guidance entitled ''Recommendations for Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T–Lymphotropic Virus Type I (HTLV–I)'' (the July 1996 guidance). This guidance does not supersede the recommendations related to HBV and HTLV–I in the July 1996 guidance.

This guidance document represents the agency's current thinking with regard to prior collections from donors testing repeatedly reactive for antibody to HCV at a later date. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

This guidance document may contain collections of information that require clearance under the Paperwork Reduction Act of 1995. FDA will seek such approval and provide opportunity for comment as appropriate.

II. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: October 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28217 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–8001–N]

RIN 0938–AJ02

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1999

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 1999 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts.

The inpatient hospital deductible will be $768. The daily coinsurance amounts will be: (a) $192 for the 61st through 90th day of hospitalization in a benefit period; (b) $384 for lifetime reserve days; and (c) $96 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

EFFECTIVE DATE: This notice is effective on January 1, 1999.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390.

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 1999

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) 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).

Under section 1886(b)(3)(B)(i) of the Act, as amended by section 4401(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33), the percentage increase used to update the payment rates for fiscal year 1999 for most hospitals paid under the prospective payment system is the market basket percentage increase minus 1.9 percentage points. Certain nonteaching, nondisproportionate share, non-Medicare-dependent hospitals, however, are allowed higher updates than those provided for other hospitals paid under the prospective payment system. These hospitals must be located in States where, for nonteaching, nondisproportionate share, non-Medicare-dependent hospitals—

- Aggregate Medicare operating payments for their cost reporting periods beginning during fiscal year 1995 are less than the aggregate allowable operating costs of inpatient hospital services for all these hospitals in the State for those cost reporting periods; and
- The Medicare operating payments for discharges in the cost reporting period involved are less than their allowable operating costs for inpatient hospital services in that period.

For hospitals meeting these criteria, the percentage increase used to update the payment rates for fiscal year 1999 is the market basket percentage increase minus 1.6 percentage points.

Under section 1886(b)(3)(B)(ii) of the Act, as amended by section 4411(a) of the Balanced Budget Act of 1997, the percentage increase used to update the payment rates for fiscal year 1999 for hospitals excluded from the prospective payment system depends on the hospital's allowable operating costs of inpatient hospital services. If the hospital's allowable operating costs of inpatient hospital services for the most recent cost reporting period for which information is available—

(1) Are equal to or exceed 110 percent of the hospital's target amount for that cost reporting period, the applicable percentage increase is the market basket percentage;

(2) Exceed 100 percent but are less than 110 percent of the hospital's target amount for that cost reporting period, the applicable percentage increase is the market basket percentage minus 0.25 percentage points for each percentage point by which the hospital's allowable operating costs are less than 110 percent of the target amount for that cost reporting period (but not less than 0 percent);

(3) Are equal to or less than 100 percent of the hospital's target amount for that cost reporting period, but exceed two-thirds of the target amount, the applicable percentage increase is 0 percent or, if greater, the market basket percentage minus 2.5 percentage points; or

(4) Do not exceed two-thirds of the hospital's target amount for that cost reporting period, the applicable percentage increase is 0 percent.

The market basket percentage increase for fiscal year 1999 is 2.4 percent, as announced in the **Federal Register** on July 31, 1998 (63 FR 40954). Therefore, the percentage increase for most hospitals paid under the prospective payment system is 0.5 percent, and the percentage increase for the certain nonteaching, nondisproportionate share, non-Medicare-dependent hospitals paid under the prospective payment system and meeting the criteria described above is 0.8 percent. The average payment percentage increase for hospitals excluded from the prospective payment system is 0.4 percent. 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 1999 is 0.5 percent.

To develop the adjustment for real case mix, we first calculated for each hospital an average case mix that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case mix for hospitals paid under the Medicare prospective payment system in fiscal year 1998 compared to fiscal year 1997. (We excluded from this calculation hospitals excluded from the prospective payment system because their payments are based on reasonable costs and are affected only by real changes in case mix.) We used bills from prospective payment hospitals received in HCFA as of July 1998. These bills represent a total of about 8.5 million discharges for fiscal year 1998 and provide the most recent case mix data available at this time. Based on these bills, the change in average case mix in fiscal year 1998 is −0.81 percent. Based on past experience, we expect the overall case mix change to be −0.6 percent as the year progresses and more fiscal year 1998 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case mix change that is determined to be real. There is a negligible change in overall case mix for fiscal year 1998. We estimate that there is no change in real case mix; that is, we estimate that the change in real case mix for fiscal year 1998 is 0.0 percent.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 0.5 percent, and the real case mix adjustment factor for the deductible is 0.0 percent. Therefore, under the statutory formula, the inpatient hospital deductible for services furnished in calendar year 1999 is $768. This deductible amount is determined by multiplying $764 (the inpatient hospital deductible for 1998) by the payment-weighted average increase in the payment rates of 1.005 multiplied by the increase in real case mix of 1.000, which equals $767.82 and is rounded to $768.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for 1999

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 1999, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit period will be $192 (one-fourth of the inpatient hospital deductible); the daily coinsurance for lifetime reserve days will be $384 (one-half of the inpatient hospital deductible); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period will be $96 (one-eighth of the inpatient hospital deductible).

IV. Cost to Beneficiaries

We estimate that in 1999 there will be about 8.4 million deductibles paid at $768 each, about 2.3 million days subject to coinsurance at $192 per day (for hospital days 61 through 90), about 1.1 million lifetime reserve days subject to coinsurance at $384 per day, and about 34.4 million extended care days subject to coinsurance at $96 per day. Similarly, we estimate that in 1998 there will be about 8.6 million deductibles paid at $764 each, about 2.3 million days subject to coinsurance at $191 per day (for hospital days 61 through 90), about 1.1 million lifetime reserve days subject to coinsurance at $382 per day, and about 32.3 million extended care days subject to coinsurance at $95.50 per day. Therefore, the estimated total increase in cost to beneficiaries is about $100 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 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. 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.

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 50 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.

This notice announces that the inpatient hospital deductible for calendar year 1999 is $768. It also announces the daily coinsurance amounts of $192 for the 61st through 90th day of hospitalization in a benefit period; $384 for lifetime reserve days; and $96 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period. We believe that the total increase in costs to beneficiaries associated with this notice is about $100 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.

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 18, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: October 8, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–28162 Filed 10–16–98; 9:34 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–8003–N]

RIN 0938–AI98

Medicare Program; Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 1999

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 1999. It also announces the monthly SMI premium rate to be paid by all enrollees during 1999. The monthly actuarial rates for 1999 are $92.30 for aged enrollees and $103.00 for disabled enrollees. The monthly SMI premium rate for 1999 is $45.50. (The 1998 premium rate was $43.80). The 1999 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 1999 (two-sixths) and the amount in Part B that is included in the premium calculation (two-sevenths).

EFFECTIVE DATE: January 1, 1999.

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 Health and Human Services 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) (Pub. L. 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 Act of 1987 (OBRA 1987) (Public Law 100–203), and section 6301 of the Omnibus Budget Reconciliation Act of