage determinations to be reviewed under the provisions of section 1869(f) of the Act apply to a broader group of beneficiaries than just the individual beneficiary who has raised the complaint. NCDs apply to all claims nationwide for the particular item or service in question and are binding on both the Medicare contractors and the ALJs who hear individual claims appeals. LCDs apply to beneficiaries within the jurisdiction specified by the contractor and are binding on the contractors making claims determinations. Due to the broad impact of these policies, review of these policies must be done in a consistent, predictable manner. It is important to establish final regulatory guidance on these provisions with the benefit of public notice and comment before the provisions are fully implemented. For example, regulatory guidance is necessary to ensure that the provisions identifying those beneficiaries with standing to file a complaint about an NCD or LCD are

interpreted consistently and that consistent remedies be available to beneficiaries whose challenge to a coverage determination is successful.

In addition, the coverage determination reviews are a new responsibility for the ALJs and the DAB. We believe that establishing a consistent system for handling these reviews from the beginning will enable these entities to process this additional workload as efficiently as possible.

Therefore, to ensure consistent handling of NCD and LCD review requests and to ensure that all aggrieved parties are afforded equal rights and protections, CMS is delaying full implementation of section 1869(f) of the Act until final regulations are issued. This delay will avoid inefficient and ad hoc proceedings that could occur if each contractor, ALJ, and the DAB establish separate procedures.

RESTRICTIONS ON MEDICARE CONTRACTORS IN ABSENCE OF A REGULATION

Until a final regulation is issued that fully implements section 1869(f) of the Act, carriers, fiscal intermediaries, and program safeguard contractors (PSCs) must not provide or furnish any materials, information, background, or any other pertinent information regarding the development or implementation of an NCD or LCD to either the DAB or an ALJ. Instead, any request for NCD or LCD documentation from the DAB or an ALJ should be referred immediately to the appropriate contact in the CMS central office (see below). Furthermore, if an administrative decision requiring the carrier, fiscal intermediary, or PSC to take any action with respect to a specific NCD or LCD is issued, the contractor must refer this request to CMS central office before taking any action.

MEDICARE CONTRACTOR ADMINISTRATIVE PROCESS FOR ANY REVIEWS OF NATIONAL OR LOCAL COVERAGE DETERMINATIONS

If a complaint under section 1869(f) of the Act is filed with a carrier, fiscal intermediary or PSC requesting a review of a national or local coverage determination under section 1869(f) of the Act, the carrier, fiscal intermediary, or PSC must within 10 business days, forward a complaint concerning an LCD to SSA's Office of Hearings and Appeals and a complaint concerning an NCD to the DAB at the addresses below. After forwarding the complaint to the Office of Hearings and Appeals or DAB, the contractor must notify the appropriate contact in the CMS central office and provide them a copy of the complaint.

LCD Referral
Office of Hearings and Appeals
Social Security Administration
One Skyline Tower
Suite 1702
Attention: LCD Complaint
5107 Leesburg Pike
Falls Church, Virginia 22041

NCD Referral
Departmental Appeals Board
U.S. Dept. of Health and Human Services
Room 637D, Humphrey Building
Attention: NCD Complaint
200 Independence Avenue, S.W.
Washington, D.C. 20201

ADMINISTRATIVE REVIEW PROCESS WITH RESPECT TO NCDs or LCDs

If a complaint under section 1869(f) of the Act is filed with or forwarded to the DAB or an ALJ, the DAB or ALJ will:

1. Within 10 business days, send a written response to the requestor informing them that the review process for the complaint is being delayed under this Ruling, and that the Department of Health and Human Services intends to publish regulations establishing uniform procedures.
2. Docket any such requests.
3. Inform the CMS of any requests received. (This should be accomplished by sending a copy of the complaint to the appropriate notification contact.)

LCD Notification Contact
Melanie Combs
7500 Security Blvd
C3-02-16
Baltimore, MD 21244-1850
Attention: LCD Challenge Staff
Telephone Number: (410) 786-7683

NCD Notification Contact
Vadim Lubarsky
7500 Security Blvd
C1-10-23
Baltimore, MD 21244-1850
Attention: NCD Challenge Staff
Telephone Number: (410) 786-0840

4. Take no further action until final regulations are effective.
5. Once the regulation is effective, inform the requestor that processing of complaints under the new review procedures will continue.

EFFECTIVE DATE

This Ruling is effective September 30, 2001.

Thomas A. Scully
Administrator,
Centers for Medicare & Medicaid Services