

Friday June 12, 1998

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 416 and 488

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; Proposed Rule

DEPARTMENT OF HEALTH AND **HUMAN SERVICES**

Health Care Financing Administration

42 CFR Parts 416 and 488

[HCFA-1885-P]

RIN 0938-AH81

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

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

SUMMARY: In this rule we propose to-Update the criteria for determining

which surgical procedures can be appropriately and safely performed in an ambulatory surgical center (ASC);

 Make additions to and deletions from the current list of Medicare covered ASC procedures based on the revised criteria;

• Rebase the ASC payment rates using cost, charge, and utilization data collected by a 1994 survey of ASCs;

 Refine the ratesetting methodology that was implemented by a final notice published on February 8, 1990 in the Federal Register;

 Require that ASC payment, coverage, and wage index updates be implemented annually on January 1 rather than having these updates occur randomly throughout the year;

 Reduce regulatory burden; and • Make several technical policy changes.

This proposed rule implements requirements of section 1833(i)(1) and (2) of the Social Security Act. DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 11, 1998. ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1885-P, P.O. Box 26688, Baltimore, MD 21207-5178.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

SUPPLEMENTARY INFORMATION: Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1885-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

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to call 202–512–1661; type swais, then login as guest (no password required).

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We are disappointed by our lack of success in the 1994 ASC survey in gathering usable resource cost data. Our inability to establish weights and base ASC payment rates on the resource cost data that we did collect is particularly frustrating in light of the fact that we expect, beginning January 1, 1999, to make payments to physicians under the Medicare physicians' fee schedule that are determined in part on the basis of resource-based practice expense relative units. We have been closely monitoring the development of the resource-based practice expense relative value units under the physicians' fee schedule and the ratesetting method for the hospital outpatient prospective payment system, which is also scheduled for implementation effective January 1, 1999. When we rebase ASC payment rates following the next ASC survey, we are committed to reexamining the resource-based practice expense relative value units established under the Medicare physicians' fee schedule and the weights developed under the hospital outpatient prospective payment system for their applicability to ASC ratesetting in order to advance towards our goal of setting rates in a manner that is consistent across different sites of service.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative History

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 payment for facility services furnished in connection with surgical procedures specified by the Secretary and performed in an ambulatory surgical center (ASC).

The Secretary is to review and update the list of ASC procedures biennially.

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 sets forth general conditions and requirements for ASCs.

Generally, there are two primary elements in the total cost of performing a surgical procedure: the cost of the physician's professional services for performing the procedure, and the cost of services furnished by the facility where the procedure is performed (for example, surgical supplies and equipment and nursing services). Section 1833(i)(2)(A) of the Act addresses what the ASC facility fee is intended to represent and how the amount of the Medicare payment for ASC facility services is to be determined. It requires us to review and update ASC payment amounts annually.

The ASC payment rate is to be a standard overhead amount established on the basis of our estimate of a fair fee that takes into account the costs incurred by ASCs generally in providing facility services in connection with performing a specific procedure. The Report of the Conference Committee accompanying section 934 of the Omnibus Budget Reconciliation Act of 1980 (Public Law 96-499), which enacted the ASC benefit in December 1980, states, "This overhead factor is expected to be calculated on a prospective basis * * * utilizing sample survey and similar techniques to establish reasonable estimated overhead allowances for each of the listed procedures which take account of volume (within reasonable limits)." (See H.R. Rep. No 1479, 96th Cong., 2nd Sess. 134 (1980).)

In order to estimate the amount of those reasonable allowances, we are required by section 1833(i)(2)(A)(i) of the Act to survey the actual audited costs incurred by a representative sample of facilities in connection with a representative sample of procedures.

This survey is to be conducted every five years, beginning no later than January 1, 1995.

Because payment for ASC facility services is subject to the usual Medicare Part B deductible and coinsurance requirements, Medicare pays participating ASCs 80 percent of the prospectively-determined rate, adjusted for regional wage variations.

Section 1833(i)(2)(A)(ii) requires that the ASC 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 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 freestanding 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 4521 of the Balanced Budget Act of 1997 (BBA 1997) (Public Law 105–33) amended section 1833(i)(3)(B)(i)(II) of the Act to eliminate the formula-driven overpayment (FDO) for ASC procedures.

Section 13531 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) (Public Law 103–66), prohibited the Secretary from providing for any inflation update in the payment amounts for ASCs determined under section 1833(i)(2)(A) of the Act for fiscal years (FYs) 1994 and 1995. Section 13533 of OBRA 1993 established \$150 as the amount of payment allowed for an IOL inserted during or subsequent to cataract surgery in an ASC on or after January 1, 1994, and before January 1, 1999.

Section 141(a)(1) of the Social Security Act Amendments of 1994 (SSAA 1994) (Public Law 103–432) amended section 1833(i)(2)(A)(i) of the Act to require that a quinquennial survey of ASCs be taken beginning not later than January 1, 1995.

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 adjustment for inflation during fiscal years when the Secretary does not update ASC rates based on actual audited costs determined by surveying a representative sample of facilities. Section 1833(i)(2)(C) of the Act provides that ASC payment rates are to 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, 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 the procedures that constitute the ASC list.

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 newtechnology IOLs. That process is the subject of a separate notice of proposed rulemaking entitled "Adjustment in Payment Amounts for New Technology Intraocular Lenses" (BPD–831–P) published in the **Federal Register** on September 9, 1997 at 62 FR 46698.

Section 4555 of BBA 1997 amended section 1833(i)(2)(C) of the Act to limit the annual adjustment of ASC payment rates provided for in that paragraph to the CPI–U increase reduced by 2.0 percentage points (but not below zero) for fiscal years 1998 through 2002.

B. Published Changes to ASC List

We published a final notice in the **Federal Register** on February 8, 1990 (55 FR 4526) in which we implemented a new ratesetting methodology that increased the number of ASC payment groups from four to the current eight groups. We assigned a new payment rate to each of the nearly 1500 current procedural technology (CPT) codes on the ASC list at that time, and we revised the ASC list to be consistent with CPT coding changes effected by The American Medical Association in 1988 and 1989. **Federal Register** notices adding codes to and deleting codes from the ASC list were subsequently published as follows:

• December 31, 1991 notice with comment period (56 FR 67666) in which we added approximately 900 CPT codes to the ASC list, including CPT code 50590, Extracorporeal shock wave lithotripsy (ESWL).

 January 26, 1995 final notice with comment period (60 FR 5185) in which we updated the ASC list to reflect CPT changes that had occurred during the interval since publication of the December 31, 1991 notice. We deleted five codes from the ASC list on the basis of modified quantitative criteria that we adopted to determine whether or not a procedures should be retained on the list. We added nearly 30 codes that met our numeric criteria of adding to the list procedures performed at least 20 percent of the time on a hospital inpatient basis but no more than 50 percent of the time in a physician's office, based on national claims history data. We solicited public comment on certain additions to and deletions from the ASC list and the payment rates assigned to the additions. We respond to those comments in this notice.

C. Published Changes to ASC Payment Rates

In a final notice published in the Federal Register on February 8, 1990 (55 FR 4526), we explained the new ASC ratesetting methodology and increased the number of ASC payment groups from four to the current eight groups on the basis of ASC survey data collected in 1986. The rates that Medicare paid for services furnished on or after March 12, 1990 under the new eight-group payment methodology were published in a separate notice with comment period in the same February 8, 1990 Federal Register (55 FR 4577). Subsequent updates of the ASC payment rates are as follows:

• July 5, 1990 **Federal Register** notice with comment period (55 FR 27690) increased payment rates by a CPI–U factor of 4.21 percent;

• December 31, 1991 **Federal Register** notice with comment period (56 FR 67666) increased payment rates by a CPI–U factor of 5.1 percent and added a ninth payment group for ESWL;

• October 1, 1992 **Federal Register** notice with comment period (57 FR 45544) increased payment rates by a CPI–U factor of 3.5 percent;

• September 26, 1995 **Federal Register** notice (60 FR 49619) increased payment rates by a CPI–U factor of 3.2 percent; • October 1, 1996 **Federal Register** notice (61 FR 51295) increased payment rates by a CPI–U factor of 2.6 percent;

• February 19, 1998 **Federal Register** notice (62 FR 8462) Increased payments rates by 0.6 percent effective for services furnished on or after October 1,1997. The ASC payment rates implemented by this notice, which are currently in effect, are:

Group 1—\$314	Group 5—\$678.
Group 2—\$422	Group 6—\$789 (639
	+ 150 for IOL).
Group 3—\$482	Group 7—\$941.
Group 4—\$595	Group 8-\$928 (778
	+ 150 for IOL).

There is no payment rate shown for group 9 because of the decision in *American Lithotripsy Society* v. *Sullivan,* 785 F. Supp. 1034 (D.D.C. 1992) that prohibits payment for these services under the ASC benefit at this time. Payment for ESWL as an ASC service is discussed below.

D. Payment Rate for Extracorporeal Shock Wave Lithotripsy

In the **Federal Register** published December 7, 1990, (55 FR 50590), we published a notice proposing additions to and deletions from the ASC list. We solicited comments on our proposal to add CPT code 50590, Lithotripsy, extracorporeal shock wave, to the ASC list and on the Group 7 payment rate of \$812 that we proposed as the ASC facility fee for the procedure. We also requested detailed information on facility charges and costs associated with providing ESWL services to help us evaluate the appropriateness of the proposed payment rate.

In the final notice with comment period published December 31, 1991 in the Federal Register (56 FR 67666), we established a payment rate for ESWL as new ASC payment group 9. We set the group 9 rate at \$1,150, effective for services furnished on or after January 30, 1992. On January 30, 1992, the American Lithotripsy Society filed a complaint and motion to enjoin enforcement and implementation of the December 31, 1991 notice insofar as it concerned ESWL. In American Lithotripsy Society v. Louis W. Sullivan, M.D., et al, 785 F. Supp. 1034 (D.D.C. 1992), the American Lithotripsy Society challenged HCFA's determination that ESWL is a surgical procedure under the ASC benefit and the amount payable for ESWL services in an ASC. The plaintiff alleged that the \$1,150 rate was not based on an estimate of a "fair fee" that took into account costs incurred by ASCs performing such services as required by section 1833(i)(2)(A) of the

Act and that the rate was not supported by the administrative record.

On March 12, 1992, the United States District Court for the District of Columbia held that HCFA's decision to classify ESWL as a surgical procedure was rationally justified. However, it remanded the final notice setting a rate for lithotripsy to the Secretary for further consideration and stayed the regulation, insofar as it related to ESWL, pending remand. On remand, the Secretary is required to publish all material information that is relevant to the setting of the ESWL rate, receive comments, and publish a final notice in accordance with the applicable statutes and regulations.

To comply with the court order, Medicare ceased paying an ASC facility fee for ESWL services furnished in Medicare approved ASCs and resumed making payment on a reasonable cost basis for ESWL furnished in a hospital outpatient setting. On October 1, 1993, we published a proposed notice with comment period in the Federal Register (58 FR 51355) in which we proposed a revised ASC payment rate of \$1,000, based on further consideration of the data and methodology that we used to determine the rate. We explained in detail in the October 1, 1993 notice how we arrived at the proposed rate, and we solicited information on ESWL costs, charges, and utilization to enable us to further evaluate the appropriateness of the assumptions that we used to develop the proposed rate. The information submitted during the public comment period persuaded us to defer publication of a final notice and implementation of an ASC facility fee for ESWL, pending completion of the 1994 ASC survey that was about to be conducted. In this notice of proposed rulemaking we respond to the comments that were submitted timely following publication of the October 1, 1993 notice, and we propose an ASC payment rate for ESWL services that we have determined in accordance with the ratesetting methodology that is also proposed in this notice. In accordance with applicable statutes and regulations, this notice of proposed rulemaking includes all material information that is relevant to the setting of ASC payment rates, which includes a payment rate for ESWL. Publication of this notice of proposed rulemaking is followed by a 60-day public comment period. When the comment period closes, and following review of all comments submitted timely, we shall publish a final notice to implement rebased ASC payment rates for procedures on the ASC list, including ESWL

E. ASC Town Meeting (July 1996)

Many of the policy changes proposed in this notice had their genesis in discussions and comments that emanated from an ASC "Town Meeting" that was held at the central office of the Health Care Financing Administration on July 25–26, 1996. The purpose of the Town Meeting was to give representatives of professional and trade associations and other parties with an interest in ASCs an opportunity to come together with HCFA staff to exchange information and ideas regarding Medicare ASC policy. More than 100 people from across the country attended, including physicians, nurses, ASC administrators, and representatives of independent and chain facilities, State licensing and certification agencies, and numerous professional societies and ASC trade associations. From the Town Meeting, we gained a greater understanding of some of the immediate and long-term issues and concerns facing ASC staff and partners, and we received numerous suggestions and recommendations on ways to strengthen the ASC benefit on behalf of Medicare beneficiaries.

The first day's meetings focussed on performance outcome measures for ASCs and conditions for coverage of ASCs. The second day of the meeting focussed on the criteria HCFA uses to determine which procedures should be placed on the ASC list and the method HCFA uses to set ASC payment rates. Following the Town Meeting, we received 79 written comments reiterating concerns and suggestions that were raised during the meeting itself.

Virtually every commenter submitted a critique of a grouping system that we presented at the meeting as a possible alternative to the current eight ASC payment groups. We had distributed to participants a listing of CPT surgical codes arranged in "Ambulatory Patient Groups'' (APGs). These groups were developed by 3M Health Information Systems with the support of HCFA. The list was taken from The Ambulatory Patient Groups Definitions Manual, Version 2.0. Only groups of CPT codes were shown; no payment rates or procedure costs were given. We were primarily interested in whether or not participants found the groups to be clinically homogeneous as well as consistent in terms of resource costs. Commenters were unanimous in disagreeing with the internal consistency of numerous APG groups across most body systems. The commenters' examples and reasons for taking issue with the homogeneity of the APGs prompted us to re-examine the groups. We did so, which resulted in the revision and reclassification of most of the groups. The product of that exercise is the ambulatory payment classification (APC) system that we propose in this notice as the basis for ASC ratesetting.

F. Revisions to the Conditions for Coverage of ASCs

The standards and conditions for coverage of an ASC currently found in subpart C of 42 CFR part 416 are being revised and are the subject of a separate notice currently under development.

II. Comments

In the final notice with comment period published January 26, 1995 in the Federal Register (60 FR 5185), we solicited comments on certain changes to the ASC list that we had not included in the proposed notice published on December 14, 1993 (58 FR 65357). Specifically, we asked for comments on our deletion from the ASC list of any codes that had been deleted in CPT 1994, and we asked for comments about our deletion from the ASC list of CPT code 36522 Photopheresis, extracorporeal. We received 9 comments supporting the deletion of CPT code 36522 from the ASC list and no comments disagreeing with our decision. We received no comments regarding the other deletions from the ASC list.

We also requested comments on the addition of, and assignment of payment groups for, certain CPT codes that were not proposed in the December 14, 1993 **Federal Register**. We have limited our response to comments that were submitted timely regarding the specified codes.

We specifically solicited comments on the addition to the ASC list of certain codes that were added to CPT 1994 as well as the appropriateness of the payment groups to which we assigned those codes. No commenters disagreed with adding the codes to the ASC list. However, commenters indicated that they believed the payment rate assigned to the following CPT codes was too low: 19125

19126

29804

31235

31238

31239

31248

31249

31251

31266

31269

31271

31280

31281

³²²⁹³

31282
31283
31284
31286
31287
31288
43216
43259
44394
45339
56309
56316
56317
56351
56356
64421
66172

Response: As a consequence of the following codes being deleted from CPT in 1995, we excluded them from the ASC list: 31248, 31249, 31251, 31266, 31269, 31271, 31280, 31281, 31282, 31283, 31284, 31286. CPT code 64421 is one of the codes that we are proposing in this notice to delete from the ASC list (section III.D). For all but four of the remaining codes, consistent with

commenters' recommendations, the payment rates that we propose in this notice using the revised ratesetting methodology and 1994 survey data are higher than what we proposed in the January 26, 1995 Federal Register. However, the same revised ratesetting methodology and 1994 survey data result in payment rates for CPT codes 19125 (APC 197), 19126 (APC 197), 43259 (APC 449), and 66172 (APC 652) that are lower than the rates we proposed in the January 26, 1995 Federal Register, which is at variance with commenters' recommendations. We welcome comments on the rebased rates that are proposed as payments for all of these codes, but request that arguments for changes in payment rates be supported by data regarding direct costs (supplies, equipment, labor, time) relative to other procedures in the same APC group that would justify a change in either the APC group assignment or the payment rate determined for the code.

III. Provisions of the Proposed Regulations

Many of the changes that we are proposing to make in 42 CFR part 416, Ambulatory Surgical Services, were stimulated by our commitment to assist in the President and Vice President's continuing drive to reinvent government and government regulations and to reform the Federal government's regulatory process. The reorganization of 42 CFR part 416 represents an effort to balance a reduction in regulatory requirements with adequate assurances that the ambulatory surgical services that we are purchasing for Medicare beneficiaries are of the highest quality and consistent with our commitment to work in partnership with the rest of the health care community to institute better, more common sense ways of operating that are in the best interests of Medicare beneficiaries. An outline of the reorganization that we propose to make to part 416 in this notice follows:

Current organization	Citation	Proposed organization	Citation
Subpart A—General Provisions and Definitions: Basis and Scope Definitions Subpart B—General Conditions and Require-	416.1 416.2	Subpart A—Definitions and General Provisions and Requirements: Basis and Scope Definitions	416.1 416.2
ments:			
Basic requirements Qualifying for an agreement	416.25 416.26	Basic requirements	416.3
Deemed Compliance	416.26(a)	Currently addressed in 42 CFR 488	42 CFR 488
Survey of ASCs	416.26(b)	Currently addressed in 42 CFR 488	42 CFR 488
Acceptance of the ASC	416.26(c)	Replaced by 416.3(h) and (i)	416.3(h), (i)
Filing of agreement	416.26(d)	Replaced by 416.3(h) and (i)	416.3(h), (i)
Acceptance; Appeal Rights	416.26(e)–(f)	Replaced by 416.3 (h) and (i)	416.3(h), (i)
Terms of agreement with HCFA	416.30(a)–(e)	Moves to Basic requirements	416.3
ASC operated by a hospital	416.30(f)	Moved to "Definitions" and "Basis for payment"	416.2 & 416.30
Additional provisions	416.30(g)	Deleted	N.A.
Termination of agreement	416.35	Termination of participation, including billing privileges.	416.4
Subpart C—Specific Conditions for Coverage:		Subpart D—Specific Conditions of Coverage:	
Compliance with State licensure law	416.40	Basic Requirements	416.3
Conditions for Coverage	416.41–416.49	Proposed Subpart D	416.41-416.49
Subpart D—Scope of Benefits:		Subpart B—Scope of Benefits:	
General rules	416.60	General rules	416.20
Scope of facility services	416.61	Scope of ASC Services	416.21
Covered surgical procedures	416.65	ASC List	416.22
Performance of listed surgical procedures on an inpatient hospital basis.	416.75	Performance of procedures on the ASC list in a hospital inpatient setting.	416.23
Subpart E—Payment for Facility Services:		Subpart C—Payment for Facility Services:	
Basis for payment	416.120	Basis for payment	416.30
ASC facility services payment rate	416.125	ASC payment rates	416.31
Publication of revised payment methodolo- gies.	416.130	Publication of revised payment rates	416.32
Surveys	416.140	Surveys	416.33
Beneficiary appeals	416.150	Beneficiary appeals	416.34

A. Basis and Scope (Proposed § 416.1)

Most of the changes in this section are of a technical nature. In $\S416.1(a)(1)$ we propose to revise the description of the ASC benefit to make it more consistent with section 1832(a)(2)(F)(i) of the Act. We further propose to add the statutory basis for the conditions for coverage of ASCs as new § 416.1(a)(2). And, we have deleted the reference to "a hospital outpatient department" in new paragraph § 416.1(a)(3) because the content of part 416 of the *Code of Federal Regulations* pertains exclusively to ASCs under the benefit provided in section 1832(a)(2)(F)(i) of the Act. The

current § 416.1(a)(3) would become new § 416.1(a)(4).

In §416.1(b), which defines the scope of the regulation, we propose to reorder paragraphs (1), (2), and (3) to parallel the reorganization of 42 CFR part 416. We are reorganizing the regulations to make them simpler, more understandable, less prescriptive, less process-oriented, and more focussed on patient-centered outcomes. Section 416.1(b)(1) applies to renamed subpart B, which describes the scope of the ASC benefit, including the scope of ASC services and the criteria that HCFA uses to determine those procedures for which Medicare pays an ASC facility fee. Section 416.1(b)(2) applies to new subpart C, which sets forth the manner in which Medicare determines and makes payments for ASC services. Section 416.1(b)(3) refers to new subpart D, to which we propose to move the conditions for coverage of a Medicare approved ASC. Revisions to the conditions for coverage that an ASC must meet in order to be certified for participation in Medicare are the subject of a separate notice of proposed rulemaking currently under development entitled "Conditions for **Coverage of Ambulatory Surgical** Centers" (HCFA-1887-P). In the reorganized part 416, there is no subpart F

B. Definitions (§ 416.2)

We propose to update and clarify the definition of several basic terms as they are used in 42 CFR part 416. Rather than being generic, these definitions are specific to Medicare approved ASCs and the implementation of the Medicare ASC benefit.

When section 934 of the Omnibus Reconciliation Act of 1980 added to the benefits available under Part B of Medicare facility services associated with certain surgical procedures provided in an ASC, the Act did not define an ASC other than to imply that it was a facility that is different from a hospital outpatient department, a physician's office, and a rural primary care hospital. Therefore, in order to implement the benefit, we must identify ASCs in order to be able to distinguish them from other types of facilities. Otherwise, we would not know if Medicare payments for ASC facility services under section 1832(a)(2)(F) were being made properly, in accordance with the statute and with Medicare rules and regulations.

The definition of an ASC that is currently found at § 416.2 became effective following publication on August 5, 1982 of the final rule (47 FR 34082) that implemented the ASC benefit initially. Since 1982, ASCs as a type of facility have evolved significantly. In 1982 there were approximately 40 ASCs in existence. By the end of 1997, the number of Medicare-approved ASCs exceeded 2400. We have found the 1982 definition of an ASC to be so broad and general that it is increasingly difficult for us to make a definitive determination whether a facility is an ASC for the purposes of Medicare approval. This is especially true in the health care delivery system of the late 1990s, which is in a state of dynamic and constant reformation. Therefore, we have revised the definition of an ASC in §416.2 to be more specific in distinguishing ASCs from other categories of facilities.

The first important criterion in distinguishing ASCs is to recognize that, for Medicare purposes, an ASC is a supplier of health care services. It is *not* a Medicare provider, as that term is defined by statute and regulation.

A second criterion critical to understanding how HCFA defines ASCs for purposes of entitlement to Medicare payment is that an ASC is an entity that is separate and must be distinguishable from any other entity or type of facility. We define "separate" as meaning totally separate with respect to licensure, accreditation, governance, professional supervision, administrative functions, clinical services, recordkeeping, financial and accounting systems, and national identifier or supplier number. The word "separate" does not necessarily refer to the actual physical space the ASC occupies. An ASC may be physically located within the space of another entity and still be considered separate for Medicare payment purposes within this definition.

If a facility that considers itself an "ASC" were to bill Medicare for services using a hospital's identification number, Medicare could not pay the facility under the benefit established in the Act at section 1832(a)(2)(F). Though a facility may be called an "ASC" and may be located in a separate building or at a site removed from a hospital's campus, Medicare does not consider the facility to be an ASC unless the facility has its own license and accreditation, governing board, system for professional supervision, clinical services, and administrative functions, and its own Medicare billing and identification number.

Similarly, Medicare cannot pay an ASC facility fee for procedures performed in a suite, treatment room, office or clinic unless the site has been approved by Medicare as an ASC in accordance with the regulations.

We recognize that this requirement that an ASC be a separate entity may be onerous to ASCs that are owned by a large health system seeking to share services or to consolidate with other member entities. The statutory requirement for setting ASC payment rates is at the heart of our requirement that an ASC be an entity or facility that is separate from any other entity or facility and that its administrative, fiscal, clinical, and patient care services be clearly distinguishable from those of any other entity or facility in every respect. In order for us to determine by survey what costs ASCs incur to furnish facility services in connection with performing a specific surgical procedure, we at HCFA and the ASC administrators must be able to distinguish costs and charges as they emanate strictly from the ASC. If costs incurred by the ASC are commingled with another entity's activities, it will be difficult for the ASC to isolate the portion of costs properly attributable only to the ASC, and therefore difficult for us to be assured that the data we are using to determine payment rates are truly reflective of ASC costs alone, and not the costs or services of another entity, such as other hospital outpatient services or the functioning of a clinic or physician's office.

We have added a definition of "hospital operated ASC" to § 416.2 both to clarify what we mean by "hospital operated ASC" and to distinguish a "hospital operated ASC" from a hospital outpatient department that furnishes surgical services.

In order to be considered a Medicare approved ASC, the entity's function and purpose must be to supply facility services, as opposed to physician or practitioner services, in connection with performing certain surgical procedures. We define such services as ASC services, and under the benefit established at section 1832(a)(2)(F) of the Act, Medicare pays a prospectively determined fee for ASC services. Section 416.21 of the revised regulation proposed in this notice lists the types of services that fall within the scope of ASC services. They include but are not limited to nursing and technician services, supplies, drugs and biologicals, surgical dressings, housekeeping services, and use of the facility. We emphasize that the professional services of physicians and other practitioners do not fall within the scope of ASC facility services, and the ASC facility fee does not include payment for the professional services of physicians and other practitioners.

Medicare pays an ASC facility fee only for procedures on the ASC list. HCFA determines which procedures will constitute the ASC list on the basis of certain criteria related to the safety, appropriateness, and effectiveness of performing the procedure in an ASC setting. The criteria that HCFA used as the standard for determining a procedure's suitability for the ASC list in this notice are proposed in §416.22. The procedures for which a Medicare participating ASC furnishes services and for which Medicare makes payment of an ASC facility fee are of a nature that does not require Medicare patients to be admitted to a hospital as inpatients either to have the procedure performed or to recover from the procedure. By "hospital," we mean an institution that meets the definition of "hospital" in section 1861(e) of the Act.

Within the framework of the definition of an ASC that we are proposing in §416.2, Medicare would not consider an entity devoted exclusively to furnishing services such as clinical laboratory services, chemotherapy, radiation treatment, cardiac catheterization, dialysis services, magnetic resonance imaging, or other diagnostic tests, to be an ASC because these are not services that are necessary to enable surgical procedures to be performed. However, an entity that meets the conditions for coverage as an ASC could also be recognized and paid by Medicare as a non-physician supplier of radiology services, as an independent diagnostic testing facility (IDTF), or as a supplier of durable medical equipment, prosthetics, and orthotics as long as it supplied these services in accordance with the statute and Medicare payment rules and regulations.

C. Basic Requirements (Proposed § 416.3 and § 416.4)

We propose to renumber § 416.25 as § 416.3. Paragraph (a) does not change. We have moved current § 416.40 to become new paragraph (b) in § 416.3, to reinforce the fundamental importance of State licensure as a basic requirement for an ASC wanting to qualify for participation and billing privileges in the Medicare program.

We have also moved §§ 416.30(a) through 416.30(e) to proposed § 416.3, Basic Requirements. By incorporating these provisions directly into the regulations at § 416.3, we emphasize their significance as binding requirements with which ASCs wishing to participate and have billing privileges in the Medicare program must agree to comply.

