

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 405, and 426

[CMS-3063-F]

RIN 0938-AK60

Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will create a new process to allow certain Medicare beneficiaries to challenge national coverage determinations (NCDs) and local coverage determinations (LCDs). It will implement portions of section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. The right to challenge NCDs and LCDs will be distinct from the existing appeal rights that Medicare beneficiaries have for the adjudication of Medicare claims.

EFFECTIVE DATE: The provisions set forth in this final rule are effective December 8, 2003.

FOR FURTHER INFORMATION CONTACT: Vadim Lubarsky, 410-786-0840 for National Coverage Determinations. Misty Whitaker, 410-786-3087 for Local Coverage Determinations.

SUPPLEMENTARY INFORMATION:

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Note: The former name of the Centers for Medicare & Medicaid Services (CMS) was the Health Care Financing Administration (HCFA). The terms CMS and HCFA can be used interchangeably.

In addition, because of the many terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below.

ALJ—Administrative Law Judge
CAC—Carrier Advisory Committee
CMP—Comprehensive Medical Plan
DMERC—Durable Medical Equipment
Regional Carrier
FI—Fiscal Intermediary
HCPP—Health Care Prepayment Plan
HMO—Health Maintenance
Organization
LCD—Local Coverage Determination
LMRP—Local Medical Review Policy
M+C—Medicare+Choice
MCAC—Medical Coverage Advisory
Committee
NCD—National Coverage Determination
QIO—Quality Improvement
Organization
RHHI—Regional Home Health
Intermediary

I. Background

A. Background of Rulemaking

On August 22, 2002, we issued a proposed rule (67 FR 54534) implementing certain provisions of section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), proposing a process for the review of local coverage determinations (LCDs) and national coverage determinations (NCDs). The notice and comment period closed on October 21, 2002. We received 31 timely comments, which were quite useful in identifying issues and concerns. We have made significant changes to this final rule to address the public comments. We believe that these changes will contribute to a fairer and more efficient process. Significant changes to the proposed rule based on public comments, which are discussed in section III, below, include:

- More broadly defining beneficiaries “in need.”
- Reducing the burden for physician certification requirements.
- Allowing for participation in the BIPA section 522 adjudicatory process as an amicus curiae (friend of the court) for NCD appeals.
- Creating a mechanism to allow new evidence to be received subject to time-limited remands.
- Expanding the effect of a final decision by the Administrative law judge (ALJ) or the HHS Departmental Appeals Board (Board).

B. Overview of Existing Statutes, Regulations, and Policies

Medicare is the nation's largest health insurance program covering approximately 41 million Americans. Beneficiaries consist primarily of individuals 65 years of age or older, some disabled people under 65 years of age, and people with end-stage renal disease (permanent kidney failure treated with dialysis or a transplant).

The original Medicare program consists of two parts. Part A, known as the hospital insurance program, covers certain care provided to inpatients in hospitals, critical access hospitals, skilled nursing facilities, as well as hospice care and some home health care. Part B, the supplementary medical insurance program, covers certain physicians' services, outpatient hospital care, and other medical services that are not covered under Part A. While the original Medicare program covers many health care items and services, it does not cover all health care expenses. The Medicare statute specifically excludes from coverage certain items and services under section 1862(a) of the Social Security Act (the Act).

In addition to the original Medicare program, beneficiaries may elect to receive health care coverage under the Medicare+Choice (M+C) program under Part C of the Medicare program. This program provides beneficiaries with various options, including the right to choose a Medicare managed care plan or a Medicare private fee-for-service plan. Under the M+C program, an individual is entitled to those items and services (other than hospice care) for which benefits are available under Part A and Part B. An M+C plan may provide additional health care items and services that are not covered under the original Medicare program.

The Act gives beneficiaries specific rights to challenge particular types of decisions. We are committed to providing beneficiaries an opportunity to fully exercise these statutory rights. Moreover, we are committed to resolution of these disputes in a fair and efficient manner.

C. Claims Appeal Process

Under the original Medicare program, a beneficiary may generally obtain health services from any institution, agency, or person qualified to participate in the Medicare program that undertakes to provide the service to the individual. Assuming that a qualified provider or supplier has furnished medical care, the health care provider or supplier, or, in some cases, a beneficiary would submit a claim for benefits under