

Addendum V—Categorization of Food and Drug Administration-Approved Investigational Device Exemptions

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes. Also, under the new categorization process to assist HCFA, the Food and Drug Administration assigns each device with a Food and Drug Administration-approved investigational device exemption to one of two categories. To obtain more information about the classes or categories, please refer to the **Federal Register** notice published on April 21, 1997 (62 FR 19328).

The following information presents the device number, category (in this case, A), and criterion code.

G960213 A2
G960218 A1
G960258 A1
G960266 A1
G970004 A1
G970007 A1
G970015 A2
G970016 A2
G970018 A2
G970022 A2
G970035 A2
G970051 A2
G970053 A2

The following information presents the device number category (in this case, B), and criterion code.

G950115 B1
G956391 B2
G960193 B4
G960199 B2
G960208 B1
G960229 B1
G960230 B2
G960231 B3
G960234 B4
G960235 B3
G960241 B2
G960243 B2
G960245 B2
G960246 B1
G960247 B1
G960248 B4
G960249 B4
G960250 B3
G960252 B2
G960253 B4
G960254 B2
G960255 B2
G960256 B1
G960257 B3
G960259 B4
G960262 B3
G960263 B3
G960264 B3
G960267 B1
G970001 B3
G970002 B4
G970003 B3
G970005 B4

G970011 B2
G970012 B4
G970019 B3
G970023 B4
G970025 B3
G970026 B3
G970028 B3
G970029 B3
G970030 B1
G970031 B3
G970032 B3
G970033 B4
G970034 B4
G970037 B4
G970038 B4
G970039 B4
G970040 B3
G970041 B4
G970046 B1
G970047 B3
G970052 B1
G970054 B4
G970059 B3

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Care Financing Administration**

[OACT-057-N]

RIN 0938-A112

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1998

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 1998 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 \$764. The daily coinsurance amounts will be: (a) \$191 for the 61st through 90th days of hospitalization in a benefit period; (b) \$382 for lifetime reserve days; and (c) \$95.50 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, 1998.

FOR FURTHER INFORMATION CONTACT: John Wandishin, (410) 786-6389. For case-mix analysis only: Gregory J. Savord, (410) 786-1521.

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 1998

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).

Section 4401(a) of the Balanced Budget Act of 1997 (Public Law 105-33, enacted on August 5, 1997) amended section 1886(b)(3)(B)(i) of the Act by making the percentage increase for hospitals paid under the prospective payment system 0 percent for fiscal year 1998. Section 4411(a) of the Balanced Budget Act of 1997 similarly amended section 1886(b)(3)(B)(ii) of the Act by making the percentage increase for hospitals excluded from the prospective payment system 0 percent for fiscal year 1998. Therefore, our best estimate of the payment-weighted average of the increase in the payment rates for fiscal year 1998 is 0 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 1997 compared to fiscal year 1996. (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 1997. These bills represent a total of about 8.3 million discharges for fiscal year 1997 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 1997 is 0.12 percent. Based on past experience, we expect overall case mix to increase to 0.5 percent as the year progresses and more fiscal year 1997 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 0.5 percent. We believe that any case mix increased up to 1 percent is real case mix increase. Therefore, for fiscal year 1997, all of the case mix increase, 0.5 percent, is real case mix increase.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 0 percent, and the real case mix adjustment factor for the deductible is 0.5 percent. Therefore, under the statutory formula, the inpatient hospital deductible for services furnished in calendar year 1998 is \$764. This deductible amount is determined by multiplying \$760 (the inpatient hospital deductible for 1997) by the payment rate increase of 1.00 multiplied by the increase in real case mix of 1.005 which equals \$763.8 and is rounded to \$764.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for 1998

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 1998, 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 \$191 (1/4 of the

inpatient hospital deductible); the daily coinsurance for lifetime reserve days will be \$382 (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 \$95.50 (1/8 of the inpatient hospital deductible).

IV. Cost to Beneficiaries

We estimate that in 1998 there will be about 9.1 million deductibles paid at \$764 each, about 2.8 million days subject to coinsurance at \$191 per day (for hospital days 61 through 90), about 1.3 million lifetime reserve days subject to coinsurance at \$382 per day, and about 25.0 million extended care days subject to coinsurance at \$95.50 per day. Similarly, we estimate that in 1997 there will be about 8.9 deductibles paid at \$760 each, about 2.7 million days subject to coinsurance at \$190 per day (for hospital days 61 through 90), about 1.3 million lifetime reserve days subject to coinsurance at \$380 per day, and about 24.6 million extended care days subject to coinsurance at \$95.00 per day. Therefore, the estimated total increase in cost to beneficiaries is about \$260 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 formal notice and comment rulemaking procedures, to make such announcements. In doing so, we acknowledge that, under the Administrative Procedure Act, interpretive rule, 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 formula 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 that formula. 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. 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 19, 1997.

Nancy-Ann Min DeParle,
Deputy Administrator, Health Care Financing Administration.

Dated: October 7, 1997.

Donna E. Shalala,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[OACT-056-N]

RIN 0938-A110

Medicare Program; Part A Premium for 1998 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

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

ACTION: Notice.

SUMMARY: This notice announces the hospital insurance premium for calendar year 1998 under Medicare's hospital insurance program (Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement. The monthly Medicare Part A premium for