

the current changes and comparing the new device to the originally cleared device, or one marketed prior to May 28, 1976, should be submitted. The new 510(k), once cleared, would form the basis of comparison for the next sequence of changes.

The draft guidance consists of a flowchart model to help manufacturers through the logic scheme necessary to arrive at a decision on when to submit a 510(k) for a change to an existing device. The flowchart includes the following three logical breakouts of changes that might be made to a device: Labeling changes, technology or performance specifications changes, and materials changes. To use the model, the questions posed in the flowchart should be answered until the 510(k) holder is directed to consider submitting a 510(k), document the decisionmaking, or notify the agency of the change being effected. The last option occurs for the addition of a contraindication and the necessary documentation would constitute an administrative addition to the 510(k) currently on file.

When contemplating changes to a device, manufacturers should use the flowchart for each individual type of proposed change, e.g., performance specification change, material change, etc. If any one of the changes results in a manufacturer's decision to submit a 510(k), then the 510(k) should be submitted and should incorporate all of the intended changes, as well as a comparison to the originally cleared device described by the 510(k) currently on file with FDA. If a manufacturer's consideration of all proposed changes results in a decision merely to document the decisionmaking, it should document the application of the model along with the necessary records of the validation of changes to the device. In those circumstances where the proposed change is not addressed in the flowchart or in a device-specific guidance document, manufacturers are encouraged to contact the Office of Device Evaluation in CDRH to find out whether other, specific guidance exists or if additional help is available.

IV. Significance of a Guidance

Guidances have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidances to state procedures or standards of general applicability that are not legal requirements, but that are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, the draft guidance is not being issued under the authority of current § 10.90(b), and it does not create or confer any rights, privileges, or benefits for or on any

person, nor does it operate to bind FDA or device manufacturers in any way.

V. Requests for Comments

Interested persons may, on or before December 15, 1995, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether to amend the current draft guidance document.

Dated: October 2, 1995.

Joseph A. Levitt,

Deputy Director for Regulations policy, Center for Devices and Radiological Health.

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Health Care Financing Administration

[OACT-049-N]

RIN 0938-AH08

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1996

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 1996 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute specifies the formulae to be used to determine these amounts.

The inpatient hospital deductible will be \$736. The daily coinsurance amounts will be: (a) \$184 for the 61st through 90th days of hospitalization in a benefit period; (b) \$368 for lifetime reserve days; and (c) \$92 for the 21st through 100th days of extended care services in a skilled nursing facility in a benefit period.

EFFECTIVE DATE: This notice is effective on January 1, 1996.

FOR FURTHER INFORMATION CONTACT: John Wandishin, (410) 786-6389. For case-mix analysis only: Gregory J. Savord, (410) 786-6384.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish between September 1 and September 15 of each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year.

II. Computing the Inpatient Hospital Deductible for 1996

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding calendar year, changed by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act). This estimate is used for updating the payment rates to hospitals for discharges in the fiscal year that begins on October 1 of the same preceding calendar year and adjusted to reflect real case mix. The adjustment to reflect real case mix is determined on the basis of the most recent case mix data available. The amount determined under this formula is rounded to the nearest multiple of \$4 (or, if midway between two multiples of \$4, to the next higher multiple of \$4).

For fiscal year 1996, section 1886(b)(3)(B)(i)(XI) of the Act provides that the applicable percentage increase for hospitals in all areas is the market basket percentage increase minus 2.0 percent. Section 1886(b)(3)(B)(ii)(V) of the Act provides that, for fiscal year 1996, the otherwise applicable rate-of-increase percentages (the market basket percentage increase) for hospitals that are excluded from the prospective payment system are reduced by the lesser of 1 percentage point or the percentage point difference between 10 percent and the percentage by which the hospital's allowable operating costs of inpatient hospital services for cost reporting periods beginning in fiscal year 1990 exceeds the hospital's target amount. Hospitals or distinct part hospital units with fiscal year 1990

operating costs exceeding target amounts by 10 percent or more receive the market basket index percentage. The market basket percentage increases for fiscal year 1996 are 3.5 percent for prospective payment system hospitals and 3.4 percent for hospitals excluded from the prospective payment system, as announced in the Federal Register on September 1, 1995 (60 FR 45778).

