

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Notification and Requests	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Notification for Carcinogenicity Protocols	30	2.0	60	8	480
Requests for Special Protocol Assessment	70	2.57	180	15	2,700
Total					3,180

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 1, 2000.

Margaret M. Dotzel,
Acting Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1085-N]

RIN 0938-AJ79

Medicare Program; Update of Ambulatory Surgical Center Payment Rates Effective for Services on or after October 1, 1999

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

ACTION: Notice.

SUMMARY: This notice implements section 1833(i)(2)(C) of the Social Security Act, which mandates an inflation adjustment to Medicare payment amounts for ambulatory surgical center (ASC) facility services during the years when the payment amounts are not updated based on a survey of the audited costs incurred by ASCs.

EFFECTIVE DATE: The payment rates contained in this notice are effective for services furnished on or after October 1, 1999.

FOR FURTHER INFORMATION CONTACT: Bob Cereghino, (410) 786-4645.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) provides that benefits under the Medicare Supplementary Medical Insurance program (Part B) include services furnished in connection with those surgical procedures that, under section 1833(i)(1)(A) of the Act, are specified by the Secretary and are performed on an inpatient basis in a hospital but that also can be performed safely on an ambulatory basis in an ambulatory

surgical center (ASC), in a critical access hospital. (Under section 4201(c)(1) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, the term "rural primary care hospital" is replaced with "critical access hospital" applicable to services furnished on or after October 1, 1997.) To participate in the Medicare program as an ASC, a facility must meet the standards specified under section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.25, which set forth basic requirements for ASCs.

Generally, there are two elements in the total charge for a surgical procedure: A charge for the physician's professional services for performing the procedure, and a charge for the facility's services (for example, use of an operating room). Section 1833(i)(2)(A) of the Act authorizes the Secretary to pay ASCs a prospectively determined rate for facility services associated with covered surgical procedures. ASC facility services are subject to the usual Medicare Part B deductible and coinsurance requirements. Therefore, Medicare pays participating ASCs 80 percent of the prospectively determined rate for facility services, adjusted for regional wage variations. This rate is intended to represent our estimate of a fair payment that takes into account the costs incurred by ASCs generally in providing the services that are furnished in connection with performing the procedure. Currently, this rate is a standard overhead amount that does not include physician fees and other medical items and services (for example, durable medical equipment for use in the patient's home) for which separate payment may be authorized under other provisions of the Medicare program.

We have grouped procedures into nine groups for purposes of ASC payment rates. The ASC facility payment for all procedures in each group is established at a single rate adjusted for geographic variation. The rate is a standard overhead amount that covers the cost of services such as nursing, supplies, equipment, and use

of the facility. (For an indepth discussion of the methodology and rate-setting procedures, see our **Federal Register** notice published on February 8, 1990, entitled "Medicare Program; Revision of Ambulatory Surgical Center Payment Rate Methodology" (55 FR 4526).)

Statutory Provisions

Section 1833(i)(2)(A) of the Act requires the Secretary to review and update standard overhead amounts annually. Section 1833(i)(2)(A)(ii) requires that the ASC facility payment rates result in substantially lower Medicare expenditures than would have been paid if the same procedure had been performed on an inpatient basis in a hospital. Section 1833(i)(2)(A)(iii) requires that payment for insertion of an intraocular lens (IOL) include an allowance for the IOL that is reasonable and related to the cost of acquiring the class of lens involved.

Under section 1833(i)(3)(A), the aggregate payment to hospital outpatient departments for covered ASC procedures is equal to the lesser of the following two amounts:

- The amount paid for the same services that would be paid to the hospital under section 1833(a)(2)(B) (that is, the lower of the hospital's reasonable costs or customary charges less deductibles and coinsurance).
- The amount determined under section 1833(i)(3)(B)(i) based on a blend of the lower of the hospital's reasonable costs or customary charges, less deductibles and coinsurance, and the amount that would be paid to a free-standing ASC in the same area for the same procedures.

