

IV. Cost to Beneficiaries

We estimate that in 2002 there will be about 8.67 million deductibles paid at \$812 each, about 2.14 million days subject to coinsurance at \$203 per day (for hospital days 61 through 90), about 0.99 million lifetime reserve days subject to coinsurance at \$406 per day, and about 26.28 million extended care days subject to coinsurance at \$101.50 per day. Similarly, we estimate that in 2001 there will be about 8.53 million deductibles paid at \$792 each, about 2.11 million days subject to coinsurance at \$198 per day (for hospital days 61 through 90), about 0.97 million lifetime reserve days subject to coinsurance at \$396 per day, and about 25.84 million extended care days subject to coinsurance at \$99 per day. Therefore, the estimated total increase in cost to beneficiaries is about \$430 million (rounded to the nearest \$10 million), due to (1) the increase in the deductible and coinsurance amounts and (2) the change in the number of deductibles and daily coinsurance amounts paid.

V. Waiver of Proposed Notice and Comment Period

The Medicare statute, as discussed previously, requires publication of the Medicare Part A inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services for each calendar year. The amounts are determined according to the statute. As has been our custom, we use general notices, rather than notice and comment rulemaking procedures, to make the announcements. In doing so, we acknowledge that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary because the formulae used to calculate the inpatient hospital deductible and hospital and extended care services coinsurance amounts is statutorily directed, and we can exercise no discretion in following those formulae. Moreover, the statute establishes the time period for which the deductible and coinsurance amounts will apply and delaying publication would be contrary to the public interest.

Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

VI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities. We have determined that this notice will not have a significant economic impact on a substantial number of small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this notice will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This notice has no consequential effect on State, local, or tribal governments or on the private sector.

As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about \$430 million due to (1) the increase in the deductible and coinsurance amounts and (2) the change in the number of deductibles and daily coinsurance amounts paid. Therefore, this notice is a major rule as defined in Title 5, United States Code, section 804(2) and is an economically significant rule under Executive Order 12866.

We have reviewed this notice under the threshold criteria of Executive Order 13132, Federalism. We have determined that it does not significantly affect the rights, roles, and responsibilities of States.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Sections 1813(b)(2) of the Social Security Act (42 U.S.C. 1395e-2(b)(2)). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance).

Dated: September 7, 2001.

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

Dated: September 27, 2001.

Tommy G. Thompson,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMSR-3080-NR]

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

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

ACTION: Notice of CMS Ruling.¹

SUMMARY: This notice announces a CMS Ruling concerning the appropriate actions to be taken 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, Public Law 106-554. The Ruling establishes the interim administrative procedures that CMS contractors, and Administrative Law Judges (ALJs) are to follow in processing such complaints until final regulations are published regarding the adjudication of the complaints and the effectuation of ALJ and Departmental Appeals Board decisions with respect to complaints.

FOR FURTHER INFORMATION CONTACT: Jim Bossenmeyer, (410) 786-9317.

¹ **EDITORIAL NOTE:** Future CMS Rulings may appear in the Rules Section of the **Federal Register** if they are interpretations of or general policy statements concerning CMS rules (See 1 CFR 5.9(b)).

SUPPLEMENTARY INFORMATION: The CMS Administrator signed Ruling CMSR-01-1 on September 24, 2001. The text of the CMS Ruling follows: 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 Protections 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

Department Appeals Board
U.S. Dept. of Health and Human
Services
Room 637D, Humphrey Building
Attention: NCD Complaint
200 Independence Avenue, SW.
Washington, DC 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.

Once the regulation is effective, inform the requestor that processing of complaints under the new review procedures will continue.

Authority: 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.

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 2, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-8010-N]

Medicare Program; Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2002

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

ACTION: Notice.

SUMMARY: In accordance with section 1839 of the Social Security Act (the Act), this notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in the Medicare Supplementary Medical Insurance (SMI) program for 2002. It also announces the monthly SMI premium to be paid by all enrollees during 2002. The monthly actuarial rates for 2002 are \$109.30 for aged enrollees and \$123.10 for disabled enrollees. The monthly SMI premium rate for 2002 is \$54.00. (The 2001 premium rate was \$50.00). This compares to projections of the 2002 SMI premium of \$58.50 in the 2001 Trustees Report and \$54.50 in the 2000 Trustees Report. The 2002 Part B premium is not equal to 50 percent of the monthly actuarial rate because of the differential between the amount of home health that is transferred into Part B in 2002 (five-sixths) and the amount in Part B that is included in the premium calculation (five-sevenths). Included in the monthly premium rate is \$3.91 for home health services being transferred into Part B.

EFFECTIVE DATE: January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Carter S. Warfield, (410) 786-6396.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Supplementary Medical Insurance (SMI) program is the voluntary Medicare Part B program that pays all or part of the costs for physicians' services, outpatient hospital services, home health services, services furnished by rural health clinics, ambulatory surgical centers, comprehensive outpatient rehabilitation facilities, and certain other medical and

health services not covered by hospital insurance (HI) (Medicare Part A). The SMI program is available to individuals who are entitled to HI and to U.S. residents who have attained age 65 and are citizens, or aliens who were lawfully admitted for permanent residence and have resided in the United States for 5 consecutive years. This program requires enrollment and payment of monthly premiums, as provided in 42 CFR part 407, subpart B, and part 408, respectively. The difference between the premiums paid by all enrollees and total incurred costs is met from the general revenues of the Federal Government.

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1839 of the Social Security Act (the Act) to issue two annual notices relating to the SMI program.

One notice announces two amounts that, according to actuarial estimates, will equal respectively, one-half the expected average monthly cost of SMI for each aged enrollee (age 65 or over) and one-half the expected average monthly cost of SMI for each disabled enrollee (under age 65) during the year beginning the following January. These amounts are called "monthly actuarial rates."

The second notice announces the monthly SMI premium rate to be paid by aged and disabled enrollees for the year beginning the following January. (Although the costs to the program per disabled enrollee are different than for the aged, the law provides that they pay the same premium amount.) Beginning with the passage of section 203 of the Social Security Amendments of 1972 (Public Law 92-603), the premium rate, which was determined on a fiscal year basis, was limited to the lesser of the actuarial rate for aged enrollees, or the current monthly premium rate increased by the same percentage as the most recent general increase in monthly Title II social security benefits.

However, the passage of section 124 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Public Law 97-248) suspended this premium determination process. Section 124 of TEFRA changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). Section 606 of the Social Security Amendments of 1983 (Public Law 98-21), section 2302 of the Deficit Reduction Act of 1984 (DRA 1984) (Public Law 98-369), section 9313 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA 1985) (Public Law 99-272), section 4080 of the Omnibus Budget Reconciliation