Section 416.3(h) replaces current § 416.26(a) and § 416.26(b) by crossreferencing part 488, "Survey, Certification, and Enforcement Procedures" and establishes compliance with the regulations in that part that pertain to suppliers generally and to ASCs in particular as a basic requirement for ASCs to participate in Medicare. In order to make this link, we propose to add ASCs to the definition of "supplier" found in § 488.1.

Proposed § 416.3(i) replaces § 416.25(b). An ASC can satisfy the requirement that it have an agreement to abide by the Medicare laws and regulations by possessing a Form HCFA–855, "Medicare Health Care Provider/Supplier Enrollment Application" that has been validated by HCFA.

We are proposing one technical change in § 416.3(g). This change requires ASCs to accept the Medicareapproved amount as full payment for all items and services covered under Part B of Medicare that it furnishes to Medicare beneficiaries. ASCs must agree to accept assignment for all facility services furnished in connection with procedures on the ASC list. We are proposing to extend the ASC's assignment acceptance to include all items and services that the ASC supplies to a beneficiary, whether those items and services are considered ASC facility services as listed in §416.21(a) or are items and services for which payment may be made under other provisions of Medicare, Part B, such as those listed in §416.21(b).

Proposed §416.4 basically restates the provisions of § 416.35 yet revises the language to reflect our proposed substitution of the "Medicare Health Care Provider/Supplier Enrollment Application" (Form HCFA 855) for the "Health Insurance Benefits Agreement— (Agreement with Ambulatory Surgical Center Pursuant to Section 1832(a)(2)(F) of the Social Security Act)" (Form HCFA 370). Since May 1996, HCFA has required all ASCs with an interest in participating and obtaining billing privileges in Medicare to complete Form HCFA 855. The certification statement that is a part of the Form HCFA 855 includes a provision that the applicant is familiar with and agrees to abide by the Medicare laws and regulations that apply to its provider/supplier type. In 42 CFR part 416, we have expanded the list of basic requirements for ASCs to include all of the provisions that are currently listed in the Form HCFA 370. We have also added to §416.3 the provision that an ASC, in order to participate and to have billing privileges in Medicare, must have in effect a Form HCFA 855 that has been validated by HCFA. Given these changes, we propose to discontinue use of Form HCFA-370 for ASCs seeking to participate and to

obtain billing privileges in Medicare beginning on the effective date of the final rule that implements the proposals contained in this notice. For ASCs whose agreement with HCFA consists of a Form HCFA 370 that has been duly executed in accordance with the provisions currently found in §§ 416.26 and 416.30, the Form HCFA 370 and the ASC's agreement with HCFA remain in effect until such time as the ASC completes a Form HCFA-855 that is validated by HCFA. We invite comments on our proposal to retire the Form HCFA 370 and replace it with a validated Form HCFA 855.

Revisions to the ASC conditions for coverage are the subject of a separate notice entitled "Conditions for Coverage of Ambulatory Surgical Centers" (HCFA–1887–P) that is currently being developed. Pending publication of that notice of proposed rulemaking, we propose to move the conditions for coverage found currently in sections § 416.41 through § 416.49 to subpart D, which we propose to rename "Specific Conditions for Coverage."

D. Additions to/Deletions From the ASC List

Section 934 of the Omnibus Reconciliation Act of 1980 amended sections 1832(a)(2) and 1833 of the Act to authorize the Secretary to specify, in consultation with appropriate medical organizations, surgical procedures that, although appropriately performed in an inpatient hospital setting, can also be performed safely on an ambulatory basis in an ASC, a hospital outpatient department, or a rural primary care hospital. The report accompanying the legislation explained that the Congress intended procedures currently performed on an ambulatory basis in a physician's office, which do not generally require the more elaborate facilities of an ASC, not be included in the list of covered procedures (H.R. Rep. No. 1167, 96th Cong. 2d Sess. 390, reprinted in the 1980 U.S.C.C.A.N 5526, 5753). In a final rule published August 5, 1982 in the Federal Register (47 FR 34082), we established regulations which included criteria for specifying which surgical procedures were to be included for purposes of implementing the ASC facility benefit. These criteria are found at 42 CFR 416.65, and include both general and specific standards. The general standards in §416.65(a) define ASC procedures as-

• Commonly performed on an inpatient basis but may be safely performed in an ASC;

• Not of a type that are commonly performed or that may be safely performed in physicians' offices;

• Requiring a dedicated operating room or suite and generally requiring a post-operative recovery room or shortterm (not overnight) convalescent room; and,

• Not otherwise excluded from Medicare coverage.

The specific standards in §416.65(b) limit ASC procedures to those that do not generally exceed 90 minutes operating time, a total of 4 hours recovery or convalescent time, and, if anesthesia is required, the anesthesia must be local or regional anesthesia or general anesthesia of not more than 90 minutes duration. Section 416.65(c) excludes from the ASC list procedures that generally result in extensive blood loss, that require major or prolonged invasion of body cavities, that directly involve major blood vessels, or that are generally emergency or life-threatening in nature.

In April 1987, we adopted numerical criteria as a tool for identifying procedures that were commonly performed either in a hospital inpatient setting or in a physician's office. Collectively, commenters responding to a notice published in the Federal Register on February 16, 1984 (49 FR 6023) had recommended that virtually every surgical CPT code be included on the ASC list. Consulting with other specialist physicians and medical organizations as appropriate, our medical staff reviewed the recommended additions to the list to determine which code or series of codes were appropriately performed on an ambulatory basis within the framework of the regulatory criteria in §416.65. However, when we arrayed the proposed procedures by the site where they were most frequently performed according to our claims payment data files (1984 Part B Medicare Data (BMAD)), we found that many codes were not commonly performed on an inpatient basis or were performed in a physician's office a majority of the time, contrary to our regulations. Therefore, we decided that if a procedure was performed on an inpatient basis 20 percent of the time or less, or in a physician's office 50 percent of the time or more, it should be excluded from the ASC list. (See Federal Register of April 21, 1987, (52 FR 13176).) At the time, we believed that these utilization thresholds best reflected the legislative objectives of moving procedures from the more expensive hospital inpatient setting to the less expensive ASC setting without encouraging the migration of procedures from the less expensive physician's office setting to the ASC. We applied these place of service tests not only to codes proposed for addition to

the ASC list, but also to the codes that were currently on the list, to delete codes that did not meet the 20/50 site of service thresholds.

The trend towards performing surgery on an ambulatory or outpatient basis grew steadily, and by 1995, we discovered that a number of procedures that were on the ASC list at the time fell short of the 20/50 threshold even though the procedures were obviously appropriate to the ASC setting. The most notable of these was cataract extraction with intraocular lens insertion, very few cases of which were being performed on an inpatient basis by the early 1990's. We were also excluding from the ASC list certain newer procedures, such as CPT code 66825, Repositioning of intraocular lens prosthesis, requiring an incision (separate procedure), that from their inception were almost never performed on a hospital inpatient basis but that were certainly appropriate for the ASC setting. And, strict adherence to the same 20/50 thresholds both to add and remove procedures did not provide latitude for minor fluctuations in utilization settings or errors that could occur in the site-of-service data drawn from the National Claims History File that we were using, replacing BMAD data, for analysis. In an effort to avoid these anomalies but still retain a relatively objective standard for determining which procedures should comprise the ASC list, we adopted in the last revision of the list, which was published in the Federal Register on January 26, 1995 (60 FR 5185), a modified standard for deleting procedures already on the ASC list. We deleted from the list only those procedures whose combined inpatient, hospital outpatient, and ASC site-ofservice volume was less than 46 percent of the procedure's total volume, and that were performed 50 percent of the time or more in a physician's office or 10 percent of the time or less in an inpatient hospital setting. We retained the 20/50 standard to determine which procedures should be added to the ASC list.

The applicability and appropriateness of the standards HCFA uses to specify procedures that constitute the ASC list were the subject of lengthy discussion at the July 1996 ASC Town Meeting. The comments of those attending the Town Meeting, as well as written comments received following the meeting, repeatedly characterized the 20/50 numerical thresholds as simplistic, arbitrary, artificial, and outdated and urged us to "modernize" the standards by which we select procedures for the ASC list. Similarly, most commenters

characterized the 90 minute limit on surgery and the four hour limit on recovery as obsolete, outdated, arbitrary and without medical significance and blind to the numerous technical advances in surgery and the development of short-acting anesthesia which have radically altered surgical practices since the early 1980's when those criteria were established. Commenters urged us to supplement or preferably replace quantitative thresholds with qualitative considerations that recognize the capabilities of modern ASCs. Some commenters took the position that the list be abandoned altogether; others recommended leaving the choice of where a surgical procedure is to be performed to those best able to determine which setting is most appropriate, namely, the physician, in consultation with the patient, and the anesthesiologist. Commenters argued that eliminating the list would allow Medicare beneficiaries who are medically unstable and for whom an office would not be a safe setting for even very simple surgery to have access to an ASC as an alternative to the hospital. Conversely, an ASC could be an appropriate alternative to the hospital for more complex procedures for beneficiaries who are healthy. At least one commenter suggested that the ASC list include any procedure which we would recognize as appropriate in a hospital outpatient setting.

The statute prevents us from eliminating the ASC list. However, in response to discussions at the Town Meeting, written comments submitted after the Town Meeting, and the growing consensus expressed by the ASC community in comments we received following publication in the **Federal Register** of proposed notices on December 7, 1990 (55 FR 50590) and December 14, 1993 (58 FR 65367), we propose to modify our approach to selecting the procedures for which Medicare pays an ASC facility fee.

1. Revision of 42 CFR 416.65

The intent of the revision to § 416.65 is to render the regulation less prescriptive in defining the kinds of procedures that are appropriate for the ASC list while allowing it to still remain within the constraints imposed by the statute. The changes to 42 CFR 416.65 that we are proposing are based on certain basic premises. First, we continue to focus on procedures that fall within the surgical range (10000 through 69999) of the HCFA Common Procedure Coding System (HCPCS) or the American Medical Association (AMA) Physicians' Current Procedural Terminology (CPT). (The AMA's CPT terminology and coding is included, with permission, in the HCPCS system. For surgical procedures, the codes are the same.) Second, we limit ASC procedures to those surgical procedures that require the kind of supplies, equipment, physical environment, staffing, and health and safety protocols that are typical of a hospital setting and required of an ASC, including a dedicated operating room or suite or procedure room that is equipped, staffed, and maintained solely for the performance of surgical procedures, and a designated recovery room or area that is equipped, staffed, and maintained solely for the use of post-operative patients. However, while necessitating the resources and set-up typical of a hospital surgical department, ASC procedures must not be those for which patients are expected to be admitted to the hospital on an inpatient basis due to the severity or risks inherent in the procedure or to the need for inpatient post-operative care before the patient can be safely discharged to recuperate at home. Finally, the ASC list must not include procedures that are excluded from Medicare coverage by statute.

We propose to remove the references to "commonly performed" found in §416.65(a) and the time limits on operating, anesthesia, and recovery time that are currently spelled out in § 416.65(b)(1) and (2). With the ambulatory payment classification (APC) system, we can rely on clinical homogeneity at least as much as site of service patterns in determining which procedures are appropriate for the ASC list. Precisely because the APC groups are clinically coherent, as a general rule we did not split up APC groups by including some procedures from an APC group on the ASC list while excluding from the list other procedures in the same APC group. We either regarded all of the procedures in an APC as appropriate for the ASC list or none of the procedures in an APC as appropriate for the ASC list.

We propose to retain the specific standards found at § 416.65(b)(3), and we shall continue to exclude from the ASC list procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, or are generally emergent or lifethreatening in nature. Because of the risks inherent in procedures that involve these characteristics, any of which suggests that the well-being of the patient could be in jeopardy, we are excluding such procedures from the ASC list because performing them in an ambulatory setting violates the statutory

safety standard of the Act (1833(i)(1)(A)). One of our reasons for revising 42 CFR Part 416 is to highlight that procedures with any of the characteristics listed in proposed § 416.22(b) are, by their nature, unsafe and inappropriate in an ASC setting and are therefore not reasonable and not medically necessary when performed in an ASC setting. Procedures with these characteristics are excluded from the ASC list and payment of a Medicare ASC facility fee for services furnished in connection with such procedures is not allowed.

Conversely, we discuss below in greater detail, procedures that do not satisfy the criteria in proposed §§ 416.22(a)(1), 416.22(a)(2), or 416.22(a)(3) are excluded from the ASC list because such procedures do *not* require the generally more elaborate and costly services and resources that characterize Medicare approved ASCs.

We solicit comments on the reasonableness and validity of the criteria that we are proposing as the basis for excluding procedures from the ASC list. We solicit comments on the reasonableness and validity of the changes to § 416.65 of the regulations, which we propose to incorporate in proposed § 416.22. We also solicit comments regarding the appropriateness of all the codes on the ASC list in Addendum B. Specifically, we welcome comments regarding any procedure in Addendum B that should be excluded from the ASC list because it is not safe outside a hospital inpatient setting or any procedure in Addendum B that can be safely and effectively performed in an office setting without the more elaborate services typical of an ASC. Comments should be framed within the context of the revised criteria proposed in proposed §416.22.

2. Eliminate Numeric Thresholds

Although the 20/50 numeric thresholds for adding procedures to the ASC list and the 46/10/50 threshold for keeping procedures on the list were not a part of the regulations, they have been the basis of our policy for determining whether a procedure belonged on the ASC list. However, beginning with this notice, we propose to discontinue using site-of-service as the principal determinant of which procedures to add to or delete from the ASC list. Instead, we regard site-of-service data as but one of several factors, such as the criteria proposed in proposed § 416.22, to be taken into account in determining whether or not a procedure should be on the ASC list.

By adhering to the principle of keeping APC groups intact, we included

on the ASC list or excluded from the list all of the procedures in a clinically homogeneous APC, notwithstanding anomalous site of service data for individual procedures within the groups.

3. Formation of Advisory Group

A number of commenters, both during and subsequent to the ASC Town Meeting, urged the creation of an advisory committee or council to work with HCFA on keeping the ASC list upto-date. One commenter suggested adding a review of the ASC list to the annual CPT/Relative Value Update Committee (RUC) process. We are deferring a decision on the creation of an advisory committee pending implementation of the provisions that are proposed in this notice and until we can investigate further the possibility of utilizing an existing group, such as the **RUC** or the Medicare Carriers Medical Directors Workgroup, whose members might give us timely advice regarding procedures that are appropriate in an ASC setting. In the meantime, we propose to continue relying on consultations with professional and medical societies and trade associations; on correspondence and comments from these groups, from individual members of the ASC community, and from the public generally; as well as on the judgement of our medical advisors to determine the appropriateness of procedures for the ASC list both within the context of the criteria we have proposed in renumbered §416.22 and the composition of APC groups.

4. Proposed Additions to the ASC List

We propose to add 422 CPT codes to the ASC list, consistent with the standards we propose in the new § 416.22. In applying the principles proposed in §416.22 for the purpose of specifying additions to the ASC list, we recognized that an ASC might be appropriate for some procedures shifting from an inpatient to an outpatient setting for the patient who is generally healthy and is capable, but that an ASC would be a questionable setting for those procedures among the greater Medicare population whose health is more likely to be compromised by age or disability. Overall, based on the advice of our medical advisors and on the written comments we have received from ASC administrators, physicians, professional societies, and trade associations since the January 26, 1995 update of ASC procedures, we have determined that the procedure codes we are proposing to add to the ASC list could be safely performed in an ASC on the general Medicare

population in at least a significant number of cases.

One commenter expressed apprehension that expanding the ASC list could result in edicts from HCFA or other purchasers of health care that once added to the ASC list, a procedure *must* be performed in an ASC, without taking into account the individual patient's condition or the suitability of an ASC for a particular procedure. We recognize that for individuals with certain medical conditions, no procedure on the ASC list may be safely performed except on an inpatient basis. Therefore, we emphasize that the choice of operating site remains ultimately a matter for the professional judgement of the patient's physician, in consultation with the patient and, often, the anesthesiologist, irrespective of whether a procedure is on the ASC list. Section 416.23 in the proposed regulations reinforces this point.

All of the proposed additions to the ASC list are designated in Addendum A, along with the ambulatory payment classification (APC) group proposed for each. We invite and encourage comments on the appropriateness of these additions to the ASC list in light of the criteria in § 416.22.

a. Additions Suggested by Commenters

Of the 422 additions to the ASC list that we are proposing, the following 52 codes were specifically suggested by the ASC community in correspondence and comments that we have received since the publication of the last **Federal Register** update of the list on January 26, 1995 (60 FR 5185). We invite comments on the appropriateness for the ASC list of the procedures identified by these CPT codes:

15822	43244	56353	67110
15823	43249	56355	67145
15824	43761	57288	67208
15825	45330	62287	67210
15826	49568	62298	67228
26608	50080	63244	67900
29848	50081	65436	68810
33222	51715	65855	68811
35875	52601	66761	68815
36862	52647	66762	68830
37731	52648	66825	
40720	55859	67028	
42415	57288	67101	
43205	62287	67105	

b. Proposed Additions Resulting From Changes to CPT

The CPT is updated annually, and occasionally new codes added to CPT affect the ASC list. The following procedures were added to the ASC list because they were added to the CPT, usually to replace a deleted code. We are requesting comments on the appropriateness of adding to the ASC list the codes new to CPT in 1995 that are indicated below, which we were unable to include in the **Federal Register** notice published on January 26, 1995 (60 FR 5185). We are also requesting comments on the appropriateness of adding to the ASC list codes new to CPT in 1996, 1997, and 1998, which are indicated below. New CPT codes added effective January

- *1, 1995:* 31254; 31255; 31256; 31267; 31276; 57522
- New CPT codes added effective January 1, 1996: 19290; 19291; 22103; 22328; 43249; 56301; 56302; 56343; 56344; 62350; 62351; 62360; 62361; 62362; 62365: 62367; 62368
- New CPT codes effective January 1, 1997: 15756; 15757; 15758; 26551; 26553: 26554: 68810: 68811: 68815
- *New 1998 CPT codes:* We are proposing to add to the ASC list the following HCPCS codes that were new in 1998: 29860; 29861; 29863; 29891; 29892; 29893; 52282; 53850; 53852; 56318; 56318; 56346; 59871; 67027; G0104; G0105

c. Proposed Additions Resulting From Ambulatory Payment Classification (APC) Groupings

We have determined that the remaining codes that we are proposing to add to the ASC list are consistent with the criteria in § 416.22, and we believe that they would be safe, appropriate, and effective if performed in an ASC setting.

5. Proposed Deletions and Exclusions From the ASC List

a. Procedures Excluded for Reasons of Safety, Reasonableness and Medical Necessity

There are a total of 2,361 CPT codes in the surgical range that are not on the revised ASC list proposed in this notice. Of these 2,361 procedures, 203 are codes that we are proposing to delete from the current ASC list because they are not safe or otherwise reasonable and necessary in an ASC setting. The proposed deletions are flagged in Addendum A.

b. Unlisted Procedures

In most surgical categories, CPT includes codes for unlisted procedures. Because codes for "unlisted" procedures, by definition, contradict the statutory mandate for an ASC list, and because there is no way of knowing in advance whether a procedure for which there is no appropriate description in CPT is consistent with our standards for the ASC list, we are continuing our policy of excluding those codes from the ASC list.

c. Exclusion of Office-Based Procedures

Some comments made during and after the ASC Town Meeting supported expansion of the ASC list to allow Medicare payment of an ASC facility fee for procedures that are ordinarily performed in an office setting but that require the more extensive resources typical of an ASC to accommodate the special health needs of a patient. We considered the effect of expanding the ASC list to include procedures that are ordinarily performed safely and appropriately in a physician's office or a physician's clinic or treatment room. Our 1994 ASC survey did not capture charge information on office-based procedures, but we had the benefit of hospital outpatient claims data and practice expense data compiled for the Medicare physician fee schedule (see the proposed rule in the Federal **Register** published June 18, 1997, 62 FR 33158, entitled "Revisions to Payment Policies Under the Physician Fee Schedule, Other Part B Payment Policies and Establishment of the Clinical Psychologist Fee Schedule for Calendar Year 1998"). We theorized that we would not encourage office-based procedures to migrate to the ASC setting by paying the ASC instead of the physician the amount allowed for inoffice practice expenses in connection with an office-based procedure on the few occasions when a patient needed a more intensive level of support because of individual health considerations. Relating payment to the costs intrinsic to performing the procedure would also move closer towards achieving a level playing field where payments are based on the service, rather than on the site where the service is furnished.

In the final analysis, we have decided that we would not, at this time, propose to add to the ASC list 340 HCPCS codes that describe procedures that can be performed safely and effectively in a physician's office, clinic or treatment room and for which the more elaborate facility services of an ASC are not required. Further, we propose to remove 63 codes that are currently on the ASC list which, we have determined, fail to meet the criteria in §416.22(a), i.e. these procedures do not require surgical facilities, they are not services of the kind that are typically provided in a hospital inpatient setting, or do they do not require a dedicated operating room or room for post-operative recovery. Including procedures that are officebased on the ASC list might be construed as running counter to Congressional intent expressed in the conference report cited above. Also, paying ASC facility fees of \$5 or \$10

appeared administratively frivolous. Finally, office-based procedures are readily identifiable precisely because they do not satisfy the ASC-appropriate standards that we are proposing in § 416.22. Therefore, we are continuing, at this time, our policy of not including office-based procedures on the ASC list. However, we do not rule out the possibility of a future change of policy on this point after we have had an opportunity to evaluate the impact of incorporating resource-based practice expense relative value units (PE RVUs) into the Medicare Physician Fee Schedule and of implementing a prospective payment system for hospital outpatient surgical services, each of which is scheduled to occur in 1999.

We have given an ASC payment policy indicator "5" to the 403 CPT codes that we consider to be officebased procedures to indicate that no payment for expenses incurred to perform these office-based procedures is allowed other than the Medicare payment to the physician performing the procedure. An ASC payment policy indicator "5" precludes additional payment if these procedures are performed in an ASC. Refer to section III.E. of this notice for a more detailed discussion of the ASC payment policy indicators.

d. Suggested Additions Not Accepted

The following procedures have been suggested by the ASC community for addition to the list since publication of the last **Federal Register** update of the list on January 26, 1995 (60 FR 5185), but we propose to exclude them from the ASC list for the reasons given.

19240—Mastectomy, modified radical. (This procedure can result in extensive blood loss; admission to a hospital on an inpatient basis to recover from the procedure is appropriate.)

21356 & 21366—Repair heel bone fracture; 31225- Removal of upper jaw; 33212 & 33213-Insertion or replacement of pacemaker pulse generators; 37201- Transcatheter therapy, infusion for thrombolysis; 41130— Partial removal of tongue; 41153—Tongue, mouth, neck surgery; 51840 & 51841—Anterior vesicourethropexies; 51845--Abdominovaginal vesical neck suspension; 54430—Revision of penis; 56308— Laparoscopy, surgical and vaginal hysterectomy; 63030-Laminotomy (hemilaminectomy), with decompression of nerve root(s). (These procedures require admission to a hospital on an inpatient basis in order to have the procedure performed or in order to recover from the procedure.)

33216, 33217, & 33218-Insertion/ replacement of electrodes and repair of pacemaker electrodes; 35475 & 35476-Transluminal balloon angioplasties; 56340, 56341 & 56342-Laparoscopy, surgical cholecystectomies. (These procedures directly involve major blood vessels, and with respect to the Medicare population in particular, the latter procedures would necessitate admission to a hospital on an inpatient basis to perform or to recover from the procedure.) One professional society takes the position that laparoscopic cholecystectomy should only be performed in a setting that is equipped and prepared to switch intra-operatively to an open procedure in the event problems arise during the laparoscopic procedures.

e. Procedures Deleted Because of CPT Coding Changes

The CPT is updated annually, and occasionally, the deletions affect the ASC list. The following is a list of procedures that were deleted from the ASC list because they were deleted from the CPT.

Deleted effective April 1, 1995: 25005; 25317; 25318; 26527; 31245; 31246; 31247; 31248; 31249; 31251; 31261; 31262; 31264; 31266; 31269; 31271; 31280; 31281; 31282; 31283; 31284; 31286; 31659; 36840; 36845; 45180; 52650

Deleted effective March 31, 1996: 28236; 63750; 63780; 67109

Deleted effective April 1, 1997: 15755; 20960; 20971; 25330; 25331; 26522; 26557; 26558; 26559; 42880; 56360; 56361; 68825

None of the procedures deleted from CPT 1998 were on the ASC list.

f. Procedures Recommended by Commenter for Deletion

One correspondent suggested that we remove several codes from the ASC list because they describe procedures that may not be safely and effectively performed in the ASC setting. Our medical staff concurs with the opinion of the correspondent, and the following codes are among those we are proposing to exclude from the ASC list: 15756; 15757; 15758.

6. Comments on the ASC List

We propose to add 422 procedures to the ASC list and to delete 203 procedures from the ASC list, consistent with the standards discussed previously in this notice. The net effect of these changes would expand the ASC list from 2280 CPT codes to 2499 CPT codes. We solicit comments on whether we have made appropriate determinations regarding the following:

• Procedures that are excluded from the ASC list because they involve one or more of the criteria in proposed § 416.22(b) and are not, as a consequence, safely performed in an ASC. (These procedures are listed in Addendum A with an ASC payment policy indicator of "3.");

• Procedures that are not on the ASC list because they do not satisfy one or more of the criteria in proposed § 416.22(a). (These procedures are listed in Addendum A with an ASC payment policy indicator of "5.");

• Procedures that are prepared as the ASC list for which Medicare should not be paying an ASC facility fee because the procedures are not consistent with the criteria in § 416.22. (The proposed ASC list is presented as Addendum B.)

We also solicit comments on 203 codes that we are proposing to delete from the current ASC list and the 422 codes that we are proposing to add to the ASC list. (See Addendum A.) We ask that all comments regarding the appropriateness of procedures for the ASC list be framed within the context of the revised criteria proposed in renumbered § 416.22.

E. Ratesetting Methodology

1. Current method

There are currently eight payment levels under the Medicare ASC benefit. Based on its cost, each of the 2280 CPT codes on the ASC list is paid one of eight prospectively determined payment rates. Collectively, all of the codes that are paid a particular rate constitute a payment group. (A ninth payment rate for extracorporeal shock wave lithotripsy (ESWL) was established in a notice published December 31, 1991 in the Federal Register (56 FR 67666). Medicare stopped paying for ESWL as an ASC service beginning in March 1992 under the provisions of a court stay, which is discussed in section III.H. of this notice.) The method by which the current eight ASC payment levels or rates were calculated is explained in the Federal Register that was published on February 8, 1990 (55 FR 4526). The steps involved in the 1990 ratesetting methodology which based rates on ASC facility overhead expenses and procedure-specific charges reported in the 1986 ASC Survey are summarized as follows:

• Adjust reported costs and charges on the basis of audit findings, eliminate incorrectly reported survey data, and adjust costs that exceed allowable limits; • Inflate per procedure charges across all facilities using the consumer price index for all urban consumers (CPI–U);

• Using the hospital prospective payment system wage index, neutralize the effect of regional wage differences across all facilities by deflating that portion of per-procedure charges attributable on average to labor costs (34.45 percent);

• Identify the median charge for each procedure (CPT code) across all facilities, weighting individual procedure charges in each facility by the total number of times the procedure was performed multiplied by the facility's ratio of Medicare patients to total number of patients;

• Calculate the median Medicare cost-to-charge ratio for audited facilities and adjust the weighted median charge for each procedure (CPT code) by the cost-to-charge ratio (0.776) to calculate a cost value;

• Form groups at \$75 intervals and set the payment rate for each group at the weighted median cost of the procedures in the group;

• Incorporate as part of the ASC facility fee for intraocular lens (IOL) insertion procedures an allowance for the lens. (Section 13533 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) (Public Law 103–66), enacted on August 10, 1993, requires that the payment for an IOL furnished by an ASC be equal to \$150 for the period beginning January 1, 1994 through December 31, 1998).

