

(6) against which a State has taken adverse action; and
(7) that meets such other measures of performance as the Secretary may develop.

The information compiled in this report must be accompanied by information that will assist in the interpretation of the report.

Accordingly, FDA is making the list and explanatory information available through this report. This report also provides background information on quality mammography and directs consumers on how to acquire a list of FDA-certified mammography facilities.

Dated: September 27, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96-25197 Filed 9-27-96; 12:11 pm]

BILLING CODE 4160-01-F

Health Care Financing Administration

[HCFA-R-117]

Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements contained in 42 CFR 447.253; *Form No.:* HCFA-R-117; *Use:* In order to receive HCFA approval of a Medicaid State plan amendment which changes the methods and standards used to establish payment rates for inpatient hospital or long-term care services, a Medicaid State Agency must provide a statement which assures the HHS Secretary that the resulting rates will conform to all the

requirements specified in section 1902(a)(13)(A) of the Social Security Act and implementing regulations at 42 CFR 447.253; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 54.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 23, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96-25060 Filed 9-30-96; 8:45 am]

BILLING CODE 4120-03-P

[BPD-874-N]

Medicare Program; Update of Ambulatory Surgical Center Payment Rates Effective for Services on or After October 1, 1996

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 automatic 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 actual audited costs incurred by ASCs.

EFFECTIVE DATE: The payment rates contained in this notice are effective for services furnished on or after October 1, 1996.

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be

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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 rural primary care hospital, or in a hospital outpatient department. 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, participating ASCs are paid 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); or

- 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 current hospital cost proportion and the ASC cost proportion are 42 and 58 percent, respectively.

Section 13531 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) (Public Law 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 Federal 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 automatic application of an inflation adjustment during a fiscal year when 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.

ASC Survey

Regulations set forth at § 416.140 ("Surveys") require us to survey a randomly selected sample of participating ASCs no more often than once a year to collect data for analysis or reevaluation of payment rates. In addition, section 1833(i)(2)(A)(i) of the Act requires 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.

In July 1992, we mailed Form HCFA-452A, Medicare Ambulatory Surgical Center Payment Rate Survey (Part I), to the nearly 1,400 ASCs that were on file as being certified by Medicare at the end of 1991. Part I data provided baseline information for selecting a sample of 320 ASCs to complete Form HCFA-452B, Medicare Ambulatory Surgical Center Payment Rate Survey (Part II). The sample was randomly selected and is representative of ASCs nationally in terms of facility age, utilization, and surgical specialty.

Part II of the ASC survey was mailed to the sample of ASCs in March 1994. Part II of the ASC survey asked for data on costs incurred by the facility that are directly related to performing certain surgical procedures, such as cataract extraction with IOL insertion, as well as information on facility overhead and personnel costs. We asked facilities to report total volume, Medicare volume, OR time, and their average billed charge for the Medicare covered procedures that were performed at the facility during the survey year. We audited 100 randomly selected Part II surveys between November 1994 and February 1995. We intend to use the 1994 survey data as the basis for updating the schedule of ASC payment rates as well as for revising our method of ratesetting, all of which will be described in a proposed notice in the Federal Register in accordance with standard notice and comment procedures. In compliance with the requirement in section 1833(i)(2)(A)(i) of the Act that we survey ASC costs every 5 years we expect to conduct the next survey of ASC costs before April 1999.

Although we have completed our preliminary analysis of procedure costs based on data from the 1994 Medicare Ambulatory Surgical Center Payment

Rate Survey, we are still revising and updating the method of using those data to determine ASC payment rates. Therefore, we are not implementing rates that reflect 1994 survey data in FY 1997.

We published our last ASC payment rate update notice on September 26, 1995 (60 FR 49619).

II. Provisions of This Notice

During years when 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. That inflation adjustment must be 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. (The CPI-U is a general index that reflects prices paid 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, 1997 is 2.6 percent. Increasing the ASC payment rates currently in effect by 2.6 percent results in the following schedule of rates that are payable for facility services furnished on or after October 1, 1996:

Group 1—\$312
Group 2—\$419
Group 3—\$479
Group 4—\$591
Group 5—\$674
Group 6—\$785 (635+150)
Group 7—\$935
Group 8—\$923 (773+150)

ASC facility fees are subject to the usual Medicare deductible and copayment requirements. Under section 13531 of OBRA 1993, the allowance for an IOL that is part of the payment rates for group 6 and group 8 is \$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 are 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 prospective payment system (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 Federal Register (55 FR 4526). Because ASC payment rates are updated concurrently with the annual update of the hospital inpatient PPS wage index, the wage index in the PPS final rule that will be implemented on October 1, 1996 will be used to adjust the ASC payment rates announced in this notice for facility services furnished beginning October 1, 1996.

