Recommendation 87-8

National Coverage Determinations Under the Medicare Program

(Adopted December 17, 1987)

In 1986, the Administrative Conference undertook a broad overview of the administrative procedures employed by the federal government (primarily the Health Care Financing Administration within the Department of Health and Human Services) in administering and deciding appeals under the Medicare program. Recommendation 86-5, Medicare Appeals, 1 CFR 305.86-5, urged the Health Care Financing Administration (HCFA) to improve its system for publishing, updating, and making accessible the standards, guidelines and procedures used in making coverage and payment determinations in the Medicare program. The recommendation also suggested some improvements in the administrative appeals system and listed some fruitful areas for further research.

This recommendation builds on Recommendation 86-5 by focusing on a major aspect of the Medicare program: the making of policy concerning what aspects of medical care are covered by, and therefore reimbursable by, the Medicare program. Implementation determinations must be made every day on a case-by-case basis by Medicare contractors (peer review organizations, carriers and fiscal intermediaries such as Blue Cross). In most of these cases the coverage question involves a determination of whether an item or service was medically necessary for the individual or was furnished in the appropriate setting. Typically, the Medicare contractor has considerable discretion in ruling on individual claims although that discretion is bounded by policy pronouncements made in various ways by HCFA. If an individual claim for reimbursement is denied by the Medicare contractor, the claimant (whether a beneficiary or provider of care) may appeal the denial of claims over $500 to an administrative law judge and then further appeal to a federal district court for claims over $1,000. Recent legislative restrictions, however, have further limited claimant's opportunities to challenge coverage determinations in court or before an ALJ, and it is difficult for equipment manufacturers to participate in or challenge national coverage determinations even though their financial, stakes can be significant.

HCFA makes coverage policy in a number of ways.[1] In some cases Medicare contractors refer questions about new medical procedures or technologies to the HCFA regional or national office which makes an informal judgment for application in that case. In other cases HCFA makes "national coverage determinations" which apply in all future similar cases. Since the beginning of the program HCFA (and its predecessor agency) have made about 200 such national determinations on medical procedures and technologies, and the number made each year is growing. However, in its recent Federal Register notice, HCFA stated a "national coverage determination" included any coverage policy published in any HCFA manual. Such rulings are published either in the Federal Register or the *Medicare Coverage Issues Manual*, although many other coverage policies are published in other manuals that are less widely available, and are not designated as national coverage determinations.

Although the making of these national coverage determinations constitutes rulemaking, HCFA does not use a notice-and-comment procedure in most cases. HCFA's Bureau of Eligibility, Reimbursement and Coverage normally simply makes rulings on coverage determinations referred from contractors unless it determines that a medical question is presented. In such cases the question is referred to the in-house HCFA Physicians Panel which meets in private to decide on these referrals. The Physicians Panel may recommend a further referral to the Public Health Service's Office of Health Technology Assessment (OHTA). Most referrals to OHTA are in the form of informal inquiries, without public notice, after which OHTA simply conducts in-house investigations and reports back to HCFA. Requests for full OHTA assessments, on the other hand, usually result in a Federal Register notice, and widespread consultation with affected groups. In either event OHTA makes a recommendation to HCFA which then makes and publishes the determination. Only then are the OHTA findings disclosed.

Except in these "formal OHTA assessments," beneficiaries, providers and manufacturers have no opportunity to participate in this policymaking process. Nor are the criteria used by HCFA and the Medicare contractors in making this policy identified or published. Moreover, once the policy is announced, opportunities to challenge it have been severely circumscribed by the 1986 Omnibus Budget Reconciliation Act. (Pub. L. 99-509, § 9341; 42 U.S.C.A. § 1395ff(b)(3)(1987)). The Act provides that administrative law judges may not review national coverage determinations in administrative appeals. It also limits judicial review by providing that national coverage determinations may not be held unlawful on the grounds of violation of the APA or

[1] HCFA's procedures for making national coverage policy had not been published until April 29, 1987, when under court order, the agency issued a notice in the Federal Register describing its process (though not its criteria) and sought comments.

lack of opportunity for public comment, and further provides that reviewing courts cannot overturn a denial based on coverage determinations without first remanding to HHS for supplementation of the record.