Both the current and proposed ASC ratesetting methodology consist of four major components: (I) Determine a perprocedure cost for every reported CPT code at the individual facility level; (II) Determine a per-procedure cost for every reported CPT code across all facilities; (III) Group procedures, and (IV) Determine a standard payment rate that is generally a fair fee for all the procedures within each group. The standard payment rate arrived at in the final step becomes the Medicare ASC facility fee or payment rate.

In developing the payment rates proposed in this notice, we have retained the same basic methodology that is explained in the final notice published in the Federal Register on February 8, 1990 (52 FR 4526) and outlined above. We have introduced a few refinements that we believe enable us to measure more precisely the costs incurred by ASCs individually and collectively to perform procedures on the ASC list. The most notable modification of the current ratesetting methodology that we are proposing affects the third component of the ratesetting process: We propose to adopt a different approach to grouping procedures, using an ambulatory payment classification system (APCS), instead of creating groups based on \$75 cost increments. The following steps explain how we arrived at the ASC payment rates that are proposed in this notice.

2. Proposed Ratesetting Method

Determine a per-procedure cost for every reported CPT code at the individual facility level:

a. Use 1994 Survey Data

Data on facility overhead expenses and procedure specific charges that were collected in 1994 via the Medicare Ambulatory Surgical Center Payment Rate Survey are the basis for the payment rates proposed in this notice. Part I of the survey instrument, "General Information and Charge Schedules' (Form HCFA-452A), was mailed in July 1992 to all ASCs that were Medicare participating at that time (1,396) for the purpose of gathering demographic data to serve as the frame for selecting a representative sample of ASCs that would be asked to complete a more comprehensive cost survey in 1994. One thousand one hundred forty-three ASCs completed and returned Part I of the ASC survey. In establishing the sample of facilities to complete Part II of the ASC survey, we excluded facilities that had been in operation for less than two years, facilities that performed fewer than 250 procedures during the 12month survey period, and facilities whose most recently completed fiscal year exceeded or was less than 12 months. The remaining 832 ASCs were stratified into four categories based on reported procedure volume: high, medium, and low procedure volume, and eye specialty facilities. Eye specialty facilities were defined as any facility where procedures in the CPT range between 65000 and 68900 (Eve and Ocular Adnexa) comprised 50 percent or more of total surgical volume. We used these strata because we found them most likely to result in a sample of facilities that would be representative of the universe of Medicare participating ASCs that completed Part I of the survey in terms of type and volume of procedures typically performed and costs incurred to furnish facility services in connection with those procedures.

Available resources for data entry required us to limit the size of the sample to approximately 300 facilities. In accordance with generally recognized statistical conventions, 320 facilities were randomly selected. In March 1994, we mailed the Medicare Ambulatory Surgical Center Payment Rate Survey, Part II—Facility Overhead and Procedure Specific Costs (Form HCFA– 452B) to the survey sample. Facilities were initially required to complete Form HCFA–452B by May 31, 1994, but because a large number of facilities experienced difficulties in meeting the deadline, we complied with most requests to extend the due date.

Part II of the survey gathered information from each ASC's most recently completed 12-month fiscal year. Most facilities reported calendar year 1993 data, with a few facilities reporting data from other fiscal years. The survey yielded a data set of procedure-specific information for 1516 of the nearly 2250 CPT codes that were on the ASC list as of December 31, 1993, including the number of times each procedure was performed on Medicare and on non-Medicare patients and the charge billed on average to all patients, both Medicare and non-Medicare, for each surgical CPT code. The survey also collected data on operating room time for high volume procedures on the ASC list and aggregate utilization and charges for procedures performed that were not on the ASC list. In addition, the survey elicited facility overhead costs for plant and property, equipment, supplies, contractual labor, employee labor, owner's compensation, bad debt, and general administrative costs. We asked ASCs to report the costs they incurred to procure intraocular lenses and to purchase "non-routine" supplies, e.g., any supply whose net unit cost exceeded \$100. Information regarding any relationship between the ASC and other organizations or entities and the ASC's financial statement for the fiscal period reported in the survey were also solicited. Part II of the ASC survey included a section intended to capture procedure specific statistical and resource cost data for 29 CPT codes, including time allocations, staffing patterns and labor costs, supply costs, and medical equipment costs.

b. Audit Representative Sample of Facilities

In accordance with the statutory requirement at section 1833(i)(2)(A)(i) that we set rates in such a way as to take into account actual audited facility costs, and in order to validate the accuracy and reasonableness of survey responses, we conducted a nationwide audit of a sample of the ASCs that completed Part II of the survey. One hundred ASCs, 25 from each sampling stratum (high utilization, medium utilization, low utilization, and eye specialty), were randomly selected for audit in accordance with standard statistical sampling procedures. The nationwide audit was conducted from November 1994 through January 1995 by Medicare fiscal intermediaries. Although ASC claims are processed by Medicare carriers, we believe intermediaries' familiarity and experience with Medicare audits better equipped them to carry out this task. In addition, the Office of Inspector General (OIG) conducted an audit of the home offices of the two principal ASC chain organizations with facilities included in the sample. We instructed the auditors to determine reasonable facility costs in accordance with Medicare payment principles.

Of the 320 facilities randomly selected to complete Part II of the Medicare ASC survey, 16 were exempted from completing the survey because of termination of Medicare participation or change in ownership prior to receipt of the survey form; inability to identify and properly allocate facility operating costs as a separate and distinct entity; or, incomplete records due to facility damage. In addition, we excluded nine other surveys from consideration in setting the rates proposed in this notice for the following various reasons: The audits revealed four facilities to have incorrectly reported their charge and utilization information; one form could not be accounted for and the facility did not have a copy to resubmit; two

facilities reported data for less than a 12 month period; and, two facilities were unable to capture charge data from their record keeping systems in the manner requested.

c. Adjust Audited Surveys

We accepted the auditors' findings, which resulted in net adjustments that reduced reported aggregate costs by 9 percent and increased reported aggregate charges by 3 percent. The major cost reductions occurred in the areas of general administrative expenses and bad debts. We then made two additional adjustments to audited adjusted wage and administrative cost data, as follows.

After an analysis of audited contractual labor expenses, employee salaries and fringe benefits, and owner's compensation, we set a maximum compensation limit for each staffing category to eliminate unreasonable, and therefore unallowable, labor expenses from our determination of facility costs. (Because payment for the professional services of physicians and certified registered nurse anesthetists is made under other provisions of Medicare, Part B, the cost of these services is excluded from determining ASC facility costs.)

• We calculated the hourly wages for administrative and medical staff, taking into account fringe benefits and paid leave, using audited 1994 survey data. In calculating hourly pay rates for each staff category, we excluded data reported as owner's compensation because the reported hourly rates of owner's compensation were excessively high relative to the hourly pay for nonowners in the same positions.

• We selected the 75th percentile as the maximum allowable hourly wage rate in each staffing category. We considered using higher levels (80th or 90th percentile) as a cap, but we found the wage rates above the 75th percentile to be too erratic. We found the wage rates at the 75th percentile to be consistent and reasonable across all staff categories.

• We adjusted audited hourly wage rates that exceeded the 75th percentile of each staffing category to the maximum allowable hourly wage rate and recalculated labor costs by multiplying the adjusted hourly wage rate by the number of reported paid hours.

We believe that this approach is an improvement over the current methodology because it adjusts unreasonable labor costs for all categories of staffing, not just administrator and medical director pay; it takes actual compensated hours into account rather than using full-time equivalents (FTEs); and, we base the maximum allowable factor on the 75th percentile of labor costs rather than on an average. Table 1 shows the limits applied to ASC labor expenses.

TABLE 1.—HOURLY WAGE CAPS AT 75TH PERCENTILE

Staff category	Number of observa- tions	Median hourly wage	Approx. an- nual salary	75th per- centile hour- ly wage	Approx. an- nual salary
Administrator	66	35.39	\$73,611	45.23	\$94,078
Director/Manager	87	24.13	50,190	31.53	65,582
Supervisors	52	21.41	44,533	26.07	54,226
Clerical	116	11.33	23,566	13.24	27,539
Nurse	117	19.53	40,622	23.60	49,088
Medical Technician	92	13.31	27,685	16.60	34,528
Other Medical	49	10.99	22,859	15.61	32,469
Other Non-medical	83	11.94	24,865	15.65	32,552

In addition to making adjustments to unreasonable labor costs, we excluded from our calculation of facility costs those expenses reported in the 96 audited surveys for services which are not allowable under Medicare Part B principles of payment. Examples of costs that were not allowed include expenses for advertising, employee morale, gifts and memorials, entertainment, and parties. d. Standardize Unaudited Costs and Charges

For the 96 audited surveys, aggregated audit adjusted expenses, including our adjustments for unreasonable labor and administrative costs, were 12 percent lower than reported overhead costs. To standardize the costs of the 199 unaudited facilities with those of the 96 audited facilities, we adjusted each category of overhead expense (plant and property, equipment, supplies, IOL, contractual labor, employee, owner's compensation, bad debts, and other expenses) in the unaudited surveys by the percent of difference between reported and audit adjusted data in each category of overhead expense for the 96 audited surveys. To standardize unaudited charges, we determined the percent of difference between aggregated reported charges and aggregated audited charges for the 96 audited surveys. We increased perprocedure charges in each of the 199 unaudited surveys by the 3.07 percent of difference between reported and audit adjusted aggregate charges. e. Calculate Facility-Specific Cost-to-Charge Ratio

When we rebased ASC payment rates using 1986 data, we used a median costto-charge ratio based on data from 90 audited surveys. At that time, we considered using a facility-specific costto-charge ratio that would have taken into account the differences in the relationship between charges and cost that exist among facilities, but we elected not to do so because the data from unaudited 1986 surveys were seriously deficient. Because most of those earlier deficiencies have been ameliorated in the 1994 survey database, we are revising our ratesetting methodology to use a facility-specific cost-to-charge ratio.

• For each of the 295 surveys, we summed costs reported for plant and property, equipment, supplies, contractual labor, salaries, owner's compensation, bad debts, and miscellaneous other administrative expenses to calculate total net adjusted costs. Note that we exclude costs incurred by ASCs to furnish intraocular lenses (IOLs) from the calculation of the facility specific cost-to-charge ratio. Otherwise, the cost of an IOL would be spread across all procedures rather than being allocated specifically to the four procedures that require IOLs. We treat IOL costs separately, as we explain below.

• For each of the 295 surveys, we calculated total net adjusted procedure charges, including charges both for procedures on the ASC list and for procedures performed at the ASC that were not on the ASC list.

• We divided each facility's total net adjusted costs by the facility's total net adjusted charges to determine the ratio of the facility's overall costs to its charges.

f. Convert Each Procedure Charge to a Procedure Cost

We multiplied the net adjusted charge reported for each CPT code by the facility-specific cost-to-charge ratio in order to convert every net adjusted perprocedure charge to a per-procedure cost value. We believe that using a facility specific cost-to-charge ratio to arrive at per-procedure costs is a distinct improvement over the current methodology of using a median facility cost-to-charge ratio across all facilities because the facility specific ratio takes into account facility variations (single vs. multi-specialty, small vs. large, single vs. multiple ownership, etc.) which may affect the relationship between facility costs and charges.

g. Remove Intraocular Lens (IOL) Costs From Four Lens Insertion Procedures

Section 4063(b) of the Omnibus Budget and Reconciliation Act of 1987 (OBRA 1987) (Public Law 100–203) amended section 1833(i)(2)(A) of the Act to mandate that HCFA include payment for an IOL furnished by an ASC for insertion during or subsequent to cataract surgery as part of the ASC facility fee rather than paying for the prosthetic lens separately, in addition to the facility fee. The payment amount must be reasonable and related to the cost of acquiring the class of IOL involved.

Section 4151(c)(3) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Public Law 101–508) froze the IOL payment amount at \$200 for the period beginning November 5, 1990 and ending December 31, 1992, and we continued the \$200 IOL allowance from January 1, 1993 through December 31, 1993. Therefore, Medicare payments to ASCs performing IOL insertion procedures in calendar year 1993, the survey period for most facilities completing the 1994 ASC survey, included a \$200 allowance for the IOL.

Section 13533 of the Omnibus Budget and Reconciliation Act of 1993 (OBRA 1993) (Public Law 103–66) mandated that, notwithstanding section 1833(i)(2)(A)(iii) of the Act, payment for an IOL furnished by an ASC must be equal to \$150 beginning January 1, 1994 through December 31, 1998.

Although the statute at section 1833(i)(2)(A)(iii) defines IOLs as an ASC facility service and mandates that the ASC facility fee for lens insertion procedures include payment for the IOL that is reasonable and related to the cost of acquiring the class of lens involved, amendments to the statute have mandated a specific dollar amount that Medicare is to pay for the IOL, irrespective of the costs incurred by ASCs generally to furnish the IOL.

Because IOLs are considered a facility service, ASCs do not bill for them separately. Rather, the charge for an IOL

is included within the procedure charge for CPT codes 66983, 66984, 66985, and 66986. After we converted procedure charges to procedure costs, we subtracted the IOL cost from the procedure cost for each of the four lens insertion codes before we neutralized per-procedure costs for regional wage variations, adjusted procedure costs for inflation, and grouped procedures in order to set payment rates. The amount that we subtracted is a facility-specific mean IOL cost based on data collected in the 1994 survey regarding the quantity and models of IOLs purchased and the total amount paid for each model net of all discounts, rebates, and credits. If we did not subtract the IOL cost from the procedure cost of the lens insertion procedures at this juncture, Medicare would be recognizing IOL costs twice: once as part of the rebased payment rate for the procedure, and again through the mandated IOL allowance that is to be added onto the payment rates set for CPT codes 66983, 66984, 66985, and 66986. Note that the payment rate of \$863 determined for CPT codes 66983, 66984, 66985 and 66986 (APC 668) includes a \$150 IOL allowance.

Rates for lens insertion procedures beginning January 1, 1999. The 1994 survey data reveal that the current IOL allowance of \$150 is neither reasonable nor related to the cost of acquiring the lens, but rather, represents an overpayment by Medicare and a lost opportunity for beneficiary and program savings. The 1994 ASC survey data show that ASCs were acquiring IOLs in 1993 for substantially less than the \$200 that Medicare was paying ASCs for IOLs at that time. Based on survey data reported by 215 ASCs (72 audited and 143 standardized by increasing IOL costs by 1.93 percent) that purchased 197,289 lenses, the weighted mean lens cost was \$100, and the weighted median cost was \$97 (weighted by frequency). Of the 215 ASCs on which these findings are based, 76 are eye specialty facilities. For eye specialty ASCs alone, the weighted mean IOL cost was \$82, and the weighted median IOL cost was \$70. Table 2 shows that even inflating 1993 IOL costs to 1998 dollars, ASCs can still acquire IOLs on average well below the \$150 allowance mandated by Congress through December 31, 1998.

TABLE 2.—1994 ASC SURVEY: INTRAOCULAR LENS (IOL) COST INFLATED TO 1998 DOLLARS

	CY 1993	CPI–U infla-	CY 1998
	dollars	tion factor	dollars
Mean Cost, weight by frequency	\$100	1.14915	\$115
Median Cost, weight by frequency	97	1.14915	108

TABLE 2.—1994 ASC SURVEY: INTRAOCULAR LENS (IOL) COST INFLATED TO 1998 DOLLARS—Continued

	CY 1993	CPI–U infla-	CY 1998
	dollars	tion factor	dollars
Medicare IOL allowance	200	NA	150

(Based on 1994 ASC survey reported by 215 ASCs that purchased 197,289 lenses).

Prior to expiration of the \$150 IOL allowance on December 31, 1998, we shall propose a revised payment rate for the four lens insertion procedures in APC 668 in order to be consistent with section 1833(i)(2)(A)(iii) of the statute, which states that lens insertion procedures are to include an IOL allowance that is reasonable and related to the cost of the lens involved. In rebasing the payment rates for the four lens insertion procedures, we expect to follow the basic ratesetting methodology proposed in this notice, with one difference: We would neutralize the charge-converted per procedure cost determined for CPT codes 66983, 66984, 66985, and 66986 to offset the effect of regional wage variations, and then, we would add the facility-specific mean IOL cost to the procedure cost for these codes. The resulting cost for the four lens insertion codes would be adjusted for inflation, and the payment rate for APC 668 would be recalculated. IOL costs would then be subject to interim year annual adjustments for inflation because they would be packaged within the facility fee for lens insertion procedures. Under the current payment method, the fixed add-on IOL allowance in payment group 6 and payment group 8 is not subject to an annual adjustment for inflation.

We solicit comments on this approach to rebasing the payment rate for IOL insertion procedures for services furnished beginning on January 1, 1999.

h. Calculate Facility Specific Portion of Procedure Cost Attributable to Labor Expenses

Having converted per procedure charges to cost values and subtracted IOL costs from CPT codes 66983, 66984, 66985, and 66986, we determined for the 295 audited and standardized surveys the percentage of facility costs attributable to labor.

• We summed each facility's expenses for contractual personnel, employee salaries and fringe benefits, and owner's compensation (laborrelated costs);

• We summed each facility's net total costs including plant and property, equipment, supplies, contractual labor, employee salaries and fringe benefits, owner's compensation, bad debts, and miscellaneous other administrative expenses.

• We divided each facility's total labor-related costs by its net total costs to determine the percentage of the facility's costs related to labor.

• We multiplied each facility's perprocedure cost by the facility's percentage of labor-related costs to apportion each procedure cost into labor-related and non-labor related components.

Under the current ratesetting methodology, as explained in the final notice published in the Federal Register on February 8, 1990 (55 FR 4526), we use an average of the labor-related percentage for all facilities based on 1986 survey data to determine the portion of procedure charges attributable to labor costs. Using 1994 survey data to determine as precisely as possible costs incurred by a facility to perform an individual surgical procedure, we reasoned that a facility specific labor-related percentage would be a more sensitive gauge of variations in hiring practices, staffing patterns, and employee expenses that influence ASC procedure costs than a national average which, by definition, flattens these variations. Therefore, to capture the influence on per procedure costs of individual facility staffing patterns and practices, we calculated a facility specific labor-related percentage preliminary to deflating per procedure costs to offset variations in labor costs that are the result of broader regional demographic differences. However, we shall continue the current method of calculating actual payment amounts for ASC facility services using an average labor-related factor to adjust rates for regional wage differences, which is consistent with the Congressional intent that Medicare pay ASCs a prospectively determined standard overhead fee. Using 1994 audited survey data, we found that, on average, the percentage of facility costs attributable to labor expenses (contractual personnel, employee salaries and fringe benefits, and owner's compensation) is 37.66 percent, a slight increase over the 34.45 percent labor-related factor based on 1986 data that carriers use currently to adjust base rates for regional wage differences.

i. Deflation by Wage Index Value

In order to remove variations in ASC per procedure costs that could be due solely to geographical differences in labor costs, we neutralized or deflated the portion of each ASC's per procedure costs attributable to labor expenses.

• We calculated a facility-specific percentage of overall costs attributable to labor expenses as explained in section 2-h, above.

• We multiplied each facility's perprocedure cost (see section 2-f, above) by the facility's percentage of laborrelated costs to determine the laborrelated portion of the procedure cost.

• We divided the labor-related portion by the wage index value applicable to the ASC's location.

• We added the deflated labor-related portion of the procedure's cost to its nonlabor-related portion to arrive at a per procedure cost that is not influenced by geographic wage variations.

As part of the ratesetting methodology explained in the final notice published in the February 8, 1990 Federal Register (55 FR 4526), we state as a matter of policy our intention to use the most recent Medicare hospital inpatient prospective payment system (PPS) wage index values both to determine ASC base payment rates and to calculate payment amounts for individual claims for ASC facility services. Therefore, the updated ASC base rates published in the February 8, 1990 notice reflect the fiscal year (FY) 1990 hospital inpatient PPS wage index that was effective for hospital discharges beginning October 1, 1989. We also included wage index values for rural counties deemed urban under sections 1886(d)(8)(B) and 1886(d)(8)(C) of the Act.

In the Federal Register published December 31, 1991 (56 FR 67666), we announced that we would continue to use the most recently updated hospital inpatient PPS wage index values for urban areas and rural areas to calculate ASC payment amounts; that we would limit recognition of reclassified wage index values resulting from reclassifications approved by the Medicare Geographic Classification Review Board (MGCRB) under section 1886(d)(10) of the Act to rural counties deemed urban under section 1886(d)(8)(B) of the Act; and, that we would annually update ASC payment

rates concurrently with the annual update of the hospital inpatient PPS wage index.

Ūse of pre-reclassification wage index values. Both the method of setting ASC payment rates and the method of calculating payment amounts for individual claims for ASC facility services proposed in this notice include a wage index adjustment to offset the effects of geographic wage differences. In this notice, we propose to continue using the most recent index that HCFA has determined from hospital wage and salary data collected from hospital cost reports. However, we propose to use wage index values that are calculated from wage and salary data before HCFA makes certain adjustments. That is, the wage index that we propose to use to adjust ASC payment rates reflects neither the effects of hospitals being redesignated or reclassified from one area to another under the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C). and 1886(d)(10) of the Act, nor the requirement stated in sections 4410 (a) and (b) of the Balanced Budget Act of 1997 (Pub. L. 105-33) that the wage index for an urban hospital not be lower than the Statewide rural wage index. We believe this "pre-classification// prefloor" wage index more directly reflects salary and wage levels for health care personnel within a given geographic area than does a wage index that is the result of a series of hospital-specific adjustments.

Å description of how HCFA determines the FY 1998 prereclassification//pre-floor wage index values for urban and rural areas that we used to determine the rebased rates that are proposed in this notice and that carriers will use to calculate wageadjusted payments to individual ASCs is in the **Federal Register** published on August 29, 1997 (62 FR 45985).

For the same reason that we are using pre-reclassification// pre-floor wage index values, we propose to eliminate special wage index designations for ASCs in rural counties deemed urban under section 1886(d)(8)(B) of the Act. The counties affected by this proposed change of policy are listed in Table 3. We propose to have carriers use the wage index value for the geographic area in which the facility is located rather than a reclassified wage index value when they calculate Medicare facility fees for ASCs in these designated counties. We solicit comments from ASCs located in these areas if they believe they will be adversely affected by our no longer providing an ASC-specific wage index value for counties deemed urban under section 1886(d)(8)(B) of the Act.

There is precedent for our decision to use pre-reclassification hospital inpatient PPS wage index values: We use pre-reclassification wage index values to determine allowable costs and Medicare payment limits for skilled nursing facilities (SNFs) and home health agencies (HHAs). We further reason that because the decisions of the MGCRB apply solely to individual hospitals, and because there is no mechanism by which we can link ASCs with individual hospitals, prereclassification// pre-floor wage index values adequately measure wage and wage-related costs for short-term, acute care hospitals located within the labor market areas defined by the Office of Management and Budget (OMB) upon which we base our definition of geographic areas. OMB updates the definitions of metropolitan areas (MAs) each June, adding new areas that qualify as MAs and cities that qualify as central areas for MAs, keeping the definitions of these geographic areas current. We also include in our definition of hospital labor market areas the New England County Metropolitan Areas (NECMAs), as defined by OMB and the special reclassification of Stanly County, North Carolina (a rural county) as part of the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina MSA (a large urban area) under section 4408 of the BBA of 1997

If the FY 1998 hospital inpatient PPS wage index is updated prior to publication of the final rule implementing the provisions of this notice, we shall recalculate all procedure costs and payment rates accordingly. The final rebased ASC rates may therefore vary somewhat from the rates proposed in this notice as a result of our using pre-reclassification//prefloor hospital inpatient PPS wage index values that are more current at the time of publication of the final notice.

During the time between implementation of the final rates proposed in this notice and the next cycle of ratesetting to rebase rates using newer survey data, we shall freeze the base rates other than to adjust them for inflation in accordance with section 1833(i)(2)(C) of the Act, as amended by section 4555 of BBA 1997. That is, we do not intend to reset the base rates during these interim years to reflect the annual update of the wage index, although carriers will continue to calculate payment amounts to facilities using the most currently available wage index values, as they do currently.

We note that one consequence of our proposal to move all ASC updates to a calendar year cycle is a three-month delay in applying to the calculation of

ASC facility fees the hospital inpatient PPS wage index values, which are updated on a fiscal year basis every October 1. We believe that the advantages of consolidating the updates of ASC rates, the ASC list, and wage index values to be effective every January 1, concurrent with the update of the Medicare Physician Fee Schedule, the Physicians' Current Procedural Terminology, and the Health Care Financing Administration (HCFA) Common Procedure Coding System (HCPCS), far outweigh any disadvantages that might result from delaying for three months implementation of the most recent wage index. We solicit comments on this point and on the other modifications we propose to make with respect to our policy for adjusting ASC payment rates to offset the effects of geographic wage differences.

TABLE 3.—COUNTIES THAT WILL NO LONGER BE DEEMED URBAN UNDER SECTION 1886(D)(8)(B) OF THE ACT TO CALCULATE ASC PAYMENTS

County

Barry, MI Cass, MI Caswell, NC Christian, IL Harnett, NC Henry, IN Indian River, FL Ionia, MI Jefferson, KS Jefferson, WI Lawrence, PA Lincoln, WV Macoupin, IL Marshall, Al Mason, IL Morrow, OH Owen, IN Preble, OH Shiawassee, MI Tuscola, MI Van Wert, OH Walworth, WI

j. Adjust Reported Costs for Inflation to Offset Fiscal Year Differences Among Facilities

The most recently completed 12month fiscal period for the majority of ASCs that submitted the 1994 survey coincided with calendar year 1993, but there were some surveys with data reported for a 12-month period ending on a date other than December 31, 1993. (The earliest beginning date for a survey period was January 1, 1992; the latest ending date for a survey period was June 30, 1994.) Therefore, both to ensure comparability in our cost assumptions and to express procedure costs in equivalent dollars, we inflated the cost amount established for every procedure at the facility level from the midpoint of the facility's reporting period to a common end period using the Consumer Price Index—All Items (Urban). We used July 1, 1998, the midpoint of the calendar year during which the rates in this notice are proposed for implementation, as the common end period. Table 4 shows the factors we used to express procedure costs in dollar levels projected for July 1, 1998. The only difference between using the factors in this table to adjust procedure costs for actual and projected changes resulting from inflation and the factors that we used to inflate the 1986 base rates is that the factors used here are sensitive to quarterly rather than just annual inflationary trends.

TABLE 4.—FACTORS TO INFLATE AMBULATORY SURGICAL CENTER PER PROCEDURE COSTS TO JULY 1, 1998 DOLLARS USING CPI-ALL ITEMS, URBAN

Survey year starts	Survey mid-point	Survey year ends	Factor needed to adjust to common end period (7/1/98)
Jan–1–92	Jul–1–92	Dec-31-92	1.18268
Feb-1-92	Aug-1-92	Jan-31-93	1.17961
Mar-1-92	Sep-1-92	Feb-28-93	1.17653
Apr–1–92	Oct-1-92	Mar–31–93	1.17347
May–1–92	Nov–1–92	Apr-30-93	1.17043
Jun-1-92	Dec-1-92	May-31-93	1.16748
Jul-1-92	Jan-1-93	Jun-30-93	1.16466
Aug-1-92	Feb-1-93	Jul-31-93	1.16198
Sep-1-92	Mar-1-93	Aug–31–93	1.15936
Oct-1-92	Apr-1-93	Sep-30-93	1.15676
Nov–1–92	May-1-93	Oct-31-93	1.15417
Dec-1-92	Jun-1-93	Nov-30-93	1.15163
Jan-1-93	Jul–1–93	Dec-31-93	1.14915
Feb-1-93	Aug-1-93	Jan-31-94	1.14674
Mar–1–93	Sep-1-93	Feb-28-94	1.14439
Apr–1–93	Oct-1-93	Mar–31–94	1.14208
May-1-93	Nov-1-93	Apr-30-94	1.13982
Jun–1–93	Dec-1-93	May-31-94	1.13751
Jul–1–93	Jan-1-94	Jun-30-94	1.13505

Source: DRI/McGraw-Hill, 4th Qtr1996;@USSIM/TRENDLONG1196@CISSIM/CONTROL964.

