

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 26, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m., on March 19, 1998, and 8 a.m. and 8:30 a.m. on March 20, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 26, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C., app. 2).

Dated: February 11, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-4079 Filed 2-18-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0082]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Devices; Classification/Reclassification; Restricted Devices; Analyte Specific Reagents" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 21, 1997 (62 FR 62243), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is

not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0361. The approval expires on January 31, 2001.

Dated: February 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-4080 Filed 2-18-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1897-N]

Medicare Program; Update of Ambulatory Surgical Center Payment Rates Effective for Services on or After October 1, 1997

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

ACTION: Notice.

SUMMARY: This notice announces the update of Ambulatory Surgical Center payment rates effective for services on or after October 1, 1997. It 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 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, 1997.

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 placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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FOR FURTHER INFORMATION CONTACT: Joan Haile Sanow, (410) 786-5723.

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 (Part B) program 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 the basic requirements for ASCs set forth in our regulations at 42 CFR 416.25.

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 in-depth 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) (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 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) (Pub. L. 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 proposed rule entitled "Adjustment in Payment Amounts for New Technology Intraocular Lenses" (BPD-831-P) was published in the **Federal Register** on September 4, 1997 at 62 FR 46698.

Section 4555 of the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA) amends section 1833(i)(2)(C) of the Act

to require, in each of the FYs 1998 through 2002, that the CPI-U factor by which ASC rates are to be adjusted be reduced (but not below zero) by 2.0 percentage points.

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, operating room 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 plan to use the 1994 survey data to rebase ASC payment rates. In accordance with rulemaking procedures, we will publish the rebased rate in the **Federal Register** and solicit public comments.

We published our last ASC payment rate update notice on October 1, 1996 (61 FR 51295).

II. Provisions of This Notice

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, as amended by BBA, 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, 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 FY that ends March 31, 1998 is 2.6 percent. Reducing the CPI-U factor by 2.0 percent results in an adjustment factor of 0.6 percent. Increasing the ASC payment rates currently in effect by 0.6 percent results in the following schedule of rates that are payable for facility services furnished on or after October 1, 1997:

- Group 1—\$314
- Group 2—\$422
- Group 3—\$482
- Group 4—\$595
- Group 5—\$678
- Group 6—\$789 (639+150)
- Group 7—\$941
- Group 8—\$928 (778+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 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 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 notice. The PPS wage index final rule published on August 29, 1997 (62 FR 45965), for implementation on October 1, 1997, will be used to adjust the ASC payment rates announced in this notice for facility services furnished on or after October 1, 1997.

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 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 0.6 percent are as follows:

PROJECTED ADDITIONAL MEDICARE COSTS

Fiscal year	In millions*
1998	15
1999	15
2000	15
2001	15
2002	15
2003	15

* Rounded to the nearest \$10 million.

The BBA is considered in the estimate, including the prospective payment system for hospital outpatient services to be implemented on January 1, 1999, 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 hospitals.

1. Impact on ASCs

Section 1833(i)(2)(C) of the Act requires that for FYs 1998 through 2002, we automatically adjust ASC rates for inflation during an FY 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, 1996 **Federal Register** notice (61 FR 51295), by incorporating the projected rate of change in the CPI-U for the 12-month period ending March 31, 1998 minus 2.0 percentage points, a net 0.6 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, 1998, 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 0.51 percent and for group 8 is 0.54 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 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 in the portion of the blended payment that 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 on or after October 1, 1997. These provisions will increase payment to ASCs by 0.6 percent (as modified by any change to 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 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 an FY, 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 9, 1997.

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

Dated: October 30, 1997.

Donna E. Shalala,
Secretary.

[FR Doc. 98-4227 Filed 2-18-98; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4193-N-03]

Announcement of Funding Awards Fair Housing Initiatives Program FY 1997

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of the FY 1997 funding awards made under the Fair Housing Initiatives Program (FHIP). The purpose of this document is to announce the names and addresses of the award winners and the amount of the awards to be used to strengthen the Department's enforcement of the Fair Housing Act and to further fair housing.

FOR FURTHER INFORMATION CONTACT: Ivy Davis, Director, FHIP/FHAP Support Division, Room 5234, 451 Seventh Street, S.W., Washington, D.C. 20410-2000. Telephone number (202) 708-0800 (this is not a toll-free number). A telecommunications device for hearing- and speech-impaired individuals (TTY) is available at 1-800-877-8339 (Federal Information Relay Service).

SUPPLEMENTARY INFORMATION: Title VIII of the Civil Rights Act of 1968, as amended, 42 U.S.C. 3601-19 (The Fair Housing Act), charges the Secretary of Housing and Urban Development with responsibility to accept and investigate complaints alleging discrimination based on race, color, religion, sex, handicap, familial status or national origin in the sale, rental, or financing of most housing. In addition, the Fair Housing Act directs the Secretary to coordinate with State and local agencies administering fair housing laws and to cooperate with and render technical assistance to public or private entities carrying out programs to prevent and eliminate discriminatory housing practices.

Section 561 of the Housing and Community Development Act of 1987, 42 U.S.C. 3616 note, established the FHIP to strengthen the Department's enforcement of the Fair Housing Act and to further fair housing. This program assists projects and activities designed to enhance compliance with the Fair Housing Act and substantially equivalent State and local fair housing laws. Implementing regulations are found at 24 CFR Part 125.

The FHIP has four funding categories: The Administrative Enforcement Initiative, the Education and Outreach Initiative, the Private Enforcement Initiative, and the Fair Housing Organizations Initiative. This notice announces awards made under the Fair Housing Organizations Initiative, Education and Outreach Initiative, and the Private Enforcement Initiative.

The Department announced in the **Federal Register** on June 26, 1997 (62