Therefore, the percentage increases for Medicare prospective payment rates are 1.5 percent for all hospitals. The average payment percentage increase for hospitals excluded from the prospective payment system is 2.84 percent. Thus, weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for fiscal year 1996 is 1.65 percent.

To develop the adjustment for real case mix, an average case mix was first calculated for each hospital that reflects the relative costliness of that hospital's mix of cases compared to that of other hospitals. We then computed the increase in average case mix for hospitals paid under the Medicare prospective payment system in fiscal year 1995 compared to fiscal year 1994. (Hospitals excluded from the prospective payment system were excluded from this calculation since their payments are based on reasonable costs and are affected only by real increases in case mix.) We used bills from prospective payment hospitals received in HCFA as of July 1995. These bills represent a total of about 8.0 million discharges for fiscal year 1995 and provide the most recent case mix data available at this time. Based on these bills, the increase in average case mix in fiscal year 1995 is 1.1 percent. Based on past experience, we expect overall case mix to increase to 1.4 percent as the year progresses and more fiscal year 1995 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be increased only by that portion of the case mix increase that is determined to be real. We estimate that the increase in real case mix is about 1 percent. Since real case mix had been assumed to be increasing at about 1 percent per year in prior years, we expect a return to this trend.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 1.65 percent, and the real case mix adjustment factor for the deductible is 1 percent. Therefore, under the statutory formula, the inpatient hospital deductible for services furnished in calendar year 1996 is \$736. This deductible amount is

determined by multiplying \$716 (the inpatient hospital deductible for 1995) by the payment rate increase of 1.0165 multiplied by the increase in real case mix of 1.01 which equals \$735.09 and is rounded to \$736.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for 1996

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same calendar year. Thus, the increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in 1996, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th days of hospitalization in a benefit period will be \$184 ($\frac{1}{4}$ of the inpatient hospital deductible); the daily coinsurance for lifetime reserve days will be \$368 ($\frac{1}{2}$ of the inpatient hospital deductible); and the daily coinsurance for the 21st through 100th days of extended care services in a skilled nursing facility in a benefit period will be \$92 ($\frac{1}{8}$ of the inpatient hospital deductible).

IV. Cost to Beneficiaries

We estimate that in 1996 there will be about 9.2 million deductibles paid at \$736 each, about 3.4 million days subject to coinsurance at \$184 per day (for hospital days 61 through 90), about 1.5 million lifetime reserve days subject to coinsurance at \$368 per day, and about 21.9 million extended care days subject to coinsurance at \$92 per day. Similarly, we estimate that in 1995 there will be about 8.9 million deductibles paid at \$716 each, about 3.3 million days subject to coinsurance at \$179 per day (for hospital days 61 through 90), about 1.5 million lifetime reserve days subject to coinsurance at \$358 per day, and about 21.2 million extended care days subject to coinsurance at \$89.50 per day. Therefore, the estimated total increase in cost to beneficiaries is about \$570 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. Impact Statement

This notice merely announces amounts required by legislation. This notice is not a proposed rule or a final rule issued after a proposal and does not alter any regulation or policy. Therefore, we have determined, and certify, that no

analyses are required under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601 through 612), or section 1102(b) of the Act.

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

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

Dated: September 26, 1995.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

Dated: September 29, 1995.

Donna E. Shalala,
Secretary.

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BILLING CODE 4120-01-P

[OACT-050-N]

RIN 0938-AH07

Medicare Program; Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 1996

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: As required by section 1839 of the Social Security Act, this notice announces the monthly actuarial rates for aged (age 65 or over) and disabled (under age 65) enrollees in the Medicare Supplementary Medical Insurance (SMI) program for 1996. It also announces the monthly SMI premium rate to be paid by all enrollees during 1996. The monthly actuarial rates for 1996 are \$84.90 for aged enrollees and \$105.10 for disabled enrollees. The monthly SMI premium rate for 1996 is \$42.50.

EFFECTIVE DATE: January 1, 1996.

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 (Medicare Part A). The SMI program is available to individuals who