3. Proposed Ratesetting Method

Determine the median per-procedure cost, across all facilities, for each reported CPT code.

a. Weights

In the 1986 ASC survey, we collected data on the total number of times a specific procedure, as defined by a CPT code, was performed in the facility. To determine Medicare utilization. the 1986 survey asked for a total count of Medicare patients served by the ASC during the survey period. The number of times specific procedures were performed on Medicare patients was not identified. Therefore, the only way to weight 1986 survey data by Medicare utilization was to apply a facilityspecific ratio of Medicare patients to all patients served during the survey period to the total number of times a specific procedure was performed. As a result, cost data for procedures with high Medicare utilization, such as cataract extraction, were weighted the same as cost data for procedures that were performed only rarely for Medicare beneficiaries.

In the 1994 ASC survey, to obtain a more accurate measure of Medicare

utilization, we not only collected information on how many times a procedure on the ASC list was performed during the survey period, but also, how many times the patient was a Medicare beneficiary when the procedure was performed. Having this utilization information available for each CPT code enables us to weight 1994 survey data with greater precision than we could with the 1986 survey data. After we adjust and then convert per procedure charges to per procedure costs, we use the procedure's total volume as a weighting factor to determine the median per procedure cost across all facilities that reported charge and utilization data for the procedure. Then, as we explain in a later section, after we assign procedures to payment groups, we use the procedure's Medicare volume as a weighting factor to determine the median cost of all the procedures in the group. This final median cost becomes the payment rate for all the procedures in the group.

b. Determination of Weighted, Trimmed Median Per Procedure Cost Across All Facilities

To determine the median cost of a procedure across all the facilities where it was performed, we arrayed each facility's net, wage-neutral, inflation adjusted cost for the procedure in descending order of cost, weighted by the number of times the procedure was performed in the facility for all patients, both Medicare and non-Medicare. After trimming observations above the 90th and below the 10th percentile, to remove costs that were aberrant extremes, we determined the median cost for the procedure code. We repeated this process for every procedure on the ASC list for which utilization was reported in the 1994 survey to arrive at a weighted median procedure cost for the 1516 CPT codes in the survey data set.

Because Medicare volume for most procedures is but a fraction of total utilization, we believe that weighting by total volume gives us a truer per procedure median cost across all ASCs than weighting by Medicare volume alone. Weighting by total volume expands our data set by pulling in procedures for which no Medicare volume was reported. Use of the median rather the mean procedure cost further minimizes the effect of individual facility cost extremes.

Having established a weighted median procedure cost that represents costs incurred by ASCs generally to perform the procedure based on audited and standardized 1994 survey data, we proceed to the final step in the ratesetting process, which is grouping procedures for the purpose of calculating prospective ASC payment rates.

4. Proposed Ratesetting Method

Establish procedure groupings.

a. Current Classification System

When we rebased ASC payment rates using 1986 survey data, we expanded from four to eight payment rates or levels, as explained in the February 8, 1990 Federal Register (55 FR 4539). (We explain elsewhere in this notice that a ninth payment level was established effective January 30, 1992 to accommodate payment for CPT code 50590, extracorporeal shock wave lithotripsy, but that payments of an ASC facility fee for this procedure were suspended following the issuance of a court stay on March 10, 1992.) We currently group codes by assigning each procedure, depending on its cost, to the appropriate level within a series of predetermined \$75 intervals. The only factor roughly common to all procedures within the six currently active non-IOL ASC payment groups is the approximate cost of performing the procedure based on 1986 survey data and/or our estimate of that cost when data are lacking.

b. Proposed Ambulatory Payment Classification System

We propose to replace the current method of grouping procedures on the ASC list with a classification system that takes factors such as time, type of surgery, and body system into account, in addition to the costs incurred by facilities in connection with performing the procedure. Addendum B lists the resulting ambulatory payment classification system (APCS) groups that are the basis for determining the payment rates for ASC facility services that we are proposing in this notice. Although the genesis of these groups was in the ambulatory patient groups (APGs) that were developed by 3M Health Care under a HCFA grant, the APC groups are not the same as APGs, and Medicare regulations and policy governing payments to ASCs using these groups do not necessarily follow the 3M APG model. $^{\rm 1}$

The APC groups are the result of intensive work on the part of HCFA staff and medical advisors who started with the 3M APGs but then reorganized the groups on the basis of several factors. First, we had a data set of 1516 CPT codes with cost and utilization information from 295 ASCs that was collected through the 1994 ASC survey. In addition, we had comments from 79 correspondents, including ASC administrators, State agencies, professional organizations and societies, trade associations, and physicians following the July 1996 Medicare ASC Town Meeting in Baltimore, that were virtually unanimous in questioning the internal consistency of a number of the 3M APG groups. (We had circulated 3M's Version 2.0 significant procedure APGs at the ASC Town Meeting, without any costs or rates attached, and asked for comments on the homogeneity of the groups.) A number of commenters suggested regrouping codes, and they supported their recommendations on the basis of the time required to perform procedures in the new groups and the costs associated with supplies and equipment needed to perform the procedures. Of particular concern were the grouping of gastrointestinal endoscopies, arthroscopies, a number of urinary tract procedures, and groups where diagnostic and therapeutic surgical procedures were put in the same APG. In cases where our data supported a recommendation, we modified a payment group accordingly. If we did not make a recommended change, it was because our data did not support the change, or because the change was inconsistent with our standards for determining procedures that are safe and appropriate in an ASC. Once we began shifting codes from one group to another, we found that other groups were affected, so we ended up reviewing and modifying virtually every grouping of surgical procedure codes.

To classify procedures with limited or aberrant ASC survey data, we relied on the medical judgement of our staff physicians in conjunction with 1993 hospital outpatient department claims data and physician practice expense relative value units (RVU) from the Medicare physician fee schedule. We also took into account Medicare utilization patterns based on 1995 physician claims site-of-service data to aid in determining levels of procedure complexity.

By adding clinical consistency to cost as a determinant for classifying surgical procedures for ratesetting purposes, we propose to expand from eight to 105 the number of ASC payment groups. Our lowest payment rate would drop to \$53 (APC #207, Closed Treatment Fracture Finger/Toe/Trunk), and our highest payment rate would increase to \$2,107 (APC #527, Lithotripsy). We believe this classification system rectifies distortions that have developed under the current ASC groups which have resulted in underpayments for a number of procedures and overpayments for some others.

Using groups that are characterized by homogeneous clinical characteristics as well as costs enables us to set rates more accurately for new procedures that are appropriate and safe in an ASC but for which we have minimal data or for infrequently performed procedures for which cost data are questionable or nonexistent.

Following the ASC Town Meeting, some commenters urged a ratesetting method for ASCs that would promote equitable reimbursement for procedures across all settings. At least one commenter stated that Medicare payment policy ought to be neutral as to site of service. In fact, one of the reasons that we have devoted so much attention to developing the APC surgical groups for ASC ratesetting is in anticipation of using them as part of the prospective payment system that is to be implemented on January 1, 1999 for hospital outpatient department services. It is our intent to keep the APC surgical groups comparable for ASCs and hospital outpatient departments (HOPDs). Currently under development is the HOPD prospective payment system, which contains as one of its elements APC surgical groups that parallel the APC surgical groups we are proposing for ASCs. In order to keep the groups comparable in the two settings, we propose to review comments on the composition of the APC groups that are submitted during the public comment period following publication of both this ASC notice and the HOPD notice. We further propose to coordinate any adjustments to the composition of the APC surgical groups that may result from our analysis of both sets of comments to ensure that the final APC surgical groups not only reflect and take into account both sets of comments, but also remain comparable for ASCs and HOPDs to the maximum extent possible within the constraints imposed by statutory and regulatory requirements.

¹Health Information Systems, 3M Health Care. The Ambulatory Patient Groups Definitions Manual, Version 2.0. Wallingford, Connecticut, 1995.

Every CPT code within the surgical range of 1998 *Physicians' Current Procedural Terminology* is accounted for in Addendum A either in an APC group or in a non-payment category. We propose to expand the list of Medicare covered procedures from 2280 to 2499, which includes the addition of 422 procedures and the deletion of 203 procedures currently on the list, consistent with the standards discussed in section II.A. of this notice. We move to the final step in determining prospective payment rates for procedures on the ASC list.

Proposed Ratesetting Methodology

Determine a standard payment rate for the procedures within each group.

a. Setting Rates Based on ASC Survey Data

Having classified procedures that are safe and appropriate in an ASC setting into 105 payment groups, we arrayed the procedures within each group in descending order of facility-specific procedure cost, weighted by each facility's procedure-specific Medicare volume, to determine the median cost of procedures in that APC. Weighting by the number of times the procedures were performed on Medicare patients gives recognition to the relative importance of each facility in furnishing procedures covered by the Medicare program. The derived median cost determined the payment rate for the group.

b. Setting Rates for Procedures With Limited Medicare Volume or Aberrant Cost Data

When we determined individual procedure costs (see section III.E.2, above), we eliminated information on costs, charges, and utilization from the ASC survey database for 345 CPT codes that were reported by fewer than 3 facilities and 199 CPT codes for which there was no reported Medicare volume. We also lacked 1994 survey data for the 422 proposed additions to the ASC list. After procedures had been assigned to APC groups (section III.E.4, above), we found 6 surgical APCs comprised entirely of codes for which we had no reported ASC survey data. In addition, there were 43 APCs with fewer than 200 Medicare cases across all procedures in the group. (We determined that using the median cost of fewer than 200 Medicare cases to set payment rates for these 43 APCs failed to represent adequately the majority of procedures within the group and did not result in a reasonable group payment rate.) We also identified 15 APCs with Medicare volume greater than 200 cases for which we did not rely on reported ASC data to determine a payment rate because we believed that reported procedure charges for codes in these groups were based more on historical ASC payment rates than on the cost of performing the procedure. We also questioned the reliability of the data reported for procedures within these groups when we found in the majority of cases that the per procedure costs of simple procedures were higher than the costs determined for similar but more complex procedures.

In order to set a payment rate for the 64 APC groups for which we had little or no Medicare volume or reliable cost data, we calculated a relative value factor for each of the 41 surgical APC groups for which we did have reliable data, which we extrapolated as a standard against which to compare and rank the 64 data deficient APC groups. To calculate the relative value factors, we divided the payment rate already set for each of the 41 APCs with adequate ASC survey data (see section III.E.5.a, above) by 504, the median rate of those 41 groups. We used the relative value factors as a gauge to compare the datadeficient groups with the 41 groups with data in terms of the type and duration of surgery, supply and equipment costs, and clinical labor requirements characteristic of each group. We reasoned that we could infer a relative value factor for each of the data-deficient groups on the basis of these comparisons. Using this analysis, combined with the expertise of our staff physicians, the comments we received following the 1996 ASC Town Meeting, and our analysis of other data sources, such as 1993 hospital outpatient claims data and relative value units established under the Medicare Physician Fee Schedule, we estimated relative value factors for the 64 ASC data-deficient APC groups. The relative value factors for procedures on the ASC list are shown in Addendum A and Addendum C

We then multiplied the relative value factor estimated for each data-deficient group by 504 to determine a payment rate for each of the 64 data-deficient APC groups. We viewed 504 as the most reasonable value to use as a conversion factor to set ASC payment rates for the data-deficient APCs because 504 was the median rate of the APC groups that had the highest ASC Medicare volume and for which we had substantive 1994 survey data.

Using this approach, we determined payment rates for 1058 CPT codes (42 percent of the 2499 codes proposed for the ASC list) for which we had little or no cost data. Of the 43 APCs that had fewer than 200 Medicare cases, nearly half were assigned a higher payment rate than would have been the case if we had relied on the limited ASC data that were available as the basis for the payment rate. In the case of two groups with more than 200 Medicare cases, one of which consisted of corneal transplant procedures, we increased the payment rate because the data-referenced costs were too low.

c. Payment Rate for CPT Code 67027, Implantation of Intravitreal Drug Delivery System

This is a new 1998 CPT code that we are proposing to add to the ASC list. Because it is new, we have no cost data in connection with this code. We ask for comments on which of the APC groups proposed for ophthalmic procedures (APC groups 649, 651, 652, 667, 668, 670, 676, 677, 683, 684, or 690) this procedure code would be most appropriately assigned both in terms of its clinical characteristics and resource costs. We request that commenters support their suggestions with information and data that elucidates the clinical characteristics and resource costs of this procedure relative to other procedures in the various APC groups for eye surgery.

6. Payment Policy Indicators

We have developed a set of payment policy indicators to assist ASCs and fiscal contractors in determining whether Medicare allows payment to an ASC for a particular procedure, item or service. Addendum A shows a payment indicator for every 1998 HCPCS code.

ASC payment policy indicators are intended to supplement, not replace, the correct coding initiative (CCI) edits that carriers already apply to claims for ASC services. (The CCI edits identify code pairs which, when billed together, represent either unbundling (the reporting of a comprehensive procedure and its component procedures) or mutually exclusive procedures (procedures which by definition cannot occur during the same operative session.)) The ASC payment policy indicators are defined as follows:

a. We use "1" to designate a procedure for which Medicare pays Medicare approved ASCs a prospectively determined ASC facility fee for ASC services. Collectively, the CPT codes with an ASC payment indicator of "1" make up the ASC list. (See Addendum B.) Medicare allows payment of an ASC facility fee only for codes with an ASC payment policy indicator of "1."

b. We use "2" to indicate a procedure, item, or service for which Medicare

does not allow a separate payment when the procedure, item, or service is furnished at a Medicare approved ASC. If the procedure, item, or service is covered, payment is always packaged into and subsumed within payment(s) made for other services not specified. Some codes with a "2" indicator describe items or services that fall within the scope of ASC facility services, whose costs are taken into account within the ASC facility fee. Examples of these include CPT code 36000, Introduction of needle or intracatheter; or, CPT code 81002, Urinalysis, by dip stick or tablet reagent; or, alphanumeric HCPCS code V2632, Posterior chamber intraocular lens. When these services are furnished at an ASC, payment for them is included as part of the ASC facility fee.

c. We use "3" to indicate a procedure, item or service that is excluded from the ASC list because it is not reasonable, not necessary, and not appropriate in an ASC setting. We have assigned an ASC payment policy indicator of "3" to procedures that our medical advisors consider to be unsafe in an ASC based on the criteria in § 416.22(b), and to CPT codes that are for unlisted procedures.

d. Codes with an ASC payment policy indicator "4" are not valid for Medicare purposes, although Medicare recognizes a 90-day grace period during which the code may be used. If Medicare covers the service, another code is to be used to bill for it. Codes with an ASC payment policy indicator "4" are assigned a procedure status code of "G" on the Medicare Physician's Fee Schedule.

e. We use "5" to indicate a procedure, item, or service that is safely and appropriately performed or furnished in a physician's office or clinic. We consider procedures with an ASC payment policy indicator "5" to be office-based because they do not generally require the more elaborate facility services of an ASC and they do not satisfy the criteria proposed in § 416.22(a). Procedures with an ASC payment policy indicator "5" are not considered to be on the ASC list.

Medicare takes into account and pays for the costs incurred to perform these procedures under the Physician Fee Schedule. If a procedure with an ASC payment policy indicator "5" were performed at an ASC and the ASC billed Medicare for the procedure, payment would be denied. The denial would be based on two factors: first, the procedure is not on the ASC list, and secondly, because the procedure is designated as an office-based procedure, Medicare payment for the procedure is made in full to the physician as determined by the physician's fee schedule. Any payment in addition to what Medicare pays the physician under the Medicare Physician Fee Schedule for procedures with an ASC payment policy indicator "5" is redundant and is not allowed. After any applicable deductible and copayment amounts are satisfied, we consider the beneficiary's obligation for a procedure with an ASC payment policy indicator "5" to be met in full by Medicare's payment to the physician.

If a procedure code with an ASC payment policy indicator "5" is subject to the site-of-service differential under the Medicare Physician Fee Schedule, the site-of-service practice expense reduction is not applied if the procedure is performed in an ASC because we do not consider the procedure to be on the ASC list and because we regard the ASC as a surrogate physician's office with respect to these procedures.

f. We use ASC payment policy indicator "6" to indicate that a procedure, item or service either falls outside the scope of ASC facility services as proposed in § 416.21(b) or that the procedure, item or service is one to which the concepts of an ASC facility fee or the ASC benefit are not relevant and do not apply. In the latter case, the procedure, item or service is outside the realm of ASC facility services and would never, by definition, be furnished by an ASC, e.g., clinical laboratory tests, maternity care and delivery, emergent procedures, or physician evaluation and management.

In the former case, although the ASC facility fee for a surgical procedure on the ASC list does not include payment for the cost of items, procedures, or services that have an ASC payment policy indicator "6", if these procedures, items, or services are covered and are reasonable and necessary, Medicare could allow a separate payment under another Part B benefit as long as Medicare recognizes and approves the entity as a supplier of the item or service. For example, we do not consider prosthetic implants, except IOLs, to fall within the scope of ASC facility services. But if an entity that is approved by Medicare as an ASC is also approved as a supplier of prosthetic implants, Medicare allows payment to the entity for a prosthetic implant in accordance with the prosthetic fee schedule in addition to payment of an ASC facility fee for services furnished by the entity in connection with a procedure on the ASC list that is performed to insert the prosthetic implant. See section III.F for further discussion of items and services that fall outside the scope of ASC services.

g. We use "7" to indicate a procedure to which special coverage instructions apply, such as CPT code 11950, Subcutaneous injection of "filling" material, (e.g. collagen); 1 cc or less, about which carriers must make a determination of reasonableness and medical necessity. If a surgical procedure with an ASC payment policy indicator "7" is performed in a Medicare approved ASC and a claim for ASC services is submitted, payment depends on whether the carrier determines that the procedure is reasonable and necessary. If the carrier determines that the procedure was reasonable and necessary, an ASC payment rate is given and the procedure would be considered to be on the ASC list for the purposes of the specific claim. Procedures with a status indicator "R" under the Medicare Physicians' Fee Schedule automatically receive an ASC payment policy indicator of "7."

h. We have reserved payment policy indicator "8" for future use.

i. We use "9" to indicate a procedure, item or service that is not covered by Medicare and for which Medicare never makes payment. ASC payment policy indicator "9" corresponds to procedure status codes "I", "N", and "E" under the Medicare Physician Fee Schedule. (Status code "I" is used to indicate codes that are not valid for Medicare purposes with no grace billing period allowed; status code "N" is used to indicate codes that describe a noncovered service; status code "E" is used to indicate codes that are excluded from the Medicare Physician Fee Schedule by regulation.)

7. Comments on Proposed Ambulatory Payment Classification Groups, Payment Policy Indicators and Payment Rates

Addendum A lists all 1998 HCPCS codes in numeric order by code and includes an ASC payment policy indicator for each code and, where applicable, a notation as to whether or not the code is proposed for addition to or deletion from the ASC list. Addendum B presents the ASC list by APC group. Addendum C is a list of 105 surgical APC groups with their respective titles, ASC relative values, and ASC payment rates. We solicit comments on the payment rates, APC grouping, and payment policy indicators proposed in these tables. However, we request that commenters who question the appropriateness of the rate or APC assignment proposed for a particular procedure support their argument with specific details related to intra-operative time, staffing requirements, and costs incurred by the

facility to furnish disposable and nondisposable supplies, pharmaceuticals, instrumentation, and equipment in connection with the procedure and that procedures more closely related in terms of cost be identified. We also solicit comments on the changes to the ASC ratesetting methodology that are proposed in this section.

8. Carrier Adjustment of Base Rates to Determine Payment Amounts

The payment rates proposed in this notice are standard base rates that have been adjusted to remove the effects of regional wage variations. When carriers process claims for ASC facility services, they adjust the base rates to reflect the wage index value applicable to the area in which the ASC is located. The Medicare payment for ASC facility services is equal to 80 percent of the wage-adjusted standard payment rate. Beneficiaries are responsible for a 20 percent copayment for ASC facility services once their deductible is satisfied. Below are some examples of how carriers adjust the ASC base rates to calculate facility fees.

Example 1

The following is an example of how to determine the wage adjusted payment rate for CPT code 28230, Tenotomy, open, flexor; foot, single or multiple (separate procedure) performed at an ASC located in Denver, Colorado. The procedure is in APC group 271, Level I foot musculoskeletal procedures. The base rate for the procedure is \$510. The ASC wage index value for Denver, Colorado is 1.0386. The labor related portion of the base rate is \$192 (\$510 x 37.66 percent); the non-labor related portion of the base rate is \$318 (\$510 x 62.34 percent).

Wage Adjusted Rate:

 $= (\$192 \ x \ 1.0386) + \318

- = \$199 + \$318
- = \$517

Example 2

The following is an example of how to determine payment for CPT code 66984, Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g. irrigation and aspiration or phacoemulsification). The procedure is in APC group 668, Cataract procedures with IOL insert. The base rate for the procedure is \$863, which includes a \$150 IOL allowance. Because IOLs are not subject to adjustment for labor costs, the IOL allowance (\$150) must be subtracted from the composite payment rate before applying the wage index adjustment. The ASC wage index value

for Denver, Colorado is 1.0386. The labor related portion subject to wage index adjustment is 37.66 percent of the base rate from which the IOL allowance has been deducted.

Wage Adjusted Rate:

- $= [\{(\$863-150) \times .3766\} \times 1.0386] + [\{863-150\} \times .6234]$
- $= [(\$713 \times .3766) \times 1.0386] + [\$713 \times .6234]$
- $= (\$269 \times 1.0386) + \$444 \\ = \$279 + \444
- = 3279 += \$723
- Composite Adjusted Rate:
- = \$723 + \$150
- = \$873

9. Using Resource Costing to Determine Procedure Costs

Resource costing involves the measurement of all the direct and indirect costs involved in the performance of a specific procedure. Direct costs include all activities, materials, and equipment that are traceable to a specific procedure. Indirect costs, such as rent, utilities, and insurance, cannot be directly traced to a specific procedure. Rather, a factor such as units or time is used to allocate indirect costs uniformly at the individual procedure level.

We introduced the collection of resource cost data in the 1994 ASC survey primarily in response to industry recommendations that we do so on the grounds that procedure-specific cost studies measure facility resource expenditures more accurately and reliably than using a cost-to-charge ratio to convert procedure charges into a proxy for procedure costs. Part II of the 1994 ASC survey collected procedure specific statistical and resource cost data for the following 29 ASC procedures.

1. 14060 Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/ or lips; defect 10 sq cm or less.

2. 19120 Excision of cyst, fibroadenoma, or other benign or malignant tumor aberrant breast tissue, duct lesion or nipple lesion (except 19140), male or female, one or more lesions.

3. 28285 Hammertoe operation; one toe (e.g., interphalangeal fusion, filleting, phalangectomy).

4. 28292 Hallux valgus (bunion) correction, with or without sesamoidectomy; Keller, McBride or Mayo type procedure.

5. 29881 Arthroscopy, knee, surgical; with meniscectomy (medial or lateral including any menuiscal shaving).

6. 43235 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/

or jejunum as appropriate; complex diagnostic.

7. 43239 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/ or jejunum as appropriate; for biopsy and/or collection of specimen by brushing or washing.

8. 45378 Colonoscopy, fiberoptic, beyond splenic flexure; diagnostic procedure.

9. 45380 Colonoscopy, fiberoptic, beyond splenic flexure; for biopsy and/ or collection of specimen by brushing or washing.

10. 45385 Colonoscopy, fiberoptic, beyond splenic flexure; with removal of polypoid lesion(s).

11. 49505 Repair inguinal hernia, age 5 or over.

12. 50590 Lithotripsy, extracorporeal shock wave.

13. 52000 Cystourethroscopy (separate procedure).

14. 55700 Biopsy, prostate; needle or punch, single or multiple, any approach.

15. 56350 Hysteroscopy, diagnostic (separate procedure).

16. 58120 Dilation and curettage, diagnostic and/or therapeutic (nonobstetrical).

17. 62278 Injection of anesthetic substance (including narcotics), diagnostic or therapeutic; lumbar or caudal epidural, single.

18. 62289 Injection of substance other than anesthetic, contrast, or neurolytic solutions; lumbar or caudal epidural (separate procedure).
19. 64721 Neuroplasty and/or

19. 64721 Neuroplasty and/or transposition; median nerve at carpal tunnel.

20. 65730 Keratoplasty (corneal transplant); penetrating (except in aphakia).

21. 66170 Fistulization of sclera for glaucoma; trabeculectomy ab externo.

22. 66821 Discission of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); laser surgery (e.g.. YAG laser) (one or more stages).

23. 66984 Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or phacoemulsification technique (e.g., irrigation and aspiration or phacoemulsification).

24. 66985 Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal.

25. 66986 Exchange of intraocular lens.

26. 67010 Removal of vitreous, anterior approach (open sky technique or limbal incision); subtotal removal with mechanical vitrectomy. 27. 67036 Vitrectomy, mechanical, pars plana approach.

28. 67107 Repair of retinal detachment, one or more sessions; scleral buckling (such as lamellar excision, imbrication or encircling procedure), with or without implant, may include procedures 67101, 67105.

29. 67904 Repair of blepharoptosis; (tarso) levator resection or advancement, external approach.

We selected these procedures because they are either high volume ASC procedures (such as 66984, 66821, 52000) or they are procedures that include an unusual cost or service (such as 67036, 65730, 50590). We asked facilities to report typical resource utilization and cost information regarding time allocations, staffing patterns and labor costs, supply costs, and equipment costs on a procedurespecific, single case basis. In order to calculate an overall per procedure cost based on the resource cost data reported in the 1994 ASC survey, we first calculated a facility-specific procedure cost for each of the 29 CPT codes targeted in the 1994 ASC survey. We then determined the median procedure cost across all facilities, weighted by total volume. We also looked at weighting by Medicare volume. We used the same wage index values and inflation factors to adjust resource based cost data that we used to convert procedure charges to costs, as explained in the preceding sections.

Step a—To remove the effect of geographical wage differences, we divided indirect and direct labor-related procedure costs by the preclassification/pre-floor hospital inpatient prospective payment system wage index value applicable to the facility's location.

Step b-We calculated an overhead factor by which to step down indirect overhead costs to a single procedure level. To determine this factor, we summed the costs reported by a facility for its plant and property; office equipment; medical equipment other than procedure specific equipment; office and housekeeping supplies; wages and fringe benefits for administrators, directors, managers, supervisors, clerical, and other non-medical personnel; bad debt; and general administrative overhead such as taxes, insurance, and interest. We divided the facility's aggregated overhead expenses by the total number of procedures performed at the facility during the survey period. The resulting figure represents the amount of indirect overhead costs apportioned to each surgical case performed in the ASC.

Step c—We summed the costs incurred by the facility to furnish the disposable and reusable supplies, pharmaceuticals, equipment, and labor that it typically furnishes in connection with the procedure (direct costs).

Step d—We added the facility's procedure-specific direct costs (Step c) to the facility's indirect cost allocation (Step b).

Step e—We inflated the facility's procedure cost to July 1998 using the appropriate inflation factor.

Step f—To ascertain what it costs ASCs generally to perform the target procedures, based on audited direct and indirect costs, we determined the median cost across all facilities, weighted by total volume.

Analysis of Resource-Based Procedure Cost Methodology: We found that for 11 of the 29 target procedures for which we collected resource cost data, the per procedure cost was lower using resource costing than it was using a cost-tocharge ratio conversion, whereas for 18 of the 29 target procedures, the per procedure cost was higher using resource-based costing. Variations in procedure costs between the two methods were extreme, and for only 11 procedures was the resource-based cost within 20% of the cost-to-charge converted cost.