Under section 1833(i)(3)(B)(i), the blend amount for a cost reporting period is the sum of the hospital cost proportion and the ASC cost proportion. Under section 1833(i)(3)(B)(ii), the hospital cost proportion and the ASC cost proportion for portions of cost reporting periods beginning on or after January 1, 1991 are 42 and 58 percent, respectively.

Section 13531 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993)

(Pub. L. 103-66), enacted on August 10, 1993, prohibited the Secretary from providing for any inflation update in the payment amounts for ASCs determined under section 1833(i)(2)(A) and (B) of the Act for fiscal years (FYs) 1994 and 1995. Section 13533 of OBRA 1993 reduced the amount of payment for an IOL inserted during or subsequent to cataract surgery in an ASC on or after January 1, 1994, and before January 1, 1999, to \$150.

Section 141(a)(1) of the Social Security Act Amendments of 1994 (SSAA 1994) (Public Law 103-432), enacted on October 31, 1994, amended section 1833(i)(2)(A)(i) of the Act to require that, for the purpose of estimating ASC payment amounts, the Secretary survey not later than January 1, 1995, and every 5 years thereafter, the actual audited costs incurred by ASCs, based upon a representative sample of procedures and facilities.

Section 141(a)(2) of SSAA 1994 added section 1833(i)(2)(C) to the Act to provide that, beginning with FY 1996, there be an application of an inflation adjustment during a fiscal year in which the Secretary does not update ASC rates based on survey data of actual audited costs. Section 1833(i)(2)(C) of the Act provides that ASC payment rates be increased by the percentage increase in the consumer price index for urban consumers (CPI-U), as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved, if the Secretary has not updated rates during a fiscal year, beginning with FY 1996.

Section 141(a)(3) of SSAA 1994 amended section 1833(i)(1) of the Act to require the Secretary to consult with appropriate trade and professional organizations in reviewing and updating the list of Medicare-covered ASC procedures.

Section 141(b) of SSAA 1994 requires the Secretary to establish a process for reviewing the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act for IOLs with respect to a class of new-technology IOLs. A notice of proposed rulemaking was published in the **Federal Register** on June 16, 1999, entitled "Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers" (BPD-3831-F) (64 FR 32198).

Section 4555 of the BBA amends section 1833(i)(2)(C) of the Act to require, in each of the fiscal years 1998 through 2002, that the percentage increase by which ASC rates are to be adjusted be reduced (but not below zero) by 2.0 percentage points.

We published our last ASC payment rate update notice on October 1, 1998 (63 FR 52663). In this notice, we explained that the current rates were frozen and we stated the comment period for proposed rule (HCFA-1885-P) published in the **Federal Register** June 12, 1998 entitled "Medicare Program; Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998" would be extended to November 13, 1998. We further extended the comment period for this proposed rule in **Federal Register** notices published January 12, 1999, March 12, 1999, and July 6, 1999. The comment periods have been running concurrently with those of another proposed rule addressing a prospective payment system (PPS) for hospital outpatient services published September 8, 1998 (63 FR 47552).

HCFA-1885-P proposes to update the criteria for determining which surgical procedures can be appropriately and safely performed in an ASC, makes additions and deletions from the current list of procedures based on the revised criteria, rebases the ASC payment rates using cost, charge, and utilization data collected by a 1994 survey of ASCs, refines the ratesetting methodology that was implemented by a final notice published on February 8, 1990 in the **Federal Register**, and requires that ASC payment, coverage and wage index updates be implemented annually on January 1 rather than having these updates occur randomly throughout the year.

II. Provisions of This Notice

As previously stated, during years in which the Secretary has not otherwise updated ASC rates based on a survey of actual audited costs, section 1833(i)(2)(C) of the Act requires application of an inflation adjustment equal to the percentage increase in the CPI-U as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved, reduced (but not below zero) by 2.0 percentage points in each of the fiscal years 1998 through 2002. (The CPI-U is a general index that reflects prices paid by urban consumers for a representative market basket of goods and services.)