In Recommendation 86-5, the Conference recommended that HHS "introduce more openness and regularity" into these important determinations through "(1) [d]evelopment of published decisional criteria; (2) providing for notice and inviting comments in such cases, both in HCFA's decisionmaking process and in the process by which [OHTA] supplies recommendations to HCFA; and (3) providing for internal administrative review or reconsideration of such decisions." The Conference commends the recent HCFA notice and request for comments on its procedures as a good first step, but urges that further steps be taken to open up the decisional criteria and procedure to public participation and also urges Congress to consider modifying the statutory limitations on the review of the reasonableness and the procedural fairness of such national coverage determinations.

Recommendation

1. Publication of Procedures and Criteria Through Rulemaking

The Health Care Financing Administration (HCFA) should continue its recent steps toward describing and seeking comments upon the procedures it uses for making national coverage determinations in the Medicare program. HCFA should follow its recent informational notice with a notice-and-comment rulemaking proceeding setting forth the procedures as well as all decisional criteria for making national coverage determinations.

2. Elements of the National Coverage Determination Process

HCFA's proposed and final rule on national coverage determinations procedures and criteria should:

(a) Specify the procedure by which HCFA selects coverage questions that will be considered in this process;

(b) Identify and describe what categories of coverage issues will be left to the decision of Medicare contractors and HCFA regional offices; and address the extent to which, and the manner in which, significant coverage determinations made by contractors and regional offices can be identified and disseminated more widely;

(c) Provide for the opportunity for public comment prior to promulgation (or if that is infeasible, an opportunity for comment after adoption)[2] of *all* national coverage policies whether or not the determination is referred to the HCFA Physicians Panel or to the Office of Health Technology Assessment;

(d) Establish internal management controls to facilitate the timely processing of requests from Medicare contractors and petitions filed by beneficiaries, providers and other affected persons for initiation of a national coverage determination;[3]

(e) Develop techniques to encourage the HCFA Physicians Panel, the Office of Health Technology Assessment, and the Public Health Service to respond expeditiously to referrals; and

(f) Identify all publications in which coverage policy will be published, and the method by which those publications will be made reasonably accessible to beneficiaries and other affected groups.

3. Use of Negotiated Rulemaking

In addition to providing for a national coverage decisionmaking process that accords beneficiaries, providers, equipment manufacturers and other interested parties an opportunity to have input into the formulation of specific national coverage determinations, HCFA should in appropriate cases also consider use of elements of a negotiated rulemaking procedure.[4]

4. Modification of Recent Legislative Restrictions on Administrative and Judicial Review

Congress should reconsider and, at minimum clarify its intent,[5] with regard to the recent restrictions it placed upon administrative and judicial review of national coverage determinations. In so doing, Congress should:

(a) Consider whether to clarify the restriction against administrative law judge review of national coverage determinations [42 U.S.C.A. 1395ff(b)(3)(A)] by (i) making clear that

[2] The agency should then re-evaluate the policy after receiving comments. See ACUS Recommendation 76-5, *Interpretive Rules of General Applicability and Statements of General Policy*, 1 CFR 305.76-5.
[3] See ACUS Recommendation 86-6,-*Petitions for Rulemaking*, Para. 2(d), 1 CFR 305.86-6(2)(d).
[4] See ACUS Recommendations 82-4 and 85-5, *Procedures for Negotiating Proposed Regulations*, 1 CFR 305.82-4, 85-5.
[5] In particular, Congress should, for the purposes of these restrictions, clarify its definition of "national coverage determination" and explain whether or not policies other than those concerning medical procedures and technologies and published in the Federal Register or *Medicare Coverage Issues Manual* are included.

administrative law judges may review the application of such determinations to claimants and (ii) specifying that this limitation only applies to those national coverage determinations that are properly published and indexed, and that have been issued after an adequate opportunity for public comment.

(b) Consider repealing 42 U.S.C.A. 1395ff(b)(3)(B), which restricts judicial review of procedures used in promulgating national coverage determinations.

(c) Eliminate the provision [42 U.S.C.A. 1395ff(b)(3)(C)] that limits reviewing courts' ability to review the validity of a national coverage determination applied in a particular case without first remanding the case to the agency for supplementation of the record.

Citations:

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