In seeking an explanation for the lack of consistency between resource costing and cost-to-charge conversion as a descriptor of procedure cost, we found resource cost data to be irretrievably flawed. We attribute the flaws in the resource cost data in part to the fact that the 1994 survey was our first attempt to capture resource costs. In spite of our efforts at clarity and several sessions in 1994 during which we met with ASC representatives to answer questions about the survey, the data reported indicate that our instructions were either misinterpreted or misunderstood altogether. In addition, we attribute the highly variable resource cost data to ASCs' lack of familiarity with the new survey form and to inconsistencies among ASC recordkeeping systems.

Our intent was for each facility to furnish a catalog or inventory of the direct resources it typically expends to perform each of the 29 target procedures. But in many instances the use of disposable and reusable supplies and pieces of equipment for the same procedure were reported inconsistently across facilities. Equipment required to perform a procedure was not listed or information reported about the useful life of equipment or its purchase price was not given, making it impossible to prorate the full cost of equipment to a single case. The unit cost of numerous items and services was omitted altogether or ASCs misinterpreted unit supply cost as the full cost of a single item or service, instead of prorating the full cost of an item or service to a single case. ASCs provided incomplete sets of resource cost data, e.g., labor costs for a procedure would be reported without the corresponding supply costs. Entries were illegible on several forms.

Because of the many problems encountered with reported resource cost data, we used only the audited data from the 96 facilities to compute resource cost. However, in many cases even audited surveys lacked direct resource cost data reported in the manner requested. Although we did consult resource cost data in our analysis of procedure costs and in assigning CPT codes to APC groups, we believe that shortcomings inherent in our resource cost data base and the limitation of cost data to only 29 codes preclude our relying on resource costing as a basis for setting payment rates at this time. Therefore, we have based the rates proposed in this notice on the methodology explained previously.

We are disappointed by our lack of success in the 1994 ASC survey in gathering usable resource cost data. Our inability to establish weights and base ASC payment rates on the resource cost data that we did collect is particularly frustrating in light of the fact that we expect, beginning January 1, 1999, to make payments to physicians under the Medicare physicians' fee schedule that are determined in part on the basis of resource-based practice expense relative units. We have been closely monitoring the development of the resource-based practice expense relative value units under the physicians' fee schedule and the ratesetting method for the hospital outpatient prospective payment system, which is also scheduled for implementation effective January 1, 1999. When we rebase ASC payment rates following the next ASC survey, we are committed to reexamining the resource-based practice expense relative value units established under the Medicare physicians' fee schedule and the weights developed under the hospital outpatient prospective payment system for their applicability to ASC ratesetting in order to advance towards our goal of setting rates in a manner that is consistent across different sites of service.

F. Scope of ASC Services (§ 416.21)

We are proposing to renumber § 416.61 to become § 416.21, and to clarify those items and services that we consider to fall within the scope of facility services for which payment is made as part of the ASC facility fee. In addition, this section of the regulation lists the types of items and services that are considered to fall outside the scope of ASC facility services, for which payment is not included in the ASC facility fee but for which payment could be made under other provisions of Medicare Part B. Recurring questions have prompted these changes, such as inquiries as to whether or not ASC facility services include fixation devices and orthopedic pins, fluoroscopy used to assist the surgeon's field of vision during surgery, electrocardiograms, the costs of procuring tissue for implant, and prosthetic implants.

1. ASC Services

We continue to consider the following to be ASC facility services: the services of nurses, technicians, and other staff involved in patient care; the patient's use of the facility, including but not limited to its operating room, recovery room, waiting room, rest rooms, locker area; administrative, recordkeeping, and housekeeping items and services that constitute indirect overhead expenses, including but not limited to employees and contracted services related to scheduling, admitting, discharging, and billing patients, to maintenance, utilities, laundry, debt service, plant and property costs, and insurance; and, intraocular lenses that are defined by the statute specifically as an ASC facility service. In addition, ASC services include medical and other health services such as surgical supplies, medical equipment, drugs, biologicals, and pharmaceuticals; materials for anesthesia, including the anesthetic itself and any equipment and supplies necessary to administer and monitor anesthesia; and, splints, casts, pins, wires, and other supplies used to reduce fractures and dislocations.

Current section 416.61(a)(4) states that facility services include "diagnostic or therapeutic services or items directly related to the provision of a surgical procedure." Section 416.61(b)lists as 'excluded services'', among other things, "X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure)." We have had a number of inquiries as to which diagnostic or therapeutic services are considered within the scope of ASC facility services and which are not. From a payment perspective the distinction is important, to determine if the diagnostic and therapeutic services can be paid for separately, in addition to the facility fee. In an effort to clarify the distinction, we have revised the regulation, and we propose to adopt the following policy. We assume that when

the descriptor for a CPT code includes explicit reference to some kind of imaging, guidance, or other diagnostic test, the cost, and therefore the ASC payment rate that we have derived for that procedure, include the imaging, guidance, or other diagnostic test, and those services are considered to be within the scope of ASC services. An example of such a procedure is CPT code 56362, Laparoscopy with guided transhepatic cholangiography; without biopsy. In the case of a procedure such as this, because the imaging is explicitly integral to and inseparable from the surgical procedure, it is considered within the scope of service and no separate payment is allowed for the imaging.

When the descriptor for a CPT code specifies "with or without" some kind of imaging, guidance, or other diagnostic test, we assume that the cost, and therefore the ASC payment rate that we have derived for that procedure, do not include the imaging, guidance, or other diagnostic test, and those services are considered to fall outside the scope of ASC facility services. Therefore, the ASC facility fee for the procedure would not include payment for costs incurred to furnish this type of monitoring. There are other procedures, such as CPT code 36533, Insertion of implantable venous access port, with or without subcutaneous reservoir, where the physician may or may not elect to use some type of imaging such as a fluoroscope to assist in placing the device. In such cases, we assume that the cost, and therefore the ASC payment rate for the procedure, do not include the imaging or guidance. In the case of these procedures, the imaging, guidance, or other diagnostic test is considered to fall outside the scope of ASC facility services, and the ASC facility fee does not include payment for the costs incurred to furnish these services.

Payment for the costs incurred by an ASC to perform any tests granted waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as part of preparing a patient for surgery on the day of surgery is included in the ASC facility fee for the surgical procedure, and no separate payment for these tests is allowed. If an entity that is approved by Medicare as an ASC also wants to be paid by Medicare for diagnostic laboratory services, other than tests granted waived status under CLIA, that entity must meet the laboratory requirements spelled out in 42 CFR Part 493. In this case, the entity would be considered a certified laboratory billing Medicare for certified laboratory services, not as a Medicare

approved ASC billing Medicare for ASC facility services. Classification as a certified laboratory or classification as a Medicare approved ASC is, for Medicare billing purposes mutually exclusive.

2. Venous Access Portals Are ASC Facility Services

In 1992 we began receiving communications informing us that the cost of certain models of implantable venous access ports that ASCs were furnishing in connection with CPT 36533, Insertion of implantable venous access port with or without subcutaneous reservoir, exceeded the total facility fee for the surgical implant procedure. Following a review of cost data available at the time, we instructed carriers to pay the acquisition cost of an implantable venous access port (HCPCS code A4300) as a temporary add-on to the ASC facility fee for CPT code 36533, even though the port is considered a supply, the cost of which would ordinarily be packaged in the ASC facility fee.

In this notice, we propose to place CPT code 36533 in APC 368. The payment rate proposed for CPT code 36533 includes an allowance for the cost incurred by an ASC to furnish A4300, Implantable access catheter (venous, arterial, epidural, or peritoneal), external access, or A4301, Implantable access total system; catheter, port/reservoir (venous, arterial or epidural), percutaneous access. Beginning on the effective date of the implementation of the rates and ratesetting methodology proposed in this notice, Medicare will cease to make a separate payment for implantable access catheters and/or ports furnished in connection with CPT code 36533 when the procedure is performed in an ASC. Alphanumeric codes A4300 and A4301 have a payment indicator "2," because the costs incurred to furnish these items, which are considered supplies, in connection with performing CPT code 36533 are considered to be within the scope of ASC services for which Medicare makes payment of an ASC facility fee.

We solicit comments on the adequacy of the payment rate for CPT code 36533 to offset the costs incurred to furnish the vascular access portal.

3. Acquisition of Corneal Tissue is an ASC Service

In 1992, ASC administrators and medical staff also pointed out a growing disparity between the payment amount established for corneal transplant procedures (CPT codes 65710, 65730, 65750, and 65755) and the costs ASCs were incurring to furnish corneal tissue, e.g., the charges imposed by eye banks and organ procurement organizations for processing, preserving and shipping corneal tissue. A review of the data that were the basis for setting the payment rates for corneal transplant procedures indicated that corneal tissue procurement costs had either not been reported or else had been imprecisely identified, and these costs did not appear to be reflected in the ASC payment rates established for corneal transplant surgery. Therefore, we instructed carriers to pay corneal tissue acquisition costs (HCPCS code V2785), subject to the usual copayment and deductible requirements, as an add-on to either the ASC facility fee or the supplying physician's fee for corneal transplant surgery performed in an ASC. The additional payment had to be supported by an invoice from an eye bank or organ procurement organization showing the actual cost of acquiring the corneal tissue.

In this notice, we propose to group corneal transplant procedures in APC 670. The payment rate for the procedures in APC 670 takes into account the costs of acquiring corneal tissue. Therefore, Medicare will cease to make a separate payment for corneal tissue procurement costs incurred in connection with CPT codes 65710, 65730, 65750, and 65755 when these procedures are performed in an ASC, beginning on the effective date of implementation of the rates and ratesetting methodology proposed in this notice. Alphanumeric code V2785 (Processing, preserving and transporting corneal tissue) has a payment indicator "2," because the costs incurred for this service are considered to be within the scope of ASC services for which payment is made as part of the ASC facility fee.

We solicit comments on the adequacy of the payment rate for the procedures in APC 670 to offset the costs incurred to procure corneal tissue in connection with performing corneal transplant surgery.

4. Outside the Scope of ASC Services

Historically, certain items and services that may be furnished in connection with surgery performed at an ASC have not been considered to fall within the scope of ASC services because payment for these items and services could be made under other provisions of Medicare Part B. None of the following is considered to be an ASC service, and Medicare does not include payment for these services in the ASC facility fee: Physicians' services, the services of certified registered nurse anesthetists, prosthetic devices and implants, durable medical equipment and supplies, artificial limbs, or braces.

As discussed above, diagnostic imaging services and other diagnostic tests are not considered to be ASC services and are not paid for as part of the ASC facility fee except when they are considered an integral and inseparable part of a surgical procedure by explicit reference or by universal agreement that they are standard medical practice as in the case of amniocentesis.

G. Basis for Payment (§ 416.30)

When an ASC furnishes services in connection with a procedure on the ASC list, Medicare pays a prospectively determined standard fee for those services. Section 416.22 of the ASC regulations proposed in this rule pertains to how we determine which procedures are safe, effective, appropriate, reasonable and necessary in an ASC and are therefore included in the ASC list. Section 416.21 of the proposed ASC regulations lists the services that are paid for within the ASC facility fee as well as describing services that might be furnished in connection with an ASC procedure but for which payment is not included in the ASC facility fee. Section 416.30 of the proposed ASC regulation is intended to delineate the differing bases by which Medicare can make payment for services furnished in connection with surgical procedures on the ASC list. Because of the manner in which the statute is written, the type of setting determines the basis for Medicare payment for services that are furnished in connection with procedures on the ASC list.

1. Hospital Outpatient Department (HOPD)

Section 1833(i)(3) of the Act provides that payment for services furnished in a hospital outpatient department in connection with procedures on the ASC list is to be based in the aggregate on a comparison between two amounts. The payment is to be the lesser of the following:

• The amount for services that would be paid to the hospital under section 1833(a)(2)(B) of the Act (that is, the lower of the hospital's reasonable costs or customary charges for the services, reduced by deductibles and coinsurance).

• An amount based on a blend of— The amount that would be paid to the hospital for the services under section 1833(a)(2)(B) of the Act reduced by deductibles and coinsurance (called the hospital-specific amount); and

—The amount paid to a Medicare approved ASC for the same procedure in the same geographic area in accordance with 1833(i)(2)(A) of the Act, which is equal to 80 percent of the standard overhead amount net of deductibles (the ASC amount). Under 1833(i)(3)(B)(ii) of the Act, the hospital specific amount and the ASC amount for portions of cost reporting periods beginning on or after January 1, 1991 are 42 and 58 percent, respectively.

Section 4523(a) of the Balanced Budget Act of 1997 (Pub. L. 105-33) requires that, beginning in 1999, the amount of Medicare payment for covered HOPD services shall be determined in accordance with a prospective payment system. This HOPD prospective payment system will replace the blended payment methodology for ASC procedures performed in an HOPD setting. It is not within the scope of this notice to describe or discuss the specific provisions of the hospital outpatient prospective payment system. However, consistent with our commitment to move toward a more unified, less fragmented approach to Medicare payment for surgical services performed on an ambulatory basis, we anticipate that there will be common elements in the Medicare ratesetting method and payment structure for surgical procedures performed in either an ASC, or in a hospital outpatient setting under the HOPD prospective payment system. These common elements include the principle of packaging payment for a range of services within a single payment rate; application of a multiple procedure discount; adjustment of base payment rates to take into account the effects of regional wage differences; and use of the same system of classifying or grouping surgical procedures for ratesetting purposes, e.g., the ambulatory payment classification system (APCS) which we discuss elsewhere in this notice. (Even though we expect to use a common grouping system to determine payment rates for both ASCs and hospital outpatient departments, note that we base ASC payment rates on cost and charge information taken from the 1994 ASC survey and that we will base hospital outpatient payment rates on data taken from 1996 Medicare claims for hospital outpatient services, on the most recently available hospital Medicare cost report information, and on projected Medicare expenditures in HOPDS in 1999.)

2. ASCs Operated by a Hospital

Our 1992 ASC survey revealed that hospital operated ASCs comprised only 3.1 percent of the 1081 ASCs from which we received completed surveys.² We propose to add an expanded definition of "hospital-operated ASC" to §416.2 to eliminate some of the confusion in terminology that seems to occur when distinguishing among ASCs, hospital outpatient departments, hospital affiliated ASCs, provider-based ASCs, etc. The term "hospital operated ASC" was coined originally simply to identify those ambulatory surgical centers that were already in existence in 1982 as part of a hospital and that wanted the option of participating in and being paid under the new ASC benefit rather than continuing to be paid on a reasonable cost basis as part of the hospital. In the August 5, 1982 Federal **Register**, we stated that if a hospital elected to have its ASC paid for ambulatory surgical services under the ASC benefit, that ASC would be subject to the same rules and regulations that apply to all ASCs approved under 42 CFR part 416, in addition to certain other restrictions directly related to the ASC's being owned and operated by a hospital. A hospital outpatient department providing ambulatory surgery would not be eligible to be paid as an ASC. (See 47 FR 34085.)

The regulations that apply solely to hospital operated ASCs are found in § 416.2 and § 416.30 of the revised ASC regulations that are proposed in this notice. We propose to continue the requirement that once an ASC operated by a hospital elects to participate in Medicare as an ASC rather than as a part of the hospital, that ASC will not have the option of reverting to be a component of the hospital unless HCFA determines there is good cause for it to do so. Costs for a hospital-operated ASC must be treated as a non-reimbursable cost center on the hospital's cost report.

We also propose to delete the requirement that a hospital operated ASC's agreement to participate as an ASC be made effective on the first day of the next Medicare cost reporting period of the hospital (42 CFR 416.30(f)(1)). We do not believe this would compromise either the interests of beneficiaries or the integrity of the Medicare program. This requirement imposes certain burdens, such as instances where a hospital's cost reporting period does not begin until many months after its ASC opens for business. We invite comments on whether this requirement is superfluous and should therefore be removed from the regulations.

3. Medicare Approved ASCs

The statute at 1832(a)(2)(f) authorizes Medicare to pay ASCs a prospectively determined fee for facility services furnished in connection with surgical procedures on the ASC list. Since 1982, HCFA has defined facility services as items and services which would otherwise be covered under Medicare if furnished on an inpatient or outpatient basis in a hospital in connection with the ASC covered procedure, excluding items and services for which payment may be made under other provisions of Medicare Part B. (See the Federal Register dated August 5, 1982 (47 FR 34097).) It is these items and services, e.g., the items and services that would be covered under Medicare if they were furnished on an inpatient or outpatient basis in a hospital in connection with a surgical procedure, for which we make payment as part of the ASC facility fee, and any service for which we include payment in the ASC facility fee is considered an ASC service. As a matter of policy, we have generally not included, as part of the ASC facility fee, payment for items and services explicitly identified in the Act as a Medicare Part B benefit for which separate payment is made, although we have made a few exceptions. In summary, we exclude from the Medicare definition of an ASC facility service any item or service for which payment is not included in the ASC facility fee or any procedure not on the ASC list, even if the item, service or procedure is furnished at the ASC in connection with a procedure that is on the ASC list. Section 416.21 of the proposed ASC regulations distinguishes between services for which payment is included in the ASC facility fee and services for which payment is not included in the ASC facility fee.

We have received numerous inquiries from ASCs asking how Medicare pays for certain services that they furnish to Medicare beneficiaries in connection with a procedure on the ASC list when Medicare does not include payment for those services as part of the ASC facility fee. We have added § 416.30(d)(2) to emphasize that excluding payment for certain services and procedures from the ASC facility fee does not preclude payment to the ASC for those services and procedures, presupposing they are covered and reasonable and necessary, under other provisions of Medicare Part B. Examples of the kinds of services furnished at an ASC in connection with an ASC procedure, for which payment is not included in the Medicare ASC facility fee, are the professional services of physicians and certified registered

nurse anesthetists, prosthetic implants, or certain diagnostic X-ray and imaging services and other diagnostic tests such as ultra sound. ASCs have asked us how they can recoup the costs they incur to furnish facility services (e.g., those expenses embodied in the technical component (TC) established for diagnostic X-ray and other diagnostic tests under the Medicare physicians' fee schedule) for diagnostic electrocardiograms or fluoroscopy or ultrasound diagnostic procedures. As discussed in Section III.F, when diagnostic X-rays, imaging, or other diagnostic tests are explicitly referenced in a CPT code descriptor, they are considered integral to the surgery and are therefore paid for within the ASC facility fee. Otherwise, in order to be paid separately for services that are furnished in connection with procedures on the ASC list that are not ASC services, the Medicare participating ASC must also be recognized and obtain Medicare approval and billing privileges as a supplier of these other services.

One example of the multiple Medicare payment modalities that could affect how an ASC is paid by Medicare is the manner in which Medicare would pay for transperineal ultrasound guided seed implants for prostate cancer performed at a Medicare approved ASC. There is a surgical component to this treatment, CPT code 55859, Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy. We are proposing to add this procedure to the ASC list in APC group 523. Once the surgical procedure is added to the ASC list, Medicare would allow payment to an ASC for facility services furnished in connection with CPT code 55859. If cystoscopy services were required, and the relevant cystoscopy codes were on the ASC list, Medicare would allow an ASC facility fee for the cystoscopy procedure(s), subject to the multiple procedure payment rules found in proposed §416.30(d)(4). The other procedures and services performed to furnish this treatment fall within the radiology range (70000-79999) of CPT. Since radiology procedures are not included on the ASC list, there is no basis for Medicare to make payment to an ASC for brachytherapy services. However, if the facility were to obtain supplier numbers from its carrier indicating that the carrier recognizes the facility both as a non-physician supplier of radiology services and as a freestanding radiation therapy center, the facility should be able to bill for and

²U.S. Department of Health and Human Services, Health Care Financing Administration, *Medicare Ambulatory Surgical Center Payment Rate Survey— 1992: Part I, General Information Summary of Data.* Baltimore: July 1994.

be paid the technical component for brachytherapy services within the radiology range under the Medicare physicians' fee schedule.

Similarly, if a Medicare approved ASC were to furnish diagnostic X-ray and other diagnostic tests in connection with performing a procedure on the ASC list, such as visualizing the preoperative placement of needle localization wires, and if payment for those services is not otherwise included in the ASC facility fee as signified by an ASC payment policy indicator "2," the facility could be paid the technical component provided for those services under the Medicare physicians' fee schedule as long as it meets the requirements for independent diagnostic testing facilities (IDTFs). The regulations at 42 CFR 410.32 and 42 CFR 410.33 published in the October 31, 1997 Federal Register (63 FR 59098) and implemented January 1, 1998 explain the IDTF requirements.

A Medicare approved ASC that is also approved as a supplier of durable medical equipment (DME), prosthetics, and orthotics can be paid the allowed Medicare fee schedule amount when it furnishes these items. We believe that many ASCs are not aware that Medicare payment for prosthetic implants in particular is separate from the ASC facility fee. Prosthetics and durable medical equipment are coded using alphanumeric HCPCS codes; the codes for prosthetic implants begin with code L8500. Claims for prosthetic implants are processed by local carriers; claims for orthotics and DME are processed by durable medical equipment regional carriers (DMERCs). ASCs wishing to be recognized as a supplier of prosthetics, orthotics, and/or durable medical equipment should contact the National Supplier Clearinghouse (NSC), Palmetto Government Benefit Administrators, P.O. Box 100141/300 Arbor Lake Drive, Columbia, South Carolina 29202-3143, FAX 317-841-4600, to obtain further information and an application.

As we explained in section III.D above, we propose to establish that procedures with any of the criteria in §416.22(b) are not safe and appropriate in an ASC. We have determined that such procedures are not reasonable and medically necessary when performed in an ASC. Therefore, we propose to add § 416.30(d)(3) to the ASC regulations to clarify that denials for such procedures, designated by ASC payment policy indicator "3," are based on the exclusion contained in section 1862(a)(1)(A) of the Act, and contained in 411.15(k)(1); that is, the services "are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." Beneficiaries are protected from liability for claims denied on this basis by the limitation on liability provision of section 1879 of the Act.

If an ASC facility fee is denied for a procedure because the procedure is not reasonable and necessary in an ASC, logic dictates that payment be denied for any other services furnished in connection with that procedure because those other services would also have to be considered not reasonable and necessary. Therefore, as a matter of policy, we propose to instruct carriers to deny payment for physicians' services, including anesthesiologists, or certified registered nurse anesthetist (CRNA) services, prosthetic implants, imaging services, etc., when such services are furnished at an ASC in connection with a surgical procedure that is excluded from the ASC list.

H. Extracorporeal Shock Wave Lithotripsy (ESWL)

1. Background

On December 31, 1991 we published a final notice with comment period in the **Federal Register** (56 FR 67666) in which we added CPT code 50590, Lithotripsy, extracorporeal shock wave (ESWL), to the list of ASC covered procedures. We set the payment rate for ESWL at \$1,150 on the basis of a procedure cost matrix model. A new payment group 9 was created solely for ESWL. Payment of a facility fee for ESWL as an ASC covered procedure was effective for services furnished beginning January 30, 1992.

On January 30, 1992 the American Lithotripsy Society (ALS) filed a complaint and motion to preliminarily enjoin enforcement and implementation of the December 31, 1991 notice insofar as it concerned ESWL. In American Lithotripsy Society v. Louis W. Sullivan, M.D., et al. 85 F. Supp. 1034 (D.D.C. 1992), the plaintiff challenged HCFA's determination that ESWL is a surgical procedure under the ASC benefit and the amount payable for the services in an ASC setting. The plaintiff alleged that the \$1,150 rate was not based on an estimate of "a fair fee" which took into account costs incurred by ASCs performing such services as required by section 1833(i)(2)(a) of the Act and that the rate was not supported by the administrative record.

On March 12, 1992, the United States District Court for the District of Columbia held that HCFA's decision to classify ESWL as a surgical procedure was reasonable. However, it remanded the rate-setting issue in the December 31, 1991 notice to the Secretary for further consideration and stayed the regulation, insofar as it related to lithotripsy, pending remand. On remand, the Secretary is required to publish all material information that is relevant to the setting of the ESWL rate, receive comments, and publish a final notice in accordance with the applicable statutes and regulations.

On March 19, 1992 we asked our regional offices to instruct carriers and intermediaries to cease payments to Medicare participating ASCs for ESWL services and to resume calculation of payments for ESWL services furnished in a hospital outpatient setting on a reasonable cost basis.

On October 1, 1993, we published a proposed notice in the **Federal Register** (58 FR 51355) in which we proposed an ASC payment rate of \$1,000 for ESWL along with the data and the methodology used to determine that rate, in accordance with the court's remand. The public comment period that was to end on November 30, 1993 was extended to December 30, 1993. (See **Federal Register** (58 FR 62128) dated November 24, 1993.)

We received timely 141 comments about the October 1, 1993 proposed notice. Commenters included certified renal lithotripsy specialists; physicians, nurses, administrators, and attorneys representing urology and lithotripsy specialty clinics and centers; hospitals; physician clinics and group practices; mobile lithotripsy suppliers; ambulatory surgical centers; a regional multihospital cooperative stone treatment service; and, professional societies and trade associations. Six commenters submitted information on ESWL costs, charges, and utilization following the format that we requested. In addition, ALS submitted in support of its comments a study entitled Proposed Payment for Extracorporeal Shock Wave Lithotripsy Services Furnished by Ambulatory Surgical Centers that was prepared by The Moore Group of Washington, D.C.

We have been considering the information contained in the comments that were submitted during the public comment period. Virtually every commenter objected to our proposed \$1,000 ESWL payment rate, the methodology and cost model that we used to set the rate, and the assumptions upon which we based the ratesetting methodology and cost model, stating that we had failed to take into account, as required by the statute, the costs incurred by facilities to furnish ESWL services. The comments raised enough question about the appropriateness of certain of the assumptions upon which

we had based the payment rate proposed in the October 1, 1993 Federal **Register** to cause us to defer setting a final ESWL rate until we had completed our survey of ASCs that we had already scheduled to begin in March 1994. That survey, entitled "The Medicare Ambulatory Surgical Center Payment Rate Survey—1994, Part II: Facility **Overhead and Procedure Specific** Costs," is described elsewhere in this notice. We made a point of including CPT code 50590 in the list of codes for which we solicited charge, utilization, and resource cost data, even though payment of a Medicare ASC facility fee for ESWL had been under remand since March 12, 1992.

The ASC payment rate that we propose in this notice for ESWL (CPT code 50590) supersedes the rate we proposed in the October 1, 1993 Federal **Register**. We followed the ratesetting methodology that is the subject of this notice to determine the ASC payment rate for ESWL. In addition to reviewing information on ESWL submitted in the 1994 ASC survey, we also took into consideration the cost data and comments submitted during the public comment period following publication of the October 1, 1993 Federal Register. All material information that is relevant to setting the rate for every ASC covered procedure contained in this notice, including but not limited to ESWL, is published herein, with the exception of our 1994 ASC survey data, which we explain how to obtain separately. Our response to comments received timely and the final notice published in accordance with applicable statutes and regulations will therefore address the rate set for ESWL services within the context of the other proposals contained in this notice.

Below is our response to the comments that were submitted timely following publication of the October 1, 1993 proposed notice.

2. Comments

Comment: The American Lithotripsy Society (ALS) commented that it continues to disagree with classifying ESWL as a surgical procedure and that it believes that ESWL does not belong on the ASC list.

Response: We do not agree with the position taken by ALS on this point. We believe that ESWL is a procedure that is appropriate for the ASC list in light of the criteria we are proposing in this notice (proposed 42 CFR 416.22). We explained our reasoning for considering ESWL appropriate for the ASC list in the final notice with comment period published December 31, 1991 in the **Federal Register** (56 FR 67673), and the

federal district court found that we had rationally justified and properly noticed our decision to classify ESWL as a surgical procedure (*American Lithotripsy Society* v. *Sullivan*, 785 F. Supp. 1034, 1037 (D.D.C. 1992). We therefore propose to retain ESWL on the ASC list in APC group 527.