Based on estimates prepared by Data Resources, Inc./McGraw Hill, the forecast rate of increase in the CPI-U for the fiscal year that ends March 31, 2000 is 2.8 percent. Reducing the CPI-U factor by 2.0 percent results in an adjustment factor of 0.8 percent. Increasing the ASC payment rates currently in effect by 0.8 percent results

in the following schedule of rates that are payable for facility services furnished on or after October 1, 1999:

- Group 1—\$317
- Group 2—\$425
- Group 3—\$486
- Group 4—\$600
- Group 5—\$683
- Group 6—\$794 (644 + 150)
- Group 7—\$949
- Group 8—\$934 (784 + 150)

ASC facility fees are subject to the usual Medicare deductible and copayment requirements. The allowance for an IOL that is part of the payment rates for group 6 and group 8 remains \$150.

A ninth payment group allotted exclusively to extracorporeal shockwave lithotripsy (ESWL) services was established in the notice with comment period published December 31, 1991 (56 FR 67666). The decision in *American Lithotripsy Society v. Sullivan*, 785 F. Supp. 1034 (D.D.C. 1992), prohibits payment for these services under the ASC benefit at this time. ESWL payment rates were the subject of a separate **Federal Register** proposed notice, which was published October 1, 1993 (58 FR 51355).

We will continue to use the inpatient hospital PPS wage index to standardize ASC payment rates for variation due to geographic wage differences in accordance with the ASC payment rate methodology published in the February 8, 1990 notice. The inpatient PPS wage index final rule published on July 30, 1999 (64 FR 41490), for implementation on October 1, 1999, will be used to adjust the ASC payment rates announced in this notice for facility services furnished on or after October 1, 1999.

III. Regulatory Impact Analysis

A. Introduction

This notice implements section 1833(i)(2) of the Act, which mandates an inflation adjustment to Medicare payment amounts for ASC facility services during the years in which the payment amounts are not updated based on a survey of the actual audited costs incurred by ASCs.

Actuarial estimates of the cost of updating the ASC rates by 0.8 percent are as follows:

PROJECTED ADDITIONAL MEDICARE COSTS
[In millions *]

FY 2000	\$10
FY 2001	10
FY 2002	10
FY 2003	10

PROJECTED ADDITIONAL MEDICARE
COSTS—Continued
[In millions *]

FY 2004	10
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*Rounded to the nearest \$10 million.

The BBA is considered in the estimate, including the PPS for hospital outpatient services, which will be implemented in the mid-2000, and the formula-driven overpayment elimination effective October 1, 1997.

B. Regulatory Flexibility Act

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) 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, most ASCs and hospitals are considered to be small entities either by non-profit status or by having resources of \$5 million or less annually.

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. This 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.

Although we believe that this notice will not have a significant impact on a substantial number of small rural hospitals, it may have a significant impact on a substantial number of ASCs. Therefore, we believe that a regulatory flexibility analysis is required for ASCs. In addition, we are voluntarily providing a brief discussion of the impact this notice may have on all hospitals.

1. Impact on ASCs

Section 1833(i)(2)(C) of the Act requires that for fiscal years 1998 through 2002, we automatically adjust ASC rates for inflation during a fiscal year in which we do not update ASC payment rates based on survey data by a CPI-U factor reduced (but not below zero) by 2.0 percent. Therefore, we are updating the current ASC payment rates, which were published in our October 1, 1997 **Federal Register** notice (63 FR 8462), by incorporating the projected rate of change in the CPI-U for the 12-month period ending March 31, 2000 minus 2.0 percentage points. There are other factors, however, that affect the actual payments to an individual ASC.

