

result, we believe that the rule will have an insignificant economic impact on health care providers or the health care industry as a whole.

3. Effects on the Medicare Program

The Medicare program would incur certain significant administrative costs associated with coverage determination reviews, the cost of being a party to coverage determination reviews, the cost of reevaluating policies, and the cost of changes to the claim review and appeals procedures.

D. Alternatives Considered

We considered various alternative approaches for implementing the ALJ or the Board decisions with respect to an LCD and NCD. One alternative we considered was to allow an ALJ or the Board to specify the type of relief that would be afforded to the aggrieved party in those instances in which an ALJ or the Board issued a finding of unreasonable under the reasonableness standard. We contemplated whether it would be feasible based on the record developed in this proceeding for an ALJ or the Board to order us to make payment for a particular claim for the individual. We determined, however, that because the record in a policy challenge adjudication focuses on the challenged policy, and not on the beneficiary's particular medical circumstances or entitlement to Medicare benefits, it is not possible to allow an ALJ or the Board to order payment in those circumstances. In some cases, other statutory restrictions may apply for a particular claim that would prevent Medicare from making payment even if the LCD or NCD were found unreasonable. For instance, if care were furnished by an excluded physician in other than an emergency situation, section 1862(e)(1) of the Act would bar Medicare payment. There are other examples where rules other than an NCD may lead to the denial of a claim (such as statutory exclusion). To avoid redundant claims/appeals processes, individual review is performed through our existing claims appeals procedures, but the LCD or NCD that was found unreasonable by the ALJ or the Board will not be applied.

Further, we do not believe that it is appropriate for an ALJ or the Board to add language to coverage determinations. LCDs and NCDs are based on clinical and scientific evidence to develop policies that are both sound and effective, and continue to ensure the highest quality of covered care for Medicare recipients. For the sake of continuing to ensure that aggrieved parties receive the same quality care as

all other Medicare recipients, and for the sake of efficiently administering this process, we believe that clinicians and scientific experts are best suited to continue to develop these policies.

In accordance with the provisions of Executive Order 12866, as amended by Executive Order 13258, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 400

Grant programs—health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 426

Administrative practice and procedure, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 400—INTRODUCTION; DEFINITIONS

■ 1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

■ 2. Amend § 400.202 by adding the definitions of “Departmental Appeals Board,” and “Local coverage determination (LCD),” and by revising the definition of “National coverage determination (NCD)” to read as follows:

§ 400.202 Definitions specific to Medicare.

* * * * *

Departmental Appeals Board means: (1) Except as provided in paragraphs (2) and (3) of this definition, a Board established in the office of the Secretary, whose members act in panels to provide impartial review of disputed decisions made by operating components of the Department or by ALJs.

(2) For purposes of review of ALJ decisions under part 405, subparts G and H; part 417, subpart Q; part 422, subpart M; and part 478, subpart B of this chapter, the Medicare Appeals Council designated by the Board Chair.

(3) For purposes of part 426 of this chapter, a Member of the Board and, at the discretion of the Board Chair, any

other Board staff appointed by the Board Chair to perform a review under that part.

* * * * *

Local coverage determination (LCD) means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with section 1862(a)(1)(A) of the Act. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

* * * * *

National coverage determination (NCD) means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act. An NCD does not include a determination of what code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

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PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1888(k) of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 4. Revise § 405.732 to read follows:

§ 405.732 Review of a national coverage determination (NCD).

(a) **General rule.** (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) 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 for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.