Comment: Every commenter objected to the \$1,000 payment rate that we proposed for ESWL services furnished in a Medicare participating ASC as being inadequate, unfair, and far below the actual cost of providing ESWL services. One commenter charged that HCFA was using the rate-setting process as a device to eliminate what HCFA viewed as underutilized facilities. Other commenters predicted that Medicare beneficiaries would be denied access to the ease and convenience of ESWL treatment of kidney stones if we were to implement a \$1,000 ASC facility fee for ESWL because ESWL suppliers could not afford to treat Medicare patients for this amount. Another commenter complained that HCFA's proposed facility fee would deprive lithotripsy facilities of a substantial portion of the lithotripsy market and adversely affect the hospitals, physicians, and others who had invested substantially in ESWL facilities with the expectation that overhead costs would be fully reimbursed by a Medicare payment rate based on actual costs.

Most commenters also challenged the cost model matrix and the assumptions underlying the model that we used to calculate the \$1,000 payment rate proposed in the October 1, 1993 Federal Register. One commenter attributed our proposed rate to an "impractically high utilization rate" combined with "an unrealistically low estimate" of the costs involved in performing an ESWL treatment. Commenters claimed that we ignored information submitted by the actual providers of ESWL services, relying instead on outdated studies and obsolete information from 1985, 1986, and 1987 when lithotripsy was first introduced and furnished primarily on an inpatient basis, or substituting our own judgment of what the facility fee should be without considering survey data that revealed the actual costs of performing the procedure, as required by the statute. In particular, commenters challenged our assumptions about optimal utilization levels and the number of procedures that could be performed in one day (too high); capital costs (understated); fixed costs (attributable to our understatement of the staff required to provide ESWL services in addition to pre-and posttreatment care and to be in compliance with state regulatory requirements); our

allowance for supplies (too low, especially for the disposable electrodes); and, our allowance for indirect overhead costs (unrealistically low, especially because lithotripsy centers perform only one procedure, which prevents them from offsetting losses from ESWL by performing other more lucrative procedures).

Every commenter urged us to review or revise the proposed rate to bring it more in line with actual expenses, which they asserted ranged from \$1,911 to as much as \$3,674, as validated by urologists and actual providers of ESWL services. Many commenters recommended that we adopt as the basis for a Medicare payment amount for ESWL services the findings and data contained in a report prepared by The Moore Group at the behest of The American Lithotripsy Society (ALS) and its counsel, Dyer, Ellis, Joseph & Mills. One commenter said the ALS survey and The Moore Group report would no longer allow HCFA to use the lack of cost data as a rationale for relying on the cost model contained in the October 1, 1993 proposed notice. The same commenter said that if HCFA was unwilling to use the ALS survey data as the basis for setting an ESWL rate, HCFA should not adopt a payment rate until it conducted its own survey of providers to determine a fair fee based on the costs derived from that survey. This commenter urged HCFA, as a last resort, to hold a formal hearing before implementing its proposed rate if HCFA would not adopt the ALS survey data or collect its own survey data.

The report prepared by The Moore Group for ALS is entitled "Proposed Payment for Extracorporeal Shock Wave Lithotripsy Services Furnished by Ambulatory Surgical Centers" and is based on the results of a survey conducted by ALS. (This report was prepared for Dyer, Ellis, Joseph & Mills, 600 New Hampshire Avenue, NW. Washington, DC 20037, telephone (202) 944-3000 by Lois A. Ehle, The Moore Group, 1212 New York Avenue, Suite 475, Washington DC 20005, telephone (202) 789-0045.) ALS sent the survey 'American Lithotripsy Society Shock Wave Lithotripsy Survey") to its membership. In addition, according to the introduction to the report, Dornier Medical Systems and Siemens Medical Systems, lithotripter manufacturers, sent the ALS survey to users of their equipment. Counsel for ALS collected survey responses and forwarded them to The Moore Group, which analyzed the responses and prepared the report. The report is based on information submitted by 105 of the 110 providers that returned a completed survey

representing approximately one third of the providers that received the survey. The report is dated December 15, 1993, and it was enclosed with comments submitted by ALS during the extended public comment period following publication of the October 1, 1993 proposed notice.

The Moore Group report concluded that HCFA's cost matrix model understated the capital, fixed, and variable costs associated with ESWL services with the result that HCFA's proposed payment rate of \$1,000 understated by 43 percent the \$2,326 average cost incurred by ESWL providers based on analysis of the ASL survey responses.

Response: The information submitted by commenters to the October 1, 1993 proposed notice has convinced us to defer implementing a \$1,000 ASC facility fee for ESWL services. We considered adopting as an interim payment rate the average cost per treatment arrived at by The Moore Group (\$2,326), but we ultimately decided not to do so for several reasons. Our principal reservation was related to the fact that of the 49 fixed lithotripter sites responding to the ALS survey, only five were actually identified as "Medicare approved" ambulatory surgical centers (ASCs), and only 30 of the 437 mobile sites for which data were reported were identified as ASCs. Our charge is to set rates for ambulatory surgical centers, as defined in the statute at Section 1832(a)(2)(F) and in regulations at 42 CFR part 416, and those rates, as so many commenters pointed out, are to take into account the costs incurred by ASCs generally in providing services in connection with procedures on the ASC list. While the ALS survey points to costs incurred by lithotripsy suppliers generally, including fixed and mobile sites and hospitals and "freestanding" centers, we could not isolate the ALS survey data as contained in The Moore Group report to costs incurred solely by ASCs.

One commenter said that if we were unwilling to use the Moore Survey, we should then, at the very least, conduct our own survey of providers to determine a fair fee for ESWL rather than implement the payment rate based on the cost model proposed in the October 1, 1993 Federal Register. As it happened, we had scheduled a survey of ASC costs, charges, and utilization generally for early 1994, our first such survey since 1986. Therefore, we decided to follow the commenter's recommendation, and we included ESWL services as a part of the Medicare ASC survey that went out in March 1994, the data from which are the

foundation for the rebased payment rates proposed in this notice. We followed the ratesetting methodology explained in this notice and, taking into account the comments submitted following publication of the October 1, 1993 proposed notice as well as information submitted through our 1994 survey, we determined a payment rate of \$2,107 (APC 527) for ESWL services furnished by a Medicare participating ASC.

We believe this is a reasonable payment amount because it approximates the average per procedure costs reported in comments to the October 1, 1993 proposed notice, including The Moore Group study of the ALS survey results, and costs derived from the 1994 Medicare survey of ASCs; and, it takes into account costs incurred by fixed as well as mobile lithotripsy delivery systems. It implicitly acknowledges the utilization levels pronounced as typical by commenters and The Moore Group and rewards facilities that maintain or exceed those utilization levels while serving as an incentive to facilities with lower utilization to improve their volume. Further attesting to the reasonableness and reliability of the payment rate proposed in this notice is the fact that it was determined in accordance with a systematic, data-oriented, comprehensive ratesetting methodology applied to more than 2400 surgical procedures rather than on the basis of an interim ratesetting methodology that was developed to fill an immediate need resulting from a lack in 1991-92 of current, reliable, disinterested data on lithotripsy costs.

Comment: One commenter wondered why we accepted cost data from ASCs to revise payment rates in February 1990 (55 FR 4526), and from payers like Blue Cross/Blue Shield and lithotripter manufacturers to support the cost model we proposed in the October 1, 1993 **Federal Register** (58 FR 51355), but refused to consider data submitted by lithotripsy providers.

Response: We did consider the data submitted by commenters following publication in the **Federal Register** of our proposed notice in October 1, 1993 (58 FR 51355), and our analysis of those comments resulted in our not implementing the October 1, 1993 proposed rate of \$1,000 pending completion of the 1994 Medicare ASC survey. In some cases such as the matter of ESWL treatment time and general ESWL utilization levels, we have reversed our earlier proposals on the basis of information and data submitted by commenters. *Comment:* One commenter stated that, in order to be considered a "fair fee," the average cost of ESWL services reported by The Moore Group (\$2,326) would have to be increased to offset three additional costs: payment for preand post-treatment services provided by a host hospital or ASC when ESWL is furnished by a mobile lithotripter; payment to offset bad debt; and, payment to provide a reasonable return on equity capital.

Response: We disagree. Our reading of the report indicates that the ALS survey and The Moore Group study took such costs into account in the calculation of an average per treatment cost. The data reported in the 1994 Medicare ASC survey would have reflected pre- and post-operative costs and bad debt. Medicare policy precludes payment allowances to provide a return on equity capital for facilities paid by a prospective payment system because it diminishes the incentive for efficient operation (47 FR 34082, 34089)

Comment: One commenter criticized our use of the CPI-U All Items Index as a measure of the effect of inflation on health care costs and our applying that factor to historical data to produce an estimate of current costs.

Response: We see no compelling argument to depart from the rationale we gave in the February 8, 1990 **Federal Register** (55 FR 4537), in which we implemented the eight payment rates that were rebased using 1986 survey data, for using the consumer price index for all urban consumers, all items index. The fact that 141(a)(1)(B)of SSAA 1994 mandated that we use the CPI-U to update ASC rates during years when we do not rebase rates using survey data makes it difficult to justify switching to a different inflationary adjustment during years when we rebase rates.

Comment: One conclusion of The Moore Group report is that HCFA's cost matrix model overstates the maximum amount of time a lithotripter can be used each year and the number of treatments that can be reasonably performed each year. Numerous commenters echoed the sentiment that basing the ESWL payment rate on a utilization level of performing 1,000 procedures annually or an average of four treatments per day was unreasonable and impractically high. One commenter noted that treatment volume is determined more by the number of patients with kidney stone disease than on the availability of "efficient" equipment. Another commenter wrote that most ASCs wishing to provide lithotripsy services will utilize a mobile lithotripter unit because few ASCs will ever have the

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volume necessary to keep a lithotripter busy at maximum possible utilization. Commenters reported annual utilization levels ranging from as few as 65 treatments to as many as 1,200 treatments, and daily utilization of no more than two procedures per day to five or six a day if the "day" were extended into the evening hours. The Moore Group report indicated that an average of seven hours was required from patient pre-admission until discharge, which was cited by other commenters as the reason why it was unrealistic to expect more than two treatments to be performed in one day. The Moore Group study also indicated that 42 of the 105 providers that returned ALS surveys performed between 400 and 700 procedures per year, accounting for 44 percent of the total cases reported by respondents to the ASL survey, with an average annual treatment level of 519. One commenter asserted that no facility actually does 1,000 cases per year. Another conceded that while six patients could indeed be treated in the course of a single day, factors important to quality care might be sacrificed. One commenter said that five to six treatments could easily be furnished in a single day, but that the length of the day would have to be extended beyond eight hours. Most commenters favored approximately 500 treatments annually as a more realistic utilization level based on their own experience. Two commenters observed that the rapid diffusion of ESWL in the 1980's had resulted in market saturation so that each lithotripter has a smaller number of patients to serve, and another commenter noted that with more than 300 lithotripters in operation, demand per machine would naturally be lower. The same commenter further objected to HCFA's basing its utilization standard for ESWL services that are furnished predominantly in outpatient settings on a 1985 Blue Cross/Blue Shield study of six investigational lithotripters that were involved in the FDA approval process and that furnished treatments strictly on an inpatient basis.

Response: Based on the comments we received and data reported in the 1994 Medicare survey of ASCs, we agree that in the early 1990's, most lithotripsy providers were probably performing only half to two-thirds of the number of treatments we assumed as an efficient annual utilization level when we proposed a payment rate of \$1,000 in the October 1, 1993 **Federal Register**. The payment rate that we are proposing in this notice for APC group 527 is more compatible with utilization levels reported by commenters and suggested

by 1994 ASC survey data. However, we emphasize that HCFA has a fiduciary responsibility to the Medicare program and its beneficiaries that compels us to promote and reinforce the efficient use of shrinking resources. We cannot condone paying for per treatment costs that are inflated by idle or underutilized equipment which is the result of redundancy. We believe that the rate we propose in this notice for ESWL services is reasonable and that it allows generously for volume levels declared by the industry to be standard without encouraging further proliferation of ESWL services in a market that is acknowledged to be at the saturation level.

Comment: Most commenters indicated that our estimate of 30 or 45 minutes to an hour as the amount of time required to administer ESWL and disintegrate the stone(s) was too low. While the Moore Group report shows a mean treatment time of 113 minutes, most other commenters indicated that 80 to 90 minutes was typically required for the actual ESWL treatment. Several commenters noted that, contrary to our supposition, treatments using newer lithotripters actually require more time than did the older generation of lithotripters because the newer lithotripters require a greater number of lower voltage shocks to be administered, depending upon the patient's heart rate.

Response: We agree that the length of time required to administer an ESWL treatment generally exceeds the 30 to 60 minutes we suggested in the October 1, 1993 notice. The information submitted by commenters, further supported by data collected in the 1994 Medicare ASC survey, indicates a mean treatment time of 82 to 113 minutes with a median treatment time of 89 to 110 minutes.

Comment: Several commenters stated that HCFA's cost matrix model does not include the cost of cystoscopy or any stent placements.

Response: We stated in the October 1, 1993 notice that the costs associated with the cystoscope procedure that frequently accompanies ESWL (CPT code 52332, Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type) were not included in the cost model for ESWL. When this procedure is performed in conjunction with ESWL (CPT code 50590), the ASC submits a claim for both procedures. In accordance with Medicare payment policy when multiple procedures are performed in an ASC, Medicare pays the full usual and customary facility fee for the procedure with the highest payment rate (CPT code 50590 in this case) and 50 percent of the usual and customary facility fee

for the procedure(s) with a lower payment rate (CPT code 52332 in this case). The payment rate we are proposing in this notice for CPT code 52332 (APC 523) is \$504.

Comment: Several commenters disagreed with our estimate of 16 percent Medicare utilization and suggested annual Medicare procedure volume ranging between 12 percent and 45 percent, the latter volume occurring in an area with a high retirement population.

Response: Our 1994 survey data indicate that Medicare beneficiaries account for 16.5 percent of total volume for ESWL services furnish in an ASC setting.

Comment: A few commenters wrote that HCFA's study fails to account for the special staffing, travel, and set-up costs incurred when a mobile unit is used to furnish ESWL services.

Response: Our October 1, 1993 cost model may not have fully recognized costs unique to mobile ESWL services. However, based on data submitted in the 1994 Medicare ASC survey, we believe that the payment rate we are proposing in this notice does take mobile unit costs into account.

Comment: One commenter stated that an increase in the number of mobile ESWL units threatens the continued viability of provider based facilities. Another commenter wrote that volume at a free-standing lithotripsy center is expected to decrease due to implementation of a mobile unit in a neighboring state.

Response: We recognize that an increase in the number of mobile ESWL units could reduce patient volume at fixed ESWL sites. We do not have current data to indicate the ratio of mobile to fixed ESWL units nationally or by state or region nor can we evaluate the extent to which increased numbers of mobile units represent redundancy in areas with existing adequate ESWL services or are a response to a demand for ESWL services in underserved or remote areas.

Comment: One commenter disagreed with our proposal that ASC facility payment be denied for bilateral ESWL renal treatment, preferring that the decision be left to the treating urologist who is in the best position to weigh the risks to his/her patients of performing one or multiple ESWL treatments in cases where there are small symptomatic stones in both kidneys.

Response: In the absence of medical evidence arguing otherwise, we propose to withdraw our October 1, 1993 proposal to deny payment for bilateral ESWL renal treatment.

Comment: Three commenters addressed our proposal to enlist the medical directors for Medicare carriers and intermediaries to develop procedure protocols and to define the indications for ESWL treatment. The commenter asserted that indications and contraindications for treating patients with ESWL are already well established in the urological and lithotripsy literature. One commenter urged that experienced urologists who have an established reputation for clinical expertise in urology and lithotripsy be enlisted if general guidelines for ESWL are to be developed. One commenter wrote that a five percent re-treatment rate doesn't suggest abuse of a type that would justify creation of indicators in the first place.

Response: In the absence of support from the provider community and having no evidence that ESWL is being performed excessively or is medically unnecessary for Medicare beneficiaries with kidney stones, we propose to defer our October 1, 1993 proposal to sponsor the development of procedure protocols and indicators of ESWL treatment.

Comment: A few commenters said it was not fair to base ESWL costs on a multi-specialty ASC that can spread overhead costs over many different procedures whereas ESWL is most often provided in single-service fixed-site or mobile units. Another commenter noted that the costs of providing ESWL in a free-standing ambulatory care facility cannot be deferred to other areas or services as they can in a full service hospital. Two commenters stated that HCFA, by asking for data on costs, charges and utilization for ESWL performed on an outpatient basis, was failing to differentiate between freestanding and hospital-based facilities, each of which furnishes ESWL services on an outpatient basis, but each of which may have very different operational costs. One commenter said that HCFA should consider implementing different overhead amounts and payment rates for different classes of centers because costs differ depending on whether ESWL treatment is furnished at a fixed lithotripsy center site, by a mobile unit, or by a multispecialty ASC

Response: We specifically requested data for outpatient ESWL services, whether furnished by a hospital, by a freestanding ESWL facility, by an ASC, or by a mobile unit, to distinguish these from inpatient ESWL services.

Based on the comments we received, we acknowledge that "outpatient" ESWL services can be furnished in a variety of forms. The rate we propose in this notice does not distinguish among the various possible types of ESWL service delivery settings partly because we do not have data to support a correlation between the cost of ESWL services with the type of site that furnishes those services and partly because our responsibility is to set a facility payment rate for ESWL services furnished by Medicare participating ASCs. The statute does not include a separate benefit for suppliers of ESWL services.

We are not aware of any mobile lithotripters that have been certified as a Medicare participating ASC. Rather, mobile lithotripters are, as a rule, contracted by ASCs or by hospitals, clinics, or other entities to furnish a lithotripter and the actual lithotripsy treatment by arrangement to a patient of the "host" entity. The most efficient utilization of mobile lithotripters seems to result when pre-operative patient preparation and post-operative recovery services are furnished by the host entity, freeing the lithotripter conveyance for the next patient. The unusual capital costs of ESWL are reflected in its being assigned to a dedicated APC group, but the fact that ESWL services can be furnished in virtually any type of setting as a consequence of the lithotripter's mobility makes it impossible to lump all lithotripsy suppliers together as a "class" of ASCs. Further, in the absence of data to support that ESWL costs are a direct function of the type of facility where the treatment is furnished, we believe that our proposed rate is fair and reasonable and takes into account the costs incurred by ASCs generally to furnish ESWL services, either directly or by arrangement.

We believe that the argument can just as well be made that single specialty ESWL providers, because they focus on only one type of procedure, can defray costs by increasing volume and by being more efficient than other providers that furnish ESWL only on an irregular basis. If sufficient volume cannot be generated due to the increase in patient access to lithotripsy services, as one commenter observed to be the case, the supply of lithotripters combined with their mobility may exceed the demand for single specialty, fixed ESWL suppliers in high saturation areas. We noted above our determination to avoid establishing Medicare payment policy that stimulates redundant services, which in turn typically result in inflated per procedure costs.

Comment: One commenter asked how payment for CPT code 52337— Cystourethroscopy, with ureteroscopy and/or pyeloscopy (includes dilation of the ureter and/or pyeloureteral junction by any method); with lithotripsy (ureteral catheterization is included) would be affected by the proposed ESWL payment scheme.

Response: Based on the ratesetting methodology proposed in this notice, CPT code 52337 is in APC group 524. The payment rate proposed for that group is \$1,131.

Comment: Capital and operating expenses vary significantly from region to region and cannot be reasonably represented with broad based adjustment factors. Do HCFA/Medicare geographic adjustment guidelines take variations in capital and operating expenses into account?

Response: No. The adjustment to ASC payment rates that Medicare makes to offset geographic differences applies only to differences in labor costs.

I. Schedule and Publication of Updates

Section 1833(i)(1) of the Act requires that the ASC list be reviewed and updated at least biennially, and section 1833(i)(2) requires that ASC payment rates be updated annually. Section 141(a)(1)(B) of SSAA 1994 added paragraph (C) to section 1833(i)(2), requiring that ASC payment rates be increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U), beginning in fiscal year 1996, during years when the rates are not updated in accordance with survey data. In the Federal Register notice published on December 31, 1991 (56 FR 67666), we tied ASC rate updates with the annual update of the PPS wage index and we said that we would coordinate rate updates with the ASC list update. In subsequent years, we have succeeded in implementing ASC rate updates resulting from a CPI-U adjustment to coincide with implementation of the annual update of the PPS wage index, but we have been less successful in coordinating the rate updates with the list updates, in part because the ASC list updates have tended to be more closely related to the calendar year revisions of CPT than to PPS wage index changes.

1. Update of ASC List There are two ways in which HCFA updates the ASC list. First, we modify the list to reflect the annual changes made to CPT and alphanumeric HCPCS codes. For example, if the American Medical Association (AMA) deletes from CPT a code that has been on the ASC list, we remove the code from the ASC list. In some cases, AMA modifies the descriptors of CPT codes or creates a new code to replace a deleted code. We have always incorporated these changes into the ASC list. In order to make the CPT changes in as timely a manner as possible, we have instructed

carriers directly to modify the ASC list to conform with the CPT changes without first publishing a notice in the **Federal Register** to announce what the changes will be. We have felt justified in by-passing the **Federal Register** because the annual CPT changes have been more editorial than substantive. And we eventually list these changes in the next **Federal Register** notice that is

published on the subject of the ASC list. When we review the ASC list against the standards for determining whether or not procedures are appropriate for the ASC setting or to determine if a code describing an altogether new procedure should be added to the ASC list, we go through the **Federal Register** notice and comment process to furnish an opportunity for public comment on additions to or deletions from the list that we propose to make. We also incorporate into these notices recommendations for change that we receive between updates to the list.

We propose to replace § 416.65(c) in the current ASC regulations with new § 416.22(c). In the revised regulation, we make explicit our intention not to publish in the **Federal Register** prior notice of changes made to the ASC list to reflect the annual changes made to CPT. We also indicate that we will go through the standard notice and comment process in the **Federal Register** when procedures are added to or deleted from the list in accordance with the standards in paragraphs (a) and (b) of § 416.22.

We further propose, as a matter of policy, to update the ASC list on a calendar year basis, to coincide with the annual updates of the HCPCS and the Medicare physicians' fee schedule.

2. Update of ASC Payment Rates

We propose to replace the current section § 416.130 with revised § 416.32. We clarify that when ASC payment rates are updated solely by a CPI-U factor to comply with 1833(i)(2)(C), we intend only to publish a notice that announces the new CPI–U adjusted rates, without a formal comment period. When HCFA rebases the ASC payment rates to reflect data collected through the quinquennial survey of ASCs required under 1833(i)(2)(A)(i) of the Act, we will go through a full notice and comment or rulemaking cycle, depending on whether or not changes to the regulations are to be proposed.

As with the updates of the ASC list, we further propose as a matter of policy to update the ASC payment rates on a calendar year basis to coincide with the annual updates of the HCPCS and the Medicare physicians' fee schedule. This represents a departure from our current policy of implementing rate updates on October 1 to coincide with the annual update of the hospital inpatient prospective payment system (PPS) wage index. We believe that the improved efficiency and reduced paperwork resulting from coordinating all of the ASC updates—the list, payment rates, and wage index— to coincide with the annual CPT update outweighs any disadvantages that might result from postponing for three months implementation of revised PPS wage index values.

J. Technical Changes to 42 CFR Part 416

1. ASC Payment Rates

We have rewritten, reorganized, and renumbered §416.125 to create new §416.31. This revised section summarizes the characteristics of ASC payment rates, e.g., they are prospectively determined; they take into account the per procedure costs of providing services by ASCs generally; they are based on audited survey data; they are updated annually by a CPI-U factor during years when they are not rebased using survey data; and, they must result in substantially less being paid by Medicare than would have been paid if the procedures on the ASC list were performed on a hospital inpatient basis.

2. ASC Survey

The purpose of the ASC survey is to furnish HCFA with data on the costs incurred by ASCs to furnish facility services in connection with procedures on the ASC list. HCFA uses these data for the purpose of setting ASC payment rates. The SSAA 1994 amended section 1833(i)(2)(A) to require that ASC costs, which are to be the basis of the standard ASC fees determined by HCFA, be determined by a survey of a representative sample of procedures and facilities that is taken every five years. The 1994 Amendments also make it a requirement that these costs be audited. We have revised §416.140 to include these new requirements and we have renumbered this section as § 416.33.

We issued the last ASC survey on March 15, 1994, and the rates that are proposed in this notice are based on the data reported in that survey which were subsequently verified by audit. The 1994 survey was entitled "Medicare Ambulatory Surgical Center Payment Rate Survey—1994: II. Facility Overhead and Procedure Specific Costs" (Form HCFA–452B, OMB No. 0938– 0434, expired March 1997). The next ASC survey must be taken in 1999. Because the survey form that we used in 1994 has expired, we have to have HCFA Form 452 reinstated and approved by the Office of Management and Budget (OMB) before we can survey ASCs in 1999. HCFA Form 452 is being revised, and decisions regarding survey format and content for the 1999 ASC survey are pending. We expect to consult representatives of the ASC industry for assistance in revising HCFA Form 452 before it is submitted to OMB for reinstatement and approval.

In § 416.33, we propose to extend the time period allowed for completion of the survey from 60 to 90 days, with the option of an additional 30-day extension if the facility can demonstrate good cause for not completing the survey within the allotted 90 days.

K. Explanation and Use of Addenda

The addenda on the following pages present in schematic form the updated ASC payment rates, additions to and deletions from the ASC list, payment policy indicators, and ambulatory payment classification (APC) groups that are proposed in this notice.

Addendum A—Proposed Ambulatory Surgical Center (ASC) Payment Status by HCPCS Code and Related Information

This addendum is a list of the 1998 HCPCS codes:

1. CPT/HCPCS code. This column is a list of the 1998 CPT and alphanumeric HCPCS codes. With the exception of the surgical CPT codes, most of the codes in Addendum A show only a payment policy indicator.

2. Payment Policy Indicator (PPI). This indicator shows whether the CPT/ HCPCS code is on the ASC list and whether it is paid for as part of the ASC facility fee, or separately payable if the service is covered, or not payable as an ASC service.

1=Procedure on ASC list. Codes with this indicator are procedures for which Medicare pays ASCs a prospectively determined facility fee. The codes with this indicator constitute the list of ASC covered procedures (ASC list).

2=Bundled service/no separate payment. Payment for covered services is always bundled into payment for other services not specified. Medicare does not make separate payment when these services are furnished in an ASC. Payment is already included within the ASC facility fee or submitted within payment(s) made for or the services.

3=Excluded from ASC list. Codes with this indicator are for a procedure, item or service that is excluded from the list of ASC covered procedures because it is not reasonable, not necessary, not appropriate or not safe in an ASC setting. Medicare does not pay an ASC facility fee for these codes.

4=Invalid code/90-day grace period. Codes with this indicator are not valid for Medicare purposes. Medicare recognizes a 90-day grace period following designation of the code as invalid, during which the code may be used, pending full implementation of the specified replacement code. ASCs and hospital outpatient departments are to use another code to bill for these services.

5=Office-based procedure. No payment is allowed for ASC facility services. If this procedure is performed in an ASC, the ASC is considered a physician's office, and the physician's fee constitutes payment in full.

6=Separate payment when furnished by an ASC. Codes with this indicator are for items or services that fall outside the scope of ASC facility services or that are unrelated to or do not apply to the ASC benefit. Medicare does not include payment for the item or service in the ASC facility fee. However, if this item or service is supplied at an ASC in connection with a surgical procedure on the ASC list, Medicare could make separate payment under other sections of Medicare Part B in accordance with applicable coverage and payment provisions and requirements.