First, variations in an ASC's Medicare case mix affect the size of the ASC's

aggregate payment increase. Although we uniformly adjusted ASC payment rates by the CPI-U forecast for the 12-month period ending March 31, 2000, we did not adjust the IOL payment allowance that is included in the payment rate for group 6 and group 8 because OBRA 1993 froze the amount of payment for an IOL furnished by an ASC at \$150 for the period beginning January 1, 1994 through December 31, 1998. Therefore, because the net adjustment for inflation for procedures in group 6 is 0.63 percent and for group 8 is 0.64 percent, ASCs that perform a high percentage of the IOL insertion procedures that comprise these groups may expect a somewhat lower increase in their aggregate payments than ASCs that perform fewer IOL insertion procedures.

A second factor determining the effect of the change in payment rates is the percentage of total revenue an ASC receives from Medicare. The larger the proportion of revenue an ASC receives from the Medicare program, the greater the impact of the updated rates in this notice. The percentage of revenue derived from the Medicare program depends on the volume and types of services furnished. Since Medicare patients account for as much as 80 percent of all IOL insertion procedures performed in ASCs, an ASC that performs a high percentage of IOL insertion procedures will probably receive a higher percentage of its revenue from Medicare than would an ASC with a case mix comprised largely of procedures that do not involve insertion of an IOL. For an ASC that receives a large portion of its revenue from the Medicare program, the changes in this notice will likely have a greater influence on the ASC's operations and management decisions than they will have on an ASC that receives a large portion of revenue from other sources.

In general, we expect the rate changes in this notice to affect ASCs positively by increasing the rates upon which payments are based.

2. Impact on Hospitals and Small Rural Hospitals

Section 1833(i)(3)(A) of the Act mandates the method of determining payments to hospitals for ASC-approved procedures performed in a hospital outpatient setting. The Congress believed some comparability should exist in the amount of payment to hospitals and ASCs for similar procedures. The Congress recognized, however, that hospitals have certain overhead costs that ASCs do not and allowed for those costs by establishing a blended payment methodology. For ASC procedures performed in an outpatient setting, hospitals are paid

based on the lower of their aggregate costs, aggregate charges, or a blend of 58 percent of the applicable wage-adjusted ASC rate and 42 percent of the lower of the hospital's aggregate costs or charges. According to statistics from the Office of Strategic Planning within HCFA, 12 percent of Medicare payments to hospitals by intermediaries is attributable to services furnished in conjunction with ASC-covered procedures.

We would not expect an ASC rate increase in every instance to keep pace with actual hospital cost increases, although we would fully recognize cost increases resulting from inflation alone to the extent that the blended payment methodology includes aggregate hospital costs. The weight of the ASC portion of the blended payment amount, which would reflect the ASC rate increase, is offset to a degree when hospital costs significantly exceed the ASC rate. Another element that would eliminate the effect of the ASC rate increase on hospital outpatient payments is the application of the lowest payment screen in determining payments. Applying the lowest of costs, charges, or a blend can result in some hospitals being paid entirely on the basis of a hospital's costs or charges. In those instances, the increase in the ASC rates will have no effect on hospital payments. The number of Medicare beneficiaries a hospital serves and its case-mix variation would also influence the total impact of the new ASC rates on Medicare payments to hospitals. Based on these factors, we have determined, and we certify that this notice will not have a significant impact on a substantial number of small rural hospitals. Therefore, we have not prepared a small rural hospital impact analysis.

