

and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 116 of the Food and Drug Administration Modernization Act (the Modernization Act) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a). This section provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such change. Elsewhere in this issue of the **Federal Register**, FDA is proposing to amend its regulations on supplements and other changes to an approved application § 514.8 (21 CFR 514.8) to conform to section 506A of the act.

The purpose of this draft guidance is to provide recommendations to holders of NADA's and ANADA's who intend to make postapproval changes in accordance with section 506A of the act and the proposed amended regulations at § 514.8. The draft guidance covers recommended reporting categories for postapproval changes for new animal drugs. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, and (6) miscellaneous changes. This draft guidance does not provide recommendations on the specific information that should be developed by an applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product. FDA has published guidances, including the Scale-up and Postapproval Changes (SUPAC) guidances, that provide recommendations on reporting categories and/or the type of information that should be developed by the applicant to validate the effect of the change on the identity, strength, quality, purity, or potency of a product as they may relate to the safety or effectiveness of the product. The draft guidance, which cites proposed § 514.8, will be revised based on public comments and implemented for use as a companion document when § 514.8 is finalized.

This draft guidance represents the agency's current thinking on this subject. 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.

**II. Comment**

Interested persons may, on or before December 15, 1999, 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. A copy of the draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the draft guidance using the World Wide Web (WWW). For WWW access, connect to CVM at "http://www.fda.gov/cvm".

Dated: June 23, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99-25492 Filed 9-30-99; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

[HCFA-3025-N]

**Medicare Program; Notice of the Implementation of the Medicare Lifestyle Modification Program Demonstration Project**

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

**ACTION:** Notice.

**SUMMARY:** This notice announces our implementation of the Medicare Lifestyle Modification Program Demonstration. Lifestyle modification programs are increasingly becoming an approach to the secondary prevention of coronary disease morbidity. Such programs may reduce the incidence of hospitalizations and invasive procedures among patients with substantial coronary occlusion.

**FOR FURTHER INFORMATION CONTACT:** Armen Thoumaian, Ph.D. at (410) 786-6672, or Athoumaian@HCFA.GOV.

**SUPPLEMENTARY INFORMATION:** The purpose of this demonstration is to test the feasibility and effectiveness of

providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries. This demonstration will test a proven and intensive program designed to reduce or reverse the progression of cardiovascular disease (CAD) of patients at risk for invasive treatment procedures. The demonstration will be conducted over a 4-year period at an estimated 15 sites. Enrollment is limited to 1,800 Part B eligible Medicare beneficiaries who satisfy clinical admission criteria.

We are preparing to expand this demonstration to at least one additional nationwide, multi-site cardiovascular lifestyle modification program. An announcement of this expanded demonstration to solicit interested programs is expected within the next several weeks.

We will conduct an independent evaluation of both demonstrations to compare the short-term and long-term outcomes and costs in providing this type of service for Medicare beneficiaries.

**Authority:** 42 U.S.C. 1395b-1(a)(1)(G) and (a)(2).

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

Dated: September 14, 1999.

**Michael M. Hash,**

*Deputy Administrator, Health Care Financing Administration.*

[FR Doc. 99-25416 Filed 9-28-99; 8:45 am]

BILLING CODE 4120-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

[HCFA-1058-FN]

RIN 0938-AJ60

**Medicare Program; Sustainable Growth Rate for Fiscal Year 2000**

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

**ACTION:** Final notice.

**SUMMARY:** This final notice announces the fiscal year 2000 Sustainable Growth Rate (SGR) for expenditures for physicians' services under the Medicare Supplementary Medical Insurance (Part B) program as required by section 1848(f) of the Social Security Act (the Act). The SGR for fiscal year 2000 is 2.1 percent.

**EFFECTIVE DATE:** The provisions of the Medicare SGR for fiscal year 2000 contained in this notice are effective on October 1, 1999.