7=ASC restricted coverage procedure. Special coverage instructions apply. The APC group shown signifies the payment rate to be paid in the event the carrier determines that the procedure or service is reasonable and necessary.

8=Reserved for future use.

9=Medicare does not allow payment for the item or service.

3. Description of Code. This is an abbreviated version of the narrative description of the code. Note: All CPT codes and descriptors are copyrighted by the American Medical Association. CPT-4 codes including both long and short descriptor shall be used in accordance with the HCFA/AMA agreement. Any other use violates the AMA copyright.

4. Current payment group. If applicable, this column gives the ASC payment group to which the code is currently assigned. 5. Current Payment Rate. If applicable, this column gives the current ASC payment rate.

6. Proposed ÅPC group. This is the payment group to which the code would be assigned under the proposed ambulatory payment classification (APC) system.

7. Proposed Payment Rate. Where applicable, this is the ASC payment rate proposed for the code.

8. Relative Value Factor. Indicates the relationship between the payment rate assigned to the code and the median payment rate (\$504) determined for the 41 surgical APC groups that are priced on the basis of 1994 ASC survey data.

9. Add/Delete. "Add" indicates that the code is proposed for addition to the ASC list. "Delete" indicates that the code is currently on the ASC list and that we propose to delete it from the ASC list.

Addendum B—Proposed Ambulatory Surgical Center (ASC) List by Ambulatory Payment Classification (APC) Groups and Related Information

This addendum lists CPT codes on the ASC list in order of ambulatory payment classification (APC) group and gives the long descriptor of each CPT/ HCPC code on the ASC list.

Note: All CPT codes and descriptors are copyrighted by the American Medical Association. CPT-4 codes including both long and short descriptor shall be used in accordance with the HCFA/AMA agreement. Any other use violates the AMA copyright.

Addendum C—List of APC Groups and Related Information

This addendum lists in numeric order the number and title of the APC groups used as the basis for setting the ASC payment rates proposed in this notice. The proposed ASC payment rate and relative value factor for each APC group are shown.

Addendum D—Ambulatory Surgical Center (ASC) Wage Index

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

• Whether the information collection is necessary and useful to carry out the proper functions of the agency;

• The accuracy of the agency's estimate of the information collection burden;

• The quality, utility, and clarity of the information to be collected; and

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

The information collection requirements and associated burden as summarized below are subject to the PRA:

Section 416.4 Termination of participation, including billing privileges

In summary, an ASC that wishes to terminate its participation and billing privileges in Medicare must send HCFA written notice of its intent. The notice must state the intended date of termination which must be the first day of a calendar month. Furthermore, the ASC must give prompt notice of the date and effect of termination to the public, through publication in local newspapers, after HCFA has approved or set a termination date.

The burden for this requirement involves sending the written intent to terminate notice to HCFA and publishing the required third party disclosure notice in a local newspaper.

The table below indicates the annual number of responses for the regulation section in this proposed rule containing information collection requirements, the average burden per response in minutes or hours, and the total annual burden hours.

ESTIMATED ANNUAL BURDEN CHART

CFR sections	Annual num- ber of re- sponses	Average burden per re- sponse	Annual burden hours
416.4 (written notice) 416.4 (publication)	25 25	10 minutes 30 minutes	4.2 12.5
Total Hours			17

Section 416.33(b)(1) Surveys

In summary, § 416.33(b)(1) requires ASCs to maintain adequate financial and facility records to allow accurate completion of the report specified in subparagarph (b)(2) of this section in the event they are selected to participate in the quinquennial ASC survey as a member of the representative sample of facilities.

Under 5 CFR 1320.3(b)(2), the burden associated with the time, effort and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of business will be excluded from an information collection. The burden in connection with such types of collection activities can be disregarded if it can be demonstrated that such collection activities are usual and customary. Each of the collection requirements referenced above is of the type that are usual and customary in the conduct of commercial business. Thus, we believe the burden to be exempt for these requirements.

Section 416.33(b)(2) Surveys

In summary, §416.33(b)(2) requires ASCs to submit within 90 days of a request, from HCFA, ASC survey data. HCFA issued the last ASC survey in 1994, "Medicare Ambulatory Surgical Center Payment Rate Survey—1994: II. Facility Overhead and Procedure Specific Costs," Form HCFA-452B, OMB No. 0938-0434, expired March 1997. Form HCFA 452 is being revised, and decisions regarding survey format and content for the 1999 ASC survey are pending. We expect to consult representatives of the ASC industry for assistance in revising Form HCFA 452 before it is submitted to OMB for approval. In addition, HCFA will publish a separate Federal Register notice soliciting public comments for the ASC Survey.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Allison Eydt, HCFA Desk Officer.

V. Regulatory Impact Analysis

We have examined the impacts of this proposed rule under Executive Order

(E.O.) 12866, the Unfunded Mandates Act of 1995, and the Regulatory Flexibility Act. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts and equity.) A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million.

The Actuarial and Health Cost Analysis Group of HCFA's Office of Strategic Planning estimates that the rebased ASC payment rates proposed in this notice reduce Medicare payments to ASCs by two percent from current spending levels, in the aggregate. Actuarial estimates of the modest savings to Medicare that are the result of the regrouping and repricing of the ASC list proposed in this notice are as follows:

PROJECTED MEDICARE SAVINGS [In millions]*

-	
FY 1998	 \$-20
FY 1999	 -20
FY 2000	 -20
FY 2001	 -20
FY 2002	 -20
FY 2003	 -20

* Rounded to the nearest \$10 million.

The Balanced Budget Act of 1997 is considered in the estimate, including the prospective payment system for hospital outpatient services to be implemented on January 1, 1999, the formula-driven overpayment elimination effective October 1, 1997, and the ASC update reduced by two percentage points for each of the fiscal years 1998 through 2002.

This proposed rule has no consequential effect on State, local, or tribal governments, and, based on the actuarial estimates shown above, we believe the private sector costs of this rule fall below the economic thresholds established by E.O. 12866 and by the Unfunded Mandates Act of 1995. Because this notice is not an economically significant regulatory action under either E.O. 12866 or the Unfunded Mandates Act of 1995, a regulatory impact analysis is not required.

Consistent with the provisions of the Regulatory Flexibility Act, we analyze options for regulatory relief for small businesses and other small entities. 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. The regulatory flexibility analysis is to include a justification of why action is being taken, the kinds and number of small entities the proposed rule will affect, and an explanation of any considered meaningful options that achieve the objectives and would lessen any significant adverse economic impact on the small entities. For purposes of the RFA, we consider ASCs to be small entities. In addition, section 1102(b) of the Social Security 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. 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.

We believe that the rebased rates proposed in this notice will affect revenues of most Medicare approved ASCs that furnish services to Medicare beneficiaries and, to a lesser extent, revenues of hospitals that perform procedures on the ASC list on an outpatient basis. We have therefore prepared the following regulatory flexibility analysis which, together with the rest of this preamble, meets all three assessment requirements under the RFA. We will have explained the rationale for and purposes of the rule, analyzed alternatives, and presented the measures we propose to minimize the burden on small entities.

A. Rebased Payment Rates

This notice implements section 1833(i)(2)(A)(i) of the Act, which mandates that payment amounts for ASC facility services take into account costs incurred by ASCs generally to furnish services in connection with procedures on the ASC list, as determined by a survey of the actual audited costs incurred by ASCs taken not later than January 1, 1995 and every five years thereafter.

1. Impact on ASCs

In the aggregate, based on actuarial estimates, we expect the revised rates

proposed in this notice to result in a two percent reduction in Medicare outlays for ASC facility services. Given the negligible magnitude of this reduction, we can say that the effect of rebasing the ASC rates and revising the ASC list is virtually budget neutral when viewed in the aggregate. This outcome is attributable primarily to the lower payment rate determined for the two procedures with the highest ASC volume: CPT codes 66984 and 66821. These two procedures alone account for approximately 46 percent of ASC Medicare volume, which helps offset the effect of increased expenditures that will result from higher payment rates for procedures such as hernia repair, hammertoe and bunion correction surgery, arthoscopic procedures, and from the addition of extracorporeal shock wave lithotripsy (ESWL) to the ASC list.

However, the change in payment rate for virtually every procedure on the ASC list—with some procedures receiving a lower rate and others receiving a higher rate than they do currently-could affect the Medicare revenues of individual ASCs, depending on factors such as patient volume and case mix and the type of procedures performed. Of the 295 facilities whose 1994 survey responses are the basis for the rates proposed in this notice, 54 (18 percent) reported that more than 60 percent their total volume in a 12-month period comprised of some combination of CPT codes in the range between 66820 and 66986 cataract procedures. For most of those facilities, Medicare utilization exceeded fifty percent, and for 16 facilities, Medicare utilization exceeded seventy-five percent. The rates proposed in this CPT range represent, overall, a drop of about eleven percent from current payment rates for cataractrelated procedures. The rate we propose for CPT code 66984, the highest volume ASC procedure representing 35 percent of all ASC Medicare volume in 1996, decreases by 8 percent. The rate for CPT code 66821, the second highest volume ASC procedure representing 11 percent of all ASC Medicare volume in 1996, decreases by 35 percent. Obviously facilities that specialize in these two cataract-related procedures are going to be affected more dramatically by the proposed rebased rates than are facilities where the volume of these procedures is lower.

The rates that we propose in this notice for certain high volume gastrointestinal and urinary tract endoscopies are also lower than current rates for the same procedures, such as CPT code 43239 (22 percent decrease), CPT code 45378 (16 percent decrease) and CPT code 52000 (32 percent decrease). As a group, endoscopies are second only to CPT codes 66984 and 66821 with respect to Medicare utilization of ASCs. Of the 295 facilities whose 1994 survey responses are the basis for the rates proposed in this notice, 17 (6 percent) reported that more than 60 percent of their total volume in a 12-month period comprised some combination of CPT codes encompassing gastrointestinal endoscopies. However, in only one of those 17 facilities did Medicare utilization exceed fifty percent, and for 11 facilities, Medicare utilization was less than thirty-five percent.

Not all of the rebased rates proposed in this notice are reductions of current rates. The rebased rates proposed for arthroscopic surgery, for some gynecological procedures, for certain podiatric procedures, for carpal tunnel release, for hernia repair, and for certain eye procedures involving the cornea and the retina are higher than the current rates for those procedures. Facilities where those procedures are now being performed will, upon implementation of the rebased rates, be paid a facility fee that more closely approximates the cost of doing the surgery and that should allow the facility a reasonable return, as will facilities performing procedures for which the rebased rates are lower than current ASC payment.

Some smaller, single specialty ASCs may experience some decrease in Medicare payment upon implementation of the rebased rates proposed in this notice, especially if their annual total volume of cases is less than 1000, if the proportion of Medicare beneficiaries that they serve greatly exceeds the 34 percent average ASC Medicare volume, or if they perform a case mix of procedures whose rebased rates are all lower than current rates. Congress does not provide us with tools such as a "hold-harmless" clause or a transition period for implementation of rebased rates that could serve to deflect some of the adverse effects of lower payment rates. However, judging from the 1994 survey data, even though efficient ASCs may experience a fractional reduction in profits, we do not think that they will suddenly be faced with serious financial reverses as a result of the rates proposed in this notice. That is because the rebased rates proposed in this notice are closer to costs based on verified data reported by ASCs than are the current rates, which are based on data collected in 1986.

We emphasize that the rates proposed in this notice have been determined in accordance with audited cost, charge, and utilization data reported by a representative sample of ASCs, as we explained in detail earlier in this notice. To summarize the process we used to establish the payment rates proposed in this notice using audit adjusted 1994 survey data—

Step 1—We standardized the original reported CPT code charges and facility overhead costs of the 199 unaudited facilities by the percent of difference between audited and original reported data of the 96 audited facilities.

Step 2—We determined each facility's cost-to-charge ratio by dividing the

facility's total costs by its total charges. Step 3—We converted each procedure charge to a procedure cost by multiplying each facility's procedure charge by the facility's cost-to-charge ratio.

Step 4—Because the facilities' IOL costs were imbedded in the calculated procedure cost for IOL insertion procedures (CPT codes 66983, 66984, 66985, and 66986), we reduced those procedure costs by the facility specific average IOL cost to offset the carrier's addition of the \$150 allowance for the IOL.

Step 5—To remove the effects of area wage differences, we neutralized the cost of each procedure by dividing the facility-specific labor-related portion of procedure cost by the hospital inpatient prospective payment system prereclassification//pre-floor wage index value applicable to the facility's location. We then added the wage adjusted labor-related portion of procedure cost back to the nonlaborrelated portion.

Step $\hat{6}$ —We applied an inflation adjustment based on the CPI–U to each procedure cost in order to account for historical and projected price changes occurring between the midpoint of the facility's fiscal period represented in our data base and the midpoint of the 12month period to which the new rates would apply (July 1, 1998).

would apply (July 1, 1998). Step 7—We grouped the procedure codes into APCs based on clinical and cost similarities.

Step 8—For the 41 APCs with sufficient ASC survey cost data, we calculated the median procedure cost for all Medicare cases within the group to determine the group payment rate.

Step 9—We designated the median of the payment rates for the 41 APCs with sufficient ASC survey cost date as a conversion factor 504.

Step 10—We assigned a value to each of the remaining 64 APCs for which we had inadequate ASC survey data based on an estimate of each APC group's relative similarity to or deviation from the 41 APCs for which we had sufficient survey data. Step 11—We multiplied the relative value of each of the 64 groups by a conversion factor of 504 to determine the group payment rate.

By using survey data reported by ASCs that was checked and verified by audit, we have determined ASC payment rates that are generally lower than current ASC payment rates. In one sense, the lower proposed payment rates are a tribute to the efficiency and success of ASCs generally in holding the line on facility costs. Lower rates reflect lower costs that are the result of improved technology, efficiency, and experience. The fact remains that regardless of the method we used to calculate payment rates, whether we used dollar intervals to group codes like the current methodology or APC groups or an individual per procedure fee schedule or weighted or unweighted medians or means, the relationship of the resulting rates relative to current rates remained the same: rates for high volume cataract-related procedures and gastrointestinal endoscopies were lower and rates for less frequently performed arthroscopies and various other general surgical procedures went up.

Another explanation for the lower rebased rates could rest with the fact that the current eight ASC payment rates are based on data that were collected in 1986, which generally reflected 1984-85 cost and charge experience. We used 1986 survey data, adjusted for inflation, to rebase ASC payment rates effective for services furnished beginning on March 12, 1990. Between March 1990 and October 1996, we adjusted the ASC payment rates five times resulting in an across the board increase of approximately 20 percentage points for procedures in groups 1, 2, 3, 4, 5, and 7. (The rates for groups 6 and 8, which are limited to intraocular lens (IOL) insertion procedures for which the IOL allowance was prescribed by statute, increased by only 7.5 percent during that time due to the statutory reduction in the IOL allowance from \$200 to \$150 effective January 1, 1994.) We did not rebase the 1990 rates, or take into account variations in cost resulting from changes in technology. The current eight ASC rates are therefore the result of across-the-board flat increases for inflation dating back to 1990 that do not reflect upward or downward changes in costs associated with individual procedures over the same period.

B. Additions to/Deletions From the ASC List

The addition of outpatient procedures that were previously kept off the list will give ASCs an opportunity to increase volume and utilization as well as expand their revenue sources. The addition of a payment rate for ESWL will allow payment to ASCs for this procedure and make it available for Medicare beneficiaries in an ASC setting.

The procedures that are being removed from the ASC list are not high volume procedures, and we do not expect their deletion from the ASC list to have any significant impact, negative or positive.

C. Impact of Technical Changes

Most of the technical changes proposed in this notice—extending to 90 days the period for completing the ASC survey; implementing all ASC updates on a calendar year basis; rearranging and reorganizing part 416 of the Code of Federal Regulations; adding payment policy indicators; clarifying that procedures excluded from the ASC list are not reasonable and necessary in an ASC—are intended to streamline the ASC benefit and reduce ambiguity to the advantage of beneficiaries and ASCs alike without compromising beneficiary safety and positive surgical outcomes.

D. 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. Congress believed some comparability should exist in the amount of payment to hospitals and ASCs for similar procedures. 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 percent of Medicare payments to hospitals by intermediaries is attributable to services furnished in conjunction with ASC-covered procedures performed on an outpatient basis

While an ASC rate change may not keep pace with actual hospital cost increases, we would recognize cost increases 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 new ASC rates, is offset to a degree when hospital costs significantly exceed the ASC rate. Another element that could mitigate the effect of the rebased ASC rates 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, changes in the ASC rates will have no effect on hospital payments. The number of Medicare beneficiaries a hospital serves and its case-mix variation influence the total impact of the new ASC rates on Medicare payments to hospitals. Based on these factors, we do not believe that the provisions of this notice will have a significant impact on a substantial number of small rural hospitals. Moreover, the impact of rebased ASC rates on hospital outpatient payments will be eliminated upon implementation of a prospective payment system for hospital outpatient services in January 1999.

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

List of Subjects

42 CFR Part 416

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV would be amended as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

A. Part 416 is amended as set forth below:

1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. The heading of subpart A is revised and §416.1 is revised to read as follows:

Subpart A—Definitions and General Provisions and Requirements

§416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F) of the Act provides for Medicare Part B payment for facility services furnished by an ambulatory surgical center (ASC) in connection with surgical procedures specified by the Secretary under section 1833(i)(1)(A) of the Act.

(2) Section 1832(a)(2)(F)(i) of the Act provides that an ASC, in order to receive Medicare payment, must meet health, safety, and other standards specified by the Secretary in regulations and must also agree to accept assignment and to accept as payment in full for facility services furnished in connection with surgical procedures specified by the Secretary under section 1883(i)(1)(A) of the Act the payment amount determined under section 1833(i)(2)(A).

(3) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ASC.

(4) Section 1833(i)(2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC or in a hospital outpatient department.

(b) *Scope*. This part sets forth—

(1) The scope of ASC facility services and the criteria for determining the procedures for which Medicare pays ASCs a facility fee;

(2) The manner by which Medicare determines payment amounts for ASC facility services; and

(3) The conditions that an ASC must meet in order to participate in the Medicare program.

3. Section 416.2 is revised to read as follows:

416.2 Definitions

As used in this part:

An Ambulatory Surgical Center or ASC means a supplier that—

(1) Has its own National Identifier under Medicare;

(2) Is a separate entity with respect to its licensure, accreditation, governance, professional supervision, administrative functions, clinical services, record keeping, and financial and accounting systems;

(3) Has as its sole purpose the furnishing of services in connection with surgical procedures that do not require inpatient hospitalization; and

(4) Meets the conditions and requirements set forth in all subparts of this part.

ASC list means the list of procedures that HCFA specifies can be safely and appropriately performed in an ASC, for which Medicare allows payment of an ASC facility fee in accordance with the provisions of this part.

ASC services means services that a Medicare approved ASC furnishes in connection with procedures on the ASC list and for which Medicare pays a prospectively-determined ASC facility fee.

Hospital-operated ASC means an ASC that is owned and operated by a hospital but that is a separate entity with respect to its licensure, accreditation, governance, professional supervision, administrative functions, clinical services, recordkeeping, and financial and accounting systems. A hospitaloperated ASC must meet all the conditions and requirements set forth in subparts A, B, C and D of this part.

4. Section 416.25 is redesignated as § 416.3 and is transferred to subpart A and is revised to read as follows:

§416.3 Basic Requirements

Participation as an ASC, including billing privileges, is limited to facilities that meet the following conditions:

(a) Meet the definition in §416.2.

(b) Have State licensure in States where licensure is required.

(c) Meet the conditions for coverage specified in subpart D of this part and report promptly to HCFA any failure to do so.

(d) Charge the beneficiary or any other person on the beneficiary's behalf only the applicable deductible and coinsurance amounts for services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter.

(e) Refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf. As used in this section, *money incorrectly collected* means sums collected in excess of those specified in paragraph (d) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(1) The beneficiary is later determined to have been entitled to Medicare benefits; and

(2) The beneficiary's entitlement period falls within the time the ASC's agreement with HCFA is in effect.

(f) Furnish to HCFA, if requested, information necessary to establish payment rates as specified in subpart C, and in the form and manner that HCFA requires;

(g) Accept assignment for all items and services that it furnishes to Medicare beneficiaries for which payment may be made under Medicare Part B in connection with procedures on the ASC list. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 of this chapter (when an individual dies before assigning the claim).

(h) Are in compliance with ASC requirements set forth in Part 488— Survey, Certification, and Enforcement Procedures.

(i) Have in effect a validated Medicare health care provider/supplier enrollment application.

5. Section 416. 4 is added to subpart A to read as follows:

§416.4 Termination of participation, including billing privileges.

(a) *Termination by the ASC*—(1) Notice to HCFA. An ASC that wishes to terminate its participation and billing privileges in Medicare must send HCFA written notice of its intent.

(2) *Date of termination.* The notice must state the intended date of termination, which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to HCFA, HCFA may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) HCFA may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) Voluntary termination. If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) Termination by HCFA. (1) Cause for termination. HCFA may terminate an ASC's participation, including its billing privileges, if it determines that the ASC—

(i) No longer meets the conditions for coverage as specified under subpart D of this part; or

(ii) Is not in substantial compliance with the provisions and the requirements of subparts A, B, and C of this part, or other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) *Notice of termination.* HCFA sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) Appeal by the ASC. An ASC may appeal the termination of its participation, including its billing privileges, in accordance with the provisions set forth in part 498 of this chapter. (c) *Effect of termination*. Payment is not available for ASC services furnished on or after the effective date of termination.

(d) Notice to the public. Prompt notice of the date and effect of termination is given to the public, through publication in local newspapers by—

(1) The ASC, after HCFA has approved or set a termination date; or

(2) HCFA, when it has terminated the ASC's participation, including its billing privileges.

(e) Conditions for reinstatement after termination by HCFA. When HCFA terminates an ASC's participation in Medicare, which includes terminating its billing privileges, the ASC may not file another application to participate in the Medicare program as an ASC unless HCFA—

(1) Finds that the reason for the prior termination has been removed; and

(2) Is assured that the reason for the termination will not recur.

6. Subpart B is revised; subpart D is removed; subpart C is redesignated as subpart D, and § 416.40 is removed; and subpart E is redesignated as subpart C and revised. The revised subparts B and C read as follows:

Subpart B—Scope of Benefits

§416.20 General rules.

The services for which payment is made under this part are facility services furnished to Medicare beneficiaries by a participating ASC in connection with procedures on the ASC list as specified by HCFA in accordance with § 416.22.

§416.21 Scope of ASC services.

(a) *Included services.* ASC services include but are not limited to:

(1) Nursing, technician, and related services.

(2) Use of the facility where the surgical procedures are performed.

(3) Items and services directly related and integral to the pre-operative preparation of patients upon their admission to the ASC for surgery, to the performance of a surgical procedure(s), and to the post-operative and/or postanesthesia care of patients prior to their discharge from the ASC. This includes, but is not limited to, any laboratory testing performed under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver; drugs and biologicals; medical and surgical supplies and equipment; surgical dressings; splints, casts and other devices used for reduction of fractures and dislocations; and, imaging services or other diagnostic tests integral to a surgical procedure.

(4) Administrative, recordkeeping, and housekeeping items and services.

(5) Materials, including supplies and equipment, for the administration and monitoring of anesthesia.

(6) Intra-ocular lenses (IOLs). (b) Excluded services. ASC services do not include certain items and services for which payment may be made under other provisions of this chapter, such as physician services, diagnostic X-ray services and other diagnostic tests (other than those integral to the performance of a surgical procedure), diagnostic laboratory tests, X-ray therapy and other radiation therapy, prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, ASC services do not include anesthetist services furnished on or after January 1, 1989.

§416.22 ASC list.

The ASC list consists of those procedures that HCFA, in consultation with appropriate trade and professional associations, specifies as being appropriately and safely performed in an ASC. Paragraphs (a) and (b) of this section list the criteria HCFA uses to determine if a procedure is to be placed on the ASC list. Medicare payment of an ASC facility fee is not allowed for ASC services furnished in connection with procedures excluded from the ASC list in accordance with the criteria in paragraph (b) of this section. The ASC list is published in accordance with paragraph (c) of this section

(a) *Procedures on the ASC list.* Procedures on the ASC list are those surgical and other medical procedures that generally—

(1) Require surgical facilities and services of the kind that are typically provided in a hospital inpatient setting;

(2) Would not be expected to necessitate admission as an inpatient to a hospital either to perform the procedure or to recover from the procedure post-operatively;

(3) Require a dedicated operating room (or suite) or procedure room and a room for post-operative recovery; and

(4) Are not otherwise excluded under § 411.15 of this chapter, or paragraph (b) of this section.

(b) *Procedures excluded from the ASC list.* A procedure with any of the following characteristics is not considered safe or appropriate in an ASC setting. A procedure with any of these characteristics is not reasonable or medically necessary in an ASC setting. Payment of an ASC facility fee for procedures excluded from the ASC list in accordance with any of the following characteristics is not allowed. A procedure is excluded from the ASC list if it—

(1) Generally results in extensive blood loss;

(2) Requires major or prolonged invasion of body cavities;

(3) Directly involves major blood vessels:

(4) Is generally emergent or lifethreatening in nature; or

(5) Requires admission to a hospital on an inpatient basis in order to have the procedure performed or to recover from the procedure.

(c) *Publication of ASC list.* HCFA publishes the ASC list in the **Federal Register** as appropriate.

(1) HCFA automatically revises the ASC list to ensure that it conforms timely with coding changes resulting from the annual update of the Health Care Financing Administration Common Procedure Coding System (HCPCS). The effective date of changes to the ASC list resulting from HCPCS coding changes are concurrent with the effective date of the HCPCS revision. HCFA announces these conforming changes in the first **Federal Register** notice published thereafter, either in accordance with paragraph (c)(2) of this section or in accordance with § 416.32.

(2) When HCFA adds procedures to or deletes procedures from the ASC list in accordance with the criteria in paragraphs (a) and (b) of this section, HCFA publishes a notice in the **Federal Register** explaining the rationale for the proposed changes and soliciting public comments on both the proposed changes and the payment rates proposed for procedures under consideration for addition to the list. After reviewing public comments, HCFA publishes a notice in the **Federal Register** to establish the final revisions to the ASC list.

§416.23 Performance of procedures on the ASC list in a hospital inpatient setting.

The fact that a procedure is on the ASC list does not preclude its coverage in a hospital inpatient setting.

Subpart C—Payment for Facility Services

§ 416.30 Basis for payment.

The basis for payment for facility services depends upon the type of entity at which the services are furnished.

(a) *Physician's office.* Payment is in accordance with part 414 of this chapter.

(b) *Hospital outpatient department.* Payment is in accordance with part 413 of this chapter. (c) *Hospital-operated ASC.* (1) The ASC participates and is paid only as an ASC without the option of converting to or being paid as a hospital outpatient department, unless HCFA first determines there is good cause to do otherwise.

(2) Costs for the ASC are treated as a nonreimbursable cost center on the hospital's cost report.

(d) *ASC—General rule*. Payment is based on a prospectively determined rate.

(1) This rate includes payment for the cost of ASC services such as supplies, nursing services, equipment, etc., as specified in § 416.21. The ASC payment rate for insertion of an intraocular lens (IOL) during or subsequent to cataract removal includes an amount for the IOL that is reasonable and related to the cost of acquiring the lens.

(2) The ASC payment rate does not include payment for certain medical and other health services that are covered but that may be billed and paid for separately under part 410 of this chapter, such as physician services, Xray services or other diagnostic tests not integral to the performance of a surgical procedure, or prosthetic implants (other than IOLs).