We have reviewed this notice under the threshold criteria of Executive Order 13132 of August 4, 1999, Federalism, published in the **Federal Register** on August 10, 1999 (64 FR 43255). The Executive Order is effective November 2, 1999, which is 90 days after the date of this Order. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

IV. Waiver of 30-Day Delay in the Effective Date

We ordinarily publish notices, such as this, subject to a 30-day delay in the effective date. However, if adherence to this procedure would be impracticable, unnecessary, or contrary to the public interest, we may waive the delay in the effective date. The provisions of this

notice are effective for services furnished on or after October 1, 1999. These provisions will increase payment rates to ASCs by 0.8 percent (before applying the wage index), in accordance with section 1833(i)(2)(C) of the Act, as amended by the BBA. As a practical matter, if we allowed a 30-day delay in the effective date of this notice, ASCs would be unable to take timely advantage of the increase in payment rates contained in this notice. Moreover, we believe a delay is impracticable and unnecessary because as explained earlier, the statute provides that ASC payment rates be increased by the percentage increase in the CPI-U if the Secretary has not updated rates during a fiscal year, beginning with FY 1996. Therefore, we find good cause to waive the delay in the effective date.

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

(Sections 1832(a)(2)(F) and 1833(i) (1) and (2) of the Social Security Act (42 U.S.C. 1395k(a)(2)(F) and 1395l(i) (1) and (2)); 42 CFR 416.120, 416.125, and 416.130)

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

Dated: October 6, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

Dated: October 25, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 00-2959 Filed 2-8-00; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding HRSA Grant Requirement—Participation in the 340B Drug Pricing Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is announcing its decision to withdraw the proposal to impose a grant award requirement that would have required HRSA grantees listed in section 340B of the Public Health Service Act and Federally Qualified Health Center (FQHC) Look-Alikes to participate in the 340B Drug Pricing Program or provide good cause for non-participation. Instead of the proposed grant

requirement, HRSA will add a statement to the Notice of Grant Award (NGA) concerning the need for grantees to determine the appropriateness of their drug purchasing practices under applicable cost principles.

FOR FURTHER INFORMATION CONTACT:

Captain Robert Staley, the Office of Drug Pricing, Bureau of Primary Health Care, Health Resources and Services Administration, 10th Floor, East West Towers, 4350 East-West Highway, Bethesda, MD 20814; Phone (800) 628-6297; Fax (301) 594-4982.

SUPPLEMENTARY INFORMATION: The proposed grant requirement for eligible HRSA grantee and FQHC Look-Alike participation in the 340B Drug Pricing Program was announced in the **Federal Register** at 63 FR 56656 on October 22, 1998. A period of 60 days was established to allow interested parties to submit comments. HRSA received 21 comments. In light of the concerns expressed about the potential adverse impact of the proposed grant requirement, HRSA has decided not to institute the requirement at this time. Instead, HRSA will implement another administrative option to increase participation in the 340B Drug Pricing Program: a statement in the HRSA Notice of Grant Award (NGA) encouraging those grantees not participating in the 340B Program to determine whether their drug purchasing practices meet Federal requirements regarding reasonable and cost effective purchasing. (See 42 CFR part 50, subpart E, and OMB Circulars A-122 and A-87 regarding cost principles). If grantees can obtain drugs through the Drug Pricing Program at lower cost, it would be reasonable to take advantage of such cost savings. This policy will be implemented during the fiscal year (FY) 2000 grant award cycle.

Dated: January 3, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00-2862 Filed 2-8-00; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: February 10, 2000.

Time: 4:30 PM to 7 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Anita Miller Sostek, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, (301) 435-1260.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: February 16, 2000.

Time: 1 PM to 4 PM.

Agenda: To review and evaluate grant applications.

Place: Governor's House Hotel, Washington, DC 20036.

Contact Person: John Bishop, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5180, MSC 7844, Bethesda, MD 20892, (301) 435-1250.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Musculoskeletal and Dental Sciences Initial Review Group, Oral Biology and Medicine Subcommittee 1.

Date: February 21-22, 2000.

Time: 8 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Old Town Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Priscilla B. Chen, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435-1787.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Infectious Diseases and Microbiology Initial Review Group, Bacteriology and Mycology Subcommittee 1.

Date: February 21-22, 2000.

Time: 8:30 AM to 6 PM.