**FOR FURTHER INFORMATION CONTACT:**  
Raymond Bulls, (410) 786-7267.  
**SUPPLEMENTARY INFORMATION:**

**I. Background**

**A. Medicare Sustainable Growth Rate**

Section 1848(f) of the Social Security Act (the Act), as amended by section 4503 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33), enacted on August 5, 1997, replaces the volume performance standard with a Sustainable Growth Rate (SGR) standard. It specifies the formula for establishing yearly SGR targets for physicians' services under Medicare. The use of SGR targets is intended to control the actual growth in Medicare expenditures for physicians' services.

The SGR targets are not limits on expenditures. Payments for services are not withheld if the SGR target is exceeded. Rather, the appropriate fee schedule update, as specified in section 1848(d)(3)(A) of the Act, is adjusted to reflect the success or failure in meeting the SGR target.

Amended section 1848(f)(2) of the Act states that " \* \* \* the sustainable growth rate for all physicians' services for a fiscal year (beginning with fiscal year 1998) shall be equal to the product of—

(A) 1 plus the Secretary's estimate of the weighted-average percentage increase (divided by 100) in the fees for all physicians' services in the fiscal year involved;

(B) 1 plus the Secretary's estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part (other than Medicare+Choice plan enrollees) from the previous fiscal year to the fiscal year involved;

(C) 1 plus the Secretary's estimate of the projected percentage growth in real gross domestic product per capita (divided by 100) from the previous fiscal year to the year involved; and

(D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the fiscal year (compared with the previous fiscal year) which will

result from changes in law or regulations, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B), minus 1 and multiplied by 100."

**B. Physicians' Services**

Because the scope of physicians' services covered by the SGR is the same as the scope of services that was covered by the Medicare volume performance standards, we are using the same definition of physicians' services for the SGR in this notice as we did for the Medicare volume performance standards published in the **Federal Register** (61 FR 59717) on November 22, 1996. That final notice announced the fiscal year 1997 volume performance standard rates and contained a detailed description of the scope of physicians' services.

**II. Provisions of This Notice**

Under the requirements in sections 1848(f)(2)(A) through (D) of the Act, as amended by section 4503 of the BBA, we have determined that the SGR for physicians' services for fiscal year 2000 is 2.1 percent. Our determination is based on the following statutory factors:

Statutory factors	Percent change
Fees .....	2.1
Enrollment .....	-1.6
Increase in Gross Domestic Product .....	1.8
Legislation .....	-0.2
<b>Total .....</b>	<b>2.1</b>

The specific calculations to determine the 2.1 percent SGR for physicians' services for fiscal year 2000 are explained below.

**III. Calculation of the Fiscal Year 2000 Sustainable Growth Rate**

Our explanation of how we determined the values for each of the four factors used in determining the SGR for fiscal year 2000 is as follows:

*Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for Fiscal Year 2000*

This factor was calculated as a weighted average of the calendar year 1999 and 2000 fee increases that apply during fiscal year 2000.

Most of the fees for physicians' services (as defined in section I. B. of this final notice) are updated by the Medicare Economic Index (MEI). However, the BBA provided for a 0.0 percent update in 1999 and 2000 for laboratory services, which represents about 11 percent of the Medicare-allowed charges for physicians' services. The following table, therefore, shows both the MEI and laboratory service updates that were used in determining the percentage increase in physicians' fees for fiscal year 2000.

MEDICARE ECONOMIC INDEX AND LABORATORY SERVICE UPDATE FOR CALENDAR YEARS 1999 AND 2000

	1999	2000
Medicare Economic Index .....	2.3	2.3
Laboratory Service ...	0.0	0.0

After taking into account all the elements described above, we estimate that the weighted-average increase in fees for physicians' services in fiscal year 2000, before applying any legislative adjustments to the MEI, will be 2.1 percent for all physicians' services.

*Factor 2—The Percentage Change in the Average Number of Part B Enrollees From Fiscal Year 1999 to Fiscal Year 2000*

Due to the growth in Medicare+Choice plan enrollees (whose Medicare-covered medical care is outside the scope of the SGR), we estimate that the average number of Medicare Part B enrollees, excluding those in Medicare+Choice plans, will decline by 1.6 percent. This decline was derived as follows:

Fiscal year	Average Medicare Part B enrollment (in millions)		
	Overall	Medicare+Choice	Overall, excluding Medicare+Choice
1999 .....	36.866	6.116	30.750
2000 .....	37.178	6.917	30.261
Percent change .....	.....	.....	-1.6

*Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in Fiscal Year 2000*

Section 1848(f)(2)(C) of the Act, as amended by section 4503 of the BBA, requires the Secretary to project real gross domestic product per capita growth for the coming fiscal year. In calculating the SGR, we estimate that this growth will be 1.8 percent in fiscal year 2000.

*Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in Fiscal Year 2000 Compared With Fiscal Year 1999*

Legislative changes contained in the BBA will have some residual effects on expenditures for physicians' services in fiscal year 2000. In addition, there are some miscellaneous provisions that will have a small impact.

Taking into account all of the changes in law or regulation that may affect expenditures for physicians' services, the decrease in expenditures for physicians' services is estimated to be -0.2 percent.

**IV. The Use of Estimates in Computing the Sustainable Growth Rate**

Section 1848(f) of the Act clearly requires that each year, the Secretary establish the SGR for the upcoming fiscal year beginning October 1 based on the Secretary's estimate[s] of four factors: The percentage increase in physicians' fees, the percentage increase in fee-for-service enrollment, the projected percentage growth in per capita gross domestic product, and the percentage change in expenditures for physicians' services resulting from changes in law or regulations. Because the calculation of the SGR for a given year is based on projected values, updates may be either lower or higher than they would have been if we had used later data. Thus, we initially considered revising estimates of the factors used in setting the SGR when later data had become available. However, as we indicated in the notice with comment period published in the **Federal Register** (63 FR 59188) on November 2, 1998, we had concerns about whether we had the statutory authority to make these revisions under current law and invited comments regarding how an adjustment could be made consistent with the law. The comments we received and our response are discussed below.

*Comment:* The American Medical Association and numerous physician organizations suggested that congressional intent should be

interpreted to authorize adjustments for projection error. These commenters also suggested a number of different approaches for making such adjustments. The various approaches suggested rely on later data.

*Response:* We do not believe that we have the authority to make adjustments based on Congressional intent because the statutory language clearly requires that estimated values be used for computing the SGR and there is no provision for revising the estimates to reflect later data. Our actions are controlled by the clear statutory language. Thus, we will not be able to make adjustments to the SGR based on later data.

However, the Administration's legislative package for fiscal year 2000, released in February 1999, contains a legislative proposal to adjust the SGR if later data are different from earlier estimates, as well as to address issues relating to the instability of the SGR discussed below. The changes proposed are all budget neutral. If Congress enacts this proposal for fiscal year 2000, we would revise the SGR for fiscal year 2000 as appropriate.

**V. Technical Problems With the Sustainable Growth Rate System**

We have begun to forecast the SGR for future years, and it appears that there is some instability in the SGR system. In the long-term, updates could oscillate between the maximum increase and decrease adjustments due to the use of mismatched time periods and the lag between measurement periods. The solution would be technical and would involve the matching of time periods for the SGR calculation, the actual versus target measurement, and the update adjustment. As discussed above the Administration has submitted a legislative proposal to the Congress that will address these factors and result in less oscillation in the physician fee schedule update.

**VI. Regulatory Impact Statement**

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a notice will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we treat all physicians and suppliers as small entities. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural

hospitals. That analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Legislative changes contained in the BBA will affect expenditures for physicians' services in fiscal year 2000, although the impact will be slight, and residual effects will result in fiscal year 2000 from the calendar year implementation of these changes.

We are not preparing an analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice will not have a significant economic impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals.

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

We have reviewed this final notice under the threshold criteria of Executive Order 13132 of August 4, 1999, and have determined that it does not significantly affect the rights, roles, and responsibilities of States.

(Sections 1848(d) and (f) of the Social Security Act) (42 U.S.C. 1395w-4(d) and (f)) (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 1, 1999.

**Michael M. Hash,**

*Deputy Administrator, Health Care Financing Administration.*

Approved: September 20, 1999.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 99-25527 Filed 9-28-99; 9:58 am]

BILLING CODE 4120-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources And Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed