discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: September 19, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–23738 Filed 9–25–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–824–N]

Medicare Program; Update of Ambulatory Surgical Center (ASC) Payment Rates Effective for Services On or After October 1, 1995

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, 1995.

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.

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 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 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.

We published our last update of ASC payment rates in the Federal Register on October 1, 1992 (57 FR 45544). Statutory provisions enacted after October 1, 1992 that affect ASCs include the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) (Pub. L. 103–66), enacted on August 10, 1993. Section 13531 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 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 specifying Medicare-covered ASC procedures and facility payment amounts. 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 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 updated charge data for all Medicare-covered procedures performed at the facility. We audited 100 randomly selected Part II surveys between November 1994 and February 1995.

Because we are still reviewing data from Part II of the 1994 Medicare Ambulatory Surgical Center Payment Rate Survey, we are not adjusting ASC payment rates in FY 1996 to reflect these data.

II. Analysis of and Responses to the Public Comments

We published our last ASC payment rate update notice on October 1, 1992 (57 FR 45544). In response to that notice, we received one public comment. Because section 13531 of OBRA 1993 prohibited the Secretary from providing for any inflation update for FYs 1994 and 1995, we did not publish update notices for those years, and, consequently, the public comment on the October 1, 1992 notice and our response have not been published. A summary of that comment and our response will be contained in a proposed rule updating the ASC payment methodology that we expect to publish in the Federal Register next year. Because the public comment relates to the wage index, we believe the comment and our response fit more appropriately in that document, which will contain a discussion of the wage index used to adjust ASC payment rates for geographic wage differences. We did not make any changes as a result of our consideration of the public comment.

III. 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) of the Act requires automatic 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, 1996 is 3.2 percent. Increasing the ASC payment rates currently in effect by 3.2 percent results in the following schedule of rates that are payable for facility services furnished on or after October 1, 1995:

Group 1—$304
Group 2—$408
Group 3—$467
Group 4—$576
Group 5—$657
Group 6—$769
Group 7—$911
Group 8—$903

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.

In order to implement the inflation adjustment required by section 141(a)(2) of SSAA 1994 beginning in FY 1996, we estimated the annual percent change in the CPI–U for the 12-month period ending March 31, 1996. However, the first 6 months of this 12-month period, April 1, 1995 through September 30, 1995, fall in FY 1995, and section 13531 of OBRA 1993 prohibited the Secretary from providing any inflation update in ASC payment amounts for FYs 1994 and 1995. We believe that determining, in part, the FY 1996 adjustment factor by reference to April 1, 1995 through September 30, 1995 does not violate or contradict the OBRA 1993 provision because our use of the adjustment factor applies only to payments for ASC services actually furnished beginning in FY 1996.

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 PPS wage index final rule that will be implemented on October 1, 1995 will be used to adjust the ASC payment rates announced in this notice for facility services furnished beginning October 1, 1995. The policy of eliminating midyear corrections to the hospital inpatient PPS wage index applies to ASCs and the calculation of individual ASC payment amounts as well.

IV. 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 3.2 percent are as follows:

PROJECTED ADDITIONAL MEDICARE COSTS

[In millions]*

FY 1996	$35
FY 1997	40
FY 1998	50
FY 1999	55
FY 2000	60

*Rounded to the nearest $5 million.

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) 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 October 1, 1992 Federal Register notice (57 FR 45544), by incorporating the projected rate of change in the CPI–U for the 12-month period ending March 31, 1996, a 3.2 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, 1996, 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 2.56 percent and for group 8 is 2.66 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, 12.7 percent of Medicare payments to hospitals by intermediaries 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 0.9 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.

V. 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, 1995, to coincide with the FY 1996 PPS updated wage index. These provisions will increase payment to ASCs by 3.2 percent (as modified by any change to the wage indices), in accordance with section 1833(i)(2) 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, which, 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.

(Sec. 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: July 28, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–23742 Filed 9–25–95; 8:45 am]

BILLING CODE 4120–01–P

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meetings

Pursuant to Pub. L. 92–463, notice is hereby given of meetings of the National Institute on Alcohol Abuse and Alcoholism.

The meetings will be open to the public, as noted below, to discuss administrative details or other issues relating to committee activities as indicated in the notice. Attendance by the public will be limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ida Nestorio at (301) 443–4376.

The following meetings will be closed to the public as indicated below in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual research grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of the meetings and the rosters of committee members may be obtained from: Ms. Ida Nestorio, NIAAA Committee Management Officer, National Institute on Alcohol Abuse and Alcoholism, Willco Building, Suite 409, 6000 Executive Blvd., Rockville, MD 20892–7003, Telephone: (301) 443–4376. Other information pertaining to the meetings can be obtained from the contact person indicated.

Name of Committee: Neuroscience and Behavior Subcommittee of the Alcohol Biomedical Research Review Committee.

Dates of Meeting: October 11–12, 1995.

Place of Meeting: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Open: October 11, 9 a.m. to 10:00 a.m.

Agenda: Discussion of issues related to Alcohol, Mental Health, and Drug Abuse grant review integration to DRG.

Closed: October 11, 10:00 a.m. to adjournment.

Agenda: Review, discussion and evaluation of individual research grant applications.

Contact Person: Antonio Noronha, Ph.D., 6000 Executive Blvd, Suite 409, Bethesda, MD 20892–7003, 301–443–9419.

Name of Committee: Biochemistry, Physiology, and Medicine Subcommittee of the Alcohol Biomedical Research Review Committee.