III. Regulatory Impact Analysis

A. Introduction

This notice implements section 1833(i)(2) of the Act, which mandates an automatic inflation adjustment to Medicare payment amounts for ASC facility services during the years when 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 2.6 percent are as follows:

PROJECTED ADDITIONAL MEDICARE COSTS [In millions]*

	Dollar amounts ¹
FY 1997	\$30
FY 1998	30
FY 1999	30
FY 2000	40
FY 2001	40

* Rounded to the nearest \$10 million.

¹ These amounts are in the Medicare budget baseline.

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, all ASCs and hospitals are considered to be small entities.

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 an impact analysis on small rural hospitals is not required, this notice 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 hospitals.

1. Impact on ASCs

Section 1833(i)(2)(C) of the Act requires that we automatically adjust ASC rates for inflation during a fiscal year when we do not update ASC payment rates based on survey data. Therefore, we are updating the current ASC payment rates, which were published in our September 26, 1995 Federal Register notice (60 FR 49619), by incorporating the projected rate of change in the CPI-U for the 12-month period ending March 31, 1997, a 2.6 percent increase. 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, 1997, 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 2.08 percent and for group 8 is 2.21 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 an 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 the Actuary within HCFA, 10.7 percent of Medicare payments to hospitals by intermediaries for outpatient department services is attributable to services furnished in conjunction with ASC-covered procedures.

We believe that, due to a variety of factors, the ASC rate increase in this notice will result in only a 0.8 percent increase in intermediary payments to hospitals for 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.

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 impractical, 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 beginning on October 1, 1996, to coincide with the FY 1997 PPS updated wage index. These provisions will increase payment to ASCs by 2.6 percent (as modified by any change to the wage indices), in accordance with section 1833(i)(2)(C) of the Act, which requires automatic application of an inflation adjustment. 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 impractical and unnecessary because the statute, as explained earlier, 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 not reviewed by the Office of Management and Budget. This rule is not a major rule as defined by U.S.C. 804(2).

(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: September 9, 1996.

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

Dated: September 26, 1996.

Donna E. Shalala,
Secretary.

[FR Doc. 96-25253 Filed 9-30-96; 8:45 am]

BILLING CODE 4120-01-P

Indian Health Service

Method for Evaluating and Establishing Reimbursement Rates for Health Care Services Authorized Under the Indian Health Service Contract Health Service Regulations—Portland, Alaska, and Nashville Areas

ACTION: Extension of project date.

SUMMARY: The termination date for the Portland Pilot Project now being conducted in the Portland, Alaska, and Nashville Areas to determine an alternative method of evaluating and establishing reimbursement rates for contract health services (CHS) has been changed from September 30, 1996 to September 30, 1997.

FOR FURTHER INFORMATION CONTACT: Nancy Davis, Chief, Contract Health Services Branch, Division of Health Care Administration/Contract Health Services, Room 6A-39, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-2694 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Indian Health Service (IHS) issued a general notice in 56 FR 10566 on March 13, 1991 to inform the public that the IHS was conducting a pilot project in the IHS Portland Area. This project is designed to determine whether an alternative method of evaluating and establishing reimbursement rates for CHS will result in greater participation by health care providers and lower costs to IHS. The project invited providers within the Portland Area to submit their most favorable rate quotations and was scheduled to end on March 31, 1992. The response was far greater than the expectations of the IHS. As a result of this greater than expected response, and the need to develop complex rate quotation analysis methodologies for facilities, outpatient and professional providers, and the need to develop preferred provider lists from these analyses, the termination date was extended to March 31, 1993, 57 FR 10671. The termination date was again extended to March 31, 1995, 58 FR 11864. Additionally, the IHS published notification on June 18, 1992, 57 FR 27262, that additional sites were being added to the pilot project to provide more information from a wide geographic area.

The evaluation of the facility component of the project was completed January 28, 1994. The overall results of the evaluation were positive. The formal review process of the professional provider component has not been completed. Extension of the project termination date to September 30, 1997 will allow the IHS time to complete the