(3) Because procedures excluded from the ASC list on the basis of the standards in § 416.22(b) are not "reasonable and necessary," Medicare does not allow payment of an ASC facility fee for those procedures. (See § 411.15(k)(1) of this chapter.)

(e) Single and multiple surgical procedures. (1) If one procedure on the ASC list is performed in a single operative session, payment of the ASC facility fee is based on the prospectively determined rate for that one procedure.

(2) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(i) The full rate for the procedure with the highest prospectively determined rate; and

(ii) One half of the prospectively determined rate for each of the other procedures.

(f) Deductibles and coinsurance. Part B deductible and coinsurance amounts apply as specified in \S 410.152 (a) and (i) of this chapter.

§416.31 ASC payment rates.

(a) The payment rate for a procedure on the ASC list is based on a standard prospectively determined per procedure overhead amount.

(1) The standard overhead amount represents HCFA's estimate of a fair perprocedure fee that takes into account the costs incurred by an ASC generally in providing facility services in connection with the performance of the procedure.

(2) HCFA surveys ASCs as described in § 416.33 to determine the costs incurred by ASCs generally in providing ASC services in connection with the performance of procedures on the ASC list.

(3) HCFA conducts an audit of a randomly-selected sample of the surveys submitted in accordance with the requirements in § 416.33 to ensure that the costs from which it derives ASC payment rates are reported accurately and in a manner consistent with Medicare principles of reasonable cost reimbursement.

(b) The ASC payment rate must result in substantially less being paid under the program than would have been paid if the procedures had been performed on an inpatient basis in a hospital.

(c) In setting ASC payment rates, HCFA may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

(d) For the years when HCFA does not rebase ASC payment rates using survey data collected in accordance with § 416.33, HCFA updates the existing ASC payment rates by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated for the 12-month period ending with the midpoint of the year involved.

§416.32 Publication of revised payment rates.

Once implemented, ASC payment rates remain in effect until HCFA publishes a notice in the **Federal Register** to change the rates.

(a) When HCFA rebases ASC payment rates using survey data collected in accordance with § 416.33, HCFA publishes a notice in the **Federal Register** describing the method it followed to rebase the rates and soliciting public comments on both the proposed new rates and the ratesetting method. After reviewing public comments, HCFA publishes a final notice in the **Federal Register** to establish the new, rebased rates.

(b) During years when HCFA updates ASC payment rates using a consumer price index factor as described in § 416.31(d), HCFA publishes a notice in the **Federal Register** to announce the updated rates.

§416.33 Surveys.

(a) *Timing, purpose, and procedures.* (1) Beginning not later than January 1, 1995 and every 5 years thereafter, HCFA conducts a survey of ASCs based upon a representative sample of procedures and facilities to collect data for the purpose of rebasing ASC payment rates.

(2) HCFA notifies ASCs by mail of their selection to participate in the ASC survey and of the form and content of the report the ASCs must submit.

(3) If the facility does not submit an adequate report in response to HCFA's survey request, HCFA may terminate the ASC's Medicare billing privileges and its participation in the Medicare program.

(4) ASCs have 90 days within which to complete and submit the survey. HCFA may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) Requirements for ASCs. ASCs must—

(1) Maintain adequate financial and facility records to allow accurate completion of the report specified in paragraph (b)(2) of this section in the event they are selected to participate in the quinquennial ASC survey as a member of the representative sample of facilities.

(2) Within 90 days of a request from HCFA for survey data submit, in the form and detail specified by HCFA, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and a list of surgical procedures performed during the period; and

(ii) Their customary charges for each surgical procedure performed during the period.

§ 416.34 Beneficiary appeals.

A beneficiary (or ASC as his or her assignee) may request a hearing by a carrier (subject to the limitations and conditions set forth in part 405, subpart H of this chapter) if the beneficiary or the ASC—

(a) Is dissatisfied with a carrier's denial of a request for payment made on his or her behalf by an ASC;

(b) Is dissatisfied with the amount of payment; or

(c) Believes the request for payment is not being acted upon with reasonable promptness.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

B. Part 488 is amended as set forth below:

1. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In §488.1 the definition of "supplier" is revised to read as follows:

§488.1 Definitions.

* * * *

Supplier means any of the following: Independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; chiropractor; or ambulatory surgical center.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program) Dated: March 20, 1998. Nancy-Ann Min DeParle, Administrator, Health Care Financing Administration. Approved: April 28, 1998.

Donna E. Shalala, Secretary.

ADDENDUM A.—PROPOSED AMBULATORY SURGICAL CENTER (ASC) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION

CPT 1/ HCPCS	ASC payment indicator	Description	Current payment group	Current payment rate	Proposed APC group	Proposed payment rate	Relative value factor	Add ² / Delete
00100	2	Anesth, skin surgery						
00102	2	Anesth, repair of cleft lip						
00103	2	Anesth, blepharoplasty						
00104	2	Anesth for electroshock						
00120	2	Anesthesia for ear surgery						
00124	2	Anesthesia for ear exam						
00126	2	Anesth, tympanotomy						
00140	2	Anesth, procedures on eye						
00142	2	Anesthesia for lens surgery						
00144	2	Anesth, corneal transplant						
00145	2	Anesth, vitrectomy						
00147	2	Anesth, iridectomy						
00148	2	Anesthesia for eye exam						
00160	2	Anesth, nose, sinus surgery						
00162	2	Anesth, nose, sinus surgery						
00164	2	Anesth, biopsy of nose						
00170	2	Anesth, procedure on mouth						
00172	2	Anesth, cleft palate repair						
00174	2	Anesth, pharyngeal surgery						
00176	2	Anesth, pharyngeal surgery						
00190	2	Anesth, facial bone surgery						
00192	2	Anesth, facial bone surgery						
00210	2	Anesth, open head surgery						
00212	2	Anesth, skull drainage						
00214	2	Anesth, skull drainage						
00215	2	Anesth, skull fracture						
00216	2	Anesth, head vessel surgery						
00218	2	Anesth, special head surgery						
00220	2	Anesth, spinal fluid shunt						
00222	2	Anesth, head nerve surgery						
00300 00320	2	Anesth, skin surgery, neck						
00320	2	Anesth, neck organ surgery Anesth, biopsy of thyroid						
00322	2	Anesth, neck vessel surgery						
00352	2	Anesth, neck vessel surgery						
00400	2	Anesth, chest skin surgery						
00402	2	Anesth, surgery of breast						
00404	2	Anesth, surgery of breast						
00406	2	Anesth, surgery of breast						
00410	2	Anesth, correct heart rhythm						
00420	2	Anesth, skin surgery, back						
00450	2	Anesth, surgery of shoulder						
00452	2	Anesth, surgery of shoulder						
00454	2	Anesth, collar bone biopsy						
00470	2	Anesth, removal of rib						
00472	2	Anesth, chest wall repair						
00474	2	Anesth, surgery of rib(s)						
00500	2	Anesth, esophageal surgery						
00520	2	Anesth, chest procedure						
00522	2	Anesth, chest lining biopsy						
00524	2	Anesth, chest drainage						
00528	2	Anesth, chest partition view						
00530	2	Anesth, pacemaker insertion						
00532	2	Anesth, vascular access						
00534	2	Anesth, cardioverter/defib						
00540	2	Anesth, chest surgery						
00542	2	Anesth, release of lung						
00544	2	Anesth, chest lining removal						
00546	2	Anesth, lung, chest wall surg			•••••			
00548	2	Anesth, trachea, bronchi surg			•••••			
00560	2	Anesth, open heart surgery						
00562	2	Anesth, open heart surgery						
00580 00600	2	Anesth, heart/lung transplant						
00000	Z	Anesth, spine, cord surgery						

¹ CPT codes and descriptions only are copyright 1997 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

²Codes proposed for additions to or deletions from ASC list.

ADDENDUM A.—PROPOSED AMBULATORY SURGICAL CENTER (ASC) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION—Continued

CPT 1/ HCPCS	ASC payment indicator	Description	Current payment group	Current payment rate	Proposed APC group	Proposed payment rate	Relative value factor	Add ² / Delete
00604	2	Anesth, surgery of vertebra						
00620	2	Anesth, spine, cord surgery						
00622	2	Anesth, removal of nerves						
00630	2	Anesth, spine, cord surgery						
00632	2	Anesth, removal of nerves						
00634	2	Anesth for chemonucleolysis						
00670	2	Anesth, spine, cord surgery						
00700 00702	2 2	Anesth, abdominal wall surg						
00702	2	Anesth, for liver biopsy Anesth, abdominal wall surg						
00740	2	Anesth, gi visualization						
00750	2	Anesth, repair of hernia						
00752	2	Anesth, repair of hernia						
00754	2	Anesth, repair of hernia						
00756	2	Anesth, repair of hernia						
00770	2	Anesth, blood vessel repair						
00790	2	Anesth, surg upper abdomen						
00792	2	Anesth, part liver removal						
00794	2	Anesth, pancreas removal						
00796 00800	2 2	Anesth, for liver transplant Anesth, abdominal wall surg						
00800	2	Anesth, fat layer removal						
00802	2	Anesth, intestine endoscopy						
00820	2	Anesth, abdominal wall surg						
00830	2	Anesth, repair of hernia						
00832	2	Anesth, repair of hernia						
00840	2	Anesth, surg lower abdomen						
00842	2	Anesth, amniocentesis						
00844	2	Anesth, pelvis surgery						
00846	2	Anesth, hysterectomy						
00848	2	Anesth, pelvic organ surg						
00850 00855	2 2	Anesth, cesarean section Anesth, hysterectomy						
00857	2	Analgesia, labor & c-section						
00860	2	Anesth, surgery of abdomen						
00862	2	Anesth, kidney, ureter surg						
00864	2	Anesth, removal of bladder						
00865	2	Anesth, removal of prostate						
00866	2	Anesth, removal of adrenal						
00868	2	Anesth, kidney transplant						
00870	2	Anesth, bladder stone surg						
00872	2	Anesth, kidney stone destruct						
00873 00880	2 2	Anesth, kidney stone destruct						
00882	2	Anesth, abdomen vessel surg Anesth, major vein ligation						
00884	2	Anesth, major vein revision						
00900	2	Anesth, perineal procedure						
00902	2	Anesth, anorectal surgery						
00904	2	Anesth, perineal surgery						
00906	2	Anesth, removal of vulva						
00908	2	Anesth, removal of prostate						
00910	2	Anesth, bladder surgery						
00912	2	Anesth, bladder tumor surg						
00914 00916	2 2	Anesth, removal of prostate Anesth, bleeding control						
00916	2	Anesth, stone removal						
00910	2	Anesth, genitalia surgery						
00922	2	Anesth, sperm duct surgery						
00924	2	Anesth, testis exploration						
00926	2	Anesth, removal of testis						
00928	2	Anesth, removal of testis						
00930	2	Anesth, testis suspension						
00932	2	Anesth, amputation of penis						
00934	2	Anesth, penis, nodes removal						
00936	2	Anesth, penis, nodes removal						
00938	2	Anesth, insert penis device						
00940 00942	2 2	Anesth, vaginal procedures						
00942	2	Anesth, surgery on vagina Anesth, vaginal hysterectomy						
00944	2	Anesth, vaginal delivery						
00948	2	Anesth, repair of cervix						
00950	2	Anesth, vaginal endoscopy						
		Anesth, uterine endoscopy						
00952	2							

ADDENDUM A.-PROPOSED AMBULATORY SURGICAL CENTER (ASC) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION—Continued

CPT 1/ HCPCS	ASC payment indicator	Description	Current payment group	Current payment rate	Proposed APC group	Proposed payment rate	Relative value factor	Add ²/ Delete
01000	2	Anesth, skin surgery, pelvis						
01000	2	Anesth, skin surgery, pelvis						
01120	2	Anesth, pelvis surgery						
01130	2	Anesth, body cast procedure						
01140	2	Anesth, amputation at pelvis						
01150	2	Anesth, pelvic tumor surgery						
01160 01170	2	Anesth, pelvis procedure Anesth, pelvis surgery						
01180	2	Anesth, pelvis nerve removal						
01190	2	Anesth, pelvis nerve removal						
01200	2	Anesth, hip joint procedure						
01202	2	Anesth, arthroscopy of hip						
01210	2	Anesth, hip joint surgery						
01212 01214	2	Anesth, hip disarticulation Anesth, replacement of hip						
01214	2	Anesth, procedure on femur						
01230	2	Anesth, surgery of femur						
01232	2	Anesth, amputation of femur						
01234	2	Anesth, radical femur surg						
01240	2	Anesth, upper leg skin surg						
01250	2	Anesth, upper leg surgery						
01260 01270	2	Anesth, upper leg veins surg Anesth, thigh arteries surg						
01270	2	Anesth, femoral artery surg						
01274	2	Anesth, femoral embolectomy						
01300	2	Anesth, skin surgery, knee						
01320	2	Anesth, knee area surgery						
01340	2	Anesth, knee area procedure						
01360 01380	2 2	Anesth, knee area surgery Anesth, knee joint procedure						
01380	2	Anesth, knee arthroscopy						
01390	2	Anesth, knee area procedure						
01392	2	Anesth, knee area surgery						
01400	2	Anesth, knee joint surgery						
01402	2	Anesth, replacement of knee						
01404 01420	2	Anesth, amputation at knee Anesth, knee joint casting						
01420	2	Anesth, knee veins surgery						
01432	2	Anesth, knee vessel surg						
01440	2	Anesth, knee arteries surg						
01442	2	Anesth, knee artery surg						
01444 01460	2	Anesth, knee artery repair Anesth, lower leg skin surg						
01462	2	Anesth, lower leg procedure						
01464	2	Anesth, ankle arthroscopy						
01470	2	Anesth, lower leg surgery						
01472	2	Anesth, achilles tendon surg						
01474 01480	2	Anesth, lower leg surgery						
01480	2	Anesth, lower leg bone surg Anesth, radical leg surgery						
01484	2	Anesth, lower leg revision						
01486	2	Anesth, ankle replacement						
01490	2	Anesth, lower leg casting						
01500	2	Anesth, leg arteries surg						
01502	2	Anesth, lowerleg embolectomy						
01520 01522	2	Anesth, lower leg vein surg Anesth, lower leg vein surg						
01600	2	Anesth, shoulder skin surg						
01610	2	Anesth, surgery of shoulder						
01620	2	Anesth, shoulder procedure						
01622	2	Anesth, shoulder arthroscopy						
01630	2	Anesth, surgery of shoulder						
01632 01634	2	Anesth, surgery of shoulder Anesth, shoulder joint amput						
01634	2	Anesth, foreguarter amput						
01638	2	Anesth, shoulder replacement						
01650	2	Anesth, shoulder artery surg						
01652	2	Anesth, shoulder vessel surg						
01654	2	Anesth, shoulder vessel surg						
01656 01670	2	Anesth, arm-leg vessel surg Anesth, shoulder vein surg						
01680	2	Anesth, shoulder casting						
01682	2	Anesth, airplane cast						
01700	2	Anesth, elbow area skin surg	۱		l	I	l	

CPT 1/ HCPCS	ASC payment indicator	Description	Current payment group	Current payment rate	Proposed APC group	Proposed payment rate	Relative value factor	Add ² / Delete
01710	2	Anesth, elbow area surgery						
01712	2	Anesth, upperarm tendon surg						
01714	2	Anesth, upperarm tendon surg						
01716	2	Anesth, biceps tendon repair						
01730	2	Anesth, upperarm procedure						
01732 01740	2	Anesth, elbow arthroscopy						
01740	2	Anesth, upper arm surgery Anesth, humerus surgery						
01744	2	Anesth, humerus repair						
01756	2	Anesth, radical humerus surg						
01758	2	Anesth, humeral lesion surg						
01760	2	Anesth, elbow replacement						
01770	2	Anesth, upperarm artery surg						
01772	2	Anesth, upperarm embolectomy						
01780	2	Anesth, upper arm vein surg						
01782	2	Anesth, upperarm vein repair						
01784	2	Anesth, av fistula repair						
01800	2	Anesth, lower arm skin surg						
01810 01820	2	Anesth, lower arm surgery						
01820	2	Anesth, lower arm surgery						
01832	2	Anesth, wrist replacement						
01840	2	Anesth, lowerarm artery surg						
01842	2	Anesth, lowerarm embolectomy						
01844	2	Anesth, vascular shunt surg						
01850	2	Anesth, lower arm vein surg						
01852	2	Anesth, lowerarm vein repair						
01860	2	Anesth, lower arm casting						
01900	2	Anesth, uterus/tube inject						
01902	2	Anesth, burr holes, skull Anesth, skull x-ray inject						
01904 01906	2	Anesth, lumbar myelography						
01908	2	Anesth, cervical myelography						
01910	2	Anesth, skull myelography						
01912	2	Anesth, lumbar discography						
01914	2	Anesth, cervical discography						
01916	2	Anesth, head arteriogram						
01918	2	Anesth, limb arteriogram						
01920	2	Anesth, catheterize heart						
01921	2	Anesth, vessel surgery						
01922	2	Anesth, cat or MRI scan						
01990 01995	6 2	Support for organ donor						
01995	2	Regional anesthesia, limb Manage daily drug therapy						
01999	3	Unlisted anesth procedure						
10040	5	Acne surgery of skin abscess						
10060	5	Drainage of skin abscess						
10061	5	Drainage of skin abscess						
10080	5	Drainage of pilonidal cyst						
10081	5	Drainage of pilonidal cyst						
10120	5	Remove foreign body						
10121	1	Remove foreign body			163	\$449	0.89	Add.
10140	5	Drainage of hematoma/fluid						
10160	5	Puncture drainage of lesion	······	¢400				Dolata
10180 11000	5 5	Complex drainage, wound Debride infected skin	2	\$422				Delete.
11000	5 5	Debride infected skin						
11010	1	Debride skin, fx			163	\$449	0.89	Add.
11010	1	Debride skin/muscle, fx			163	\$449	0.89	Add.
11012	1	Debride skin/muscle/bone, fx			163	\$449	0.89	Add.
11040	5	Debride skin partial						
11041	5	Debride skin full						
11042	5	Debride skin/tissue	2	\$422				Delete.
11043	1	Debride tissue/muscle	2	\$422	162	\$187	0.37	
11044	1	Debride tissue/muscle/bone	2	\$422	162	\$187	0.37	
11055	5	Trim skin lesion						
11056 11057	5 5	Trim 2 to 4 skin lesions						
11057 11100	5	Trim over 4 skin lesions Biopsy of skin lesion						
11100	5	Biopsy, each added lesion						
11200	5 5	Removal of skin tags						
11200	5	Removal of added skin tags						
11300	5	Shave skin lesion						
	5							

ADDENDUM A.-PROPOSED AMBULATORY SURGICAL CENTER (ASC) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION—Continued

CPT 1/ HCPCS	ASC payment indicator	Description	Current payment group	Current payment rate	Proposed APC group	Proposed payment rate	Relative value factor	Add ^{2/} Delete
11302	5	Shave skin lesion						
11303	5	Shave skin lesion						
11305	5	Shave skin lesion						
11306 11307	5 5	Shave skin lesion Shave skin lesion						
11308	5	Shave skin lesion						
11310	5	Shave skin lesion						
11311 11312	5 5	Shave skin lesion Shave skin lesion						
11312	5	Shave skin lesion						
11400	5	Removal of skin lesion						
11401	5	Removal of skin lesion						
11402 11403	5 5	Removal of skin lesion Removal of skin lesion						
11403	1	Removal of skin lesion		\$314		\$187	0.37	
11406	1	Removal of skin lesion	2	\$422	163	\$449	0.89	
11420	5	Removal of skin lesion						
11421 11422	5 5	Removal of skin lesion						
11422	5	Removal of skin lesion Removal of skin lesion						
11424	1	Removal of skin lesion	2	\$422	162	\$187	0.37	
11426	1	Removal of skin lesion	2	\$422	163	\$449	0.89	
11440	5 5	Removal of skin lesion						
11441 11442	5	Removal of skin lesion Removal of skin lesion						l l
11443	5	Removal of skin lesion						
11444	1	Removal of skin lesion	1	\$314	162	\$187	0.37	
11446	1	Removal of skin lesion	2	\$422	163	\$449	0.89	
11450 11451	1	Removal, sweat gland lesion Removal, sweat gland lesion	2	\$422 \$422	163 163	\$449 \$449	0.89 0.89	
11462	1	Removal, sweat gland lesion	2	\$422	163	\$449	0.89	
11463	1	Removal, sweat gland lesion	2	\$422	163	\$449	0.89	
11470	1	Removal, sweat gland lesion	2	\$422	163	\$449	0.89	
11471 11600	15	Removal, sweat gland lesion Removal of skin lesion	2	\$422	163	\$449	0.89	
11601	5	Removal of skin lesion						
11602	5	Removal of skin lesion						
11603	5	Removal of skin lesion		 ¢400		 ¢107		
11604 11606	1	Removal of skin lesion Removal of skin lesion	2	\$422 \$422	162 163	\$187 \$449	0.37 0.89	
11620	5	Removal of skin lesion		Ψ=ΖΖ		φ++5		
11621	5	Removal of skin lesion						
11622	5	Removal of skin lesion						
11623 11624	5	Removal of skin lesion Removal of skin lesion	2	 \$422		\$449	0.89	
11626	1	Removal of skin lesion	2	\$422	163	\$449	0.89	
11640	5	Removal of skin lesion						
11641	5	Removal of skin lesion						
11642 11643	5 5	Removal of skin lesion Removal of skin lesion						
11644	1	Removal of skin lesion	2	\$422	163	\$449	0.89	
11646	1	Removal of skin lesion	2	\$422	163	\$449	0.89	
11719	5 5	Trim nail(s)						
11720 11721	5	Debride nail, 1-5 Debride nail, 6 or more						l l
11730	5	Removal of nail plate						
11731	5	Removal of second nail plate						
11732	5	Remove additional nail plate						
11740 11750	5 5	Drain blood from under nail Removal of nail bed						
11752	1	Remove nail bed/finger tip			163	\$449	0.89	Add.
11755	5	Biopsy, nail unit						
11760	1	Reconstruction of nail bed			181	\$150 \$150	0.30	Add.
11762 11765	15	Reconstruction of nail bed Excision of nail fold, toe			181	\$150	0.30	Add.
11703	1	Removal of pilonidal lesion	3	\$482	162	\$187	0.37	l
11771	1	Removal of pilonidal lesion	3	\$482	163	\$449	0.89	
11772	1	Removal of pilonidal lesion	3	\$482	163	\$449	0.89	
11900 11901	5	Injection into skin lesions Add.ed skin lesions injection						
11901	7	Correct skin color defects				\$150	0.30	Add.
11921	7	Correct skin color defects			181	\$150	0.30	Add.
11922	7	Correct skin color defects			181	\$150 \$150	0.30	Add.
11950	ı <i>1</i>	Therapy for contour defects	I		181	\$150	0.30	Ada.

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CPT 1/ HCPCS	ASC payment indicator	Description	Current payment group	Current payment rate	Proposed APC group	Proposed payment rate	Relative value factor	Add ² / Delete
11951	7	Therapy for contour defects			181	\$150	0.30	Add.
11952	7	Therapy for contour defects			181	\$150	0.30	Add.
11954	7	Therapy for contour defects			181	\$150	0.30	Add.
11960	1	Insert tissue expander(s)	2	\$422	183	\$465	0.92	
11970	1	Replace tissue expander		\$482	183	\$465	0.92	
11971	1	Remove tissue expander(s)	1	\$314	163	\$449	0.89	
11975	9 5	Insert contraceptive cap						
11976 11977	9	Removal of contraceptive cap Removal/reinsert contra cap						
12001	1	Repair superficial wound(s)			181	\$150	0.30	Add.
12002	1	Repair superficial wound(s)			181	\$150	0.30	Add.
12004	1	Repair superficial wound(s)			181	\$150	0.30	Add.
12005	1	Repair superficial wound(s)	2	\$422	181	\$150	0.30	
12006	1	Repair superficial wound(s)		\$422	181	\$150	0.30	
12007	1	Repair superficial wound(s)	2	\$422	181	\$150	0.30	
12011	1	Repair superficial wound(s)			181	\$150	0.30	Add.
12013	1	Repair superficial wound(s)			181	\$150 \$150	0.30	Add.
12014 12015	1	Repair superficial wound(s) Repair superficial wound(s)			181	\$150 \$150	0.30 0.30	Add. Add.
12015	1	Repair superficial wound(s)	2	\$422	181 181	\$150	0.30	Auu.
12010		Repair superficial wound(s)	2	\$422	181	\$150	0.30	
12017	1	Repair superficial wound(s)		\$422	181	\$150	0.30	
12020	. 1	Closure of split wound		\$314	181	\$150	0.30	
12021	1	Closure of split wound	1	\$314	181	\$150	0.30	
12031	1	Layer closure of wound(s)			181	\$150	0.30	Add.
12032	1	Layer closure of wound(s)			181	\$150	0.30	Add.
12034	1	Layer closure of wound(s)	2	\$422	181	\$150	0.30	
12035	1	Layer closure of wound(s)	2	\$422	181	\$150	0.30	
12036	1	Layer closure of wound(s)	2 2	\$422 \$422	181	\$150 \$165	0.30	
12037 12041	1	Layer closure of wound(s)		\$422	183 181	\$465 \$150	0.92 0.30	Add.
12041		Layer closure of wound(s)			181	\$150	0.30	Add. Add.
12042		Layer closure of wound(s)	2	\$422	181	\$150	0.30	Auu.
12045	1	Layer closure of wound(s)	2	\$422	181	\$150	0.30	
12046	1	Layer closure of wound(s)	2	\$422	181	\$150	0.30	
12047	1	Layer closure of wound(s)	2	\$422	183	\$465	0.92	
12051	1	Layer closure of wound(s)			181	\$150	0.30	Add.
12052	1	Layer closure of wound(s)			181	\$150	0.30	Add.
12053	1	Layer closure of wound(s)		·····	181	\$150	0.30	Add.
12054	1	Layer closure of wound(s)	2	\$422	181	\$150	0.30	
12055 12056		Layer closure of wound(s)	2 2	\$422 \$422	181 181	\$150 \$150	0.30 0.30	
12056	1	Layer closure of wound(s) Layer closure of wound(s)	2	\$422 \$422	183	\$465	0.30	
13100	1	Repair of wound or lesion	2	\$422	182	\$383	0.32	
13101	1	Repair of wound or lesion	3	\$482	182	\$383	0.76	
13120	1	Repair of wound or lesion	2	\$422	182	\$383	0.76	
13121	1	Repair of wound or lesion	3	\$482	182	\$383	0.76	
13131	1	Repair of wound or lesion	2	\$422	182	\$383	0.76	
13132	1	Repair of wound or lesion	3	\$482	182	\$383	0.76	
13150	1	Repair of wound or lesion	3	\$482	182	\$383	0.76	
13151	1	Repair of wound or lesion	3	\$482 \$482	182	\$383	0.76	
13152 13160	1	Repair of wound or lesion	3 2	\$482 \$422	182 182	\$383	0.76 0.76	
13160	1	Late closure of wound Repair of wound or lesion	2 4	\$422 \$595	182	\$383 \$383	0.76	
14000	1	Skin tissue rearrangement	4	\$422	182	\$363 \$465	0.78	
14000	1	Skin tissue rearrangement	3	\$482	183	\$465 \$465	0.92	
14020	1	Skin tissue rearrangement	3	\$482	183	\$465	0.92	
14021	1	Skin tissue rearrangement	3	\$482	183	\$465	0.92	
14040	1	Skin tissue rearrangement	2	\$422	183	\$465	0.92	
14041	1	Skin tissue rearrangement	3	\$482	183	\$465	0.92	
14060	1	Skin tissue rearrangement	3	\$482	183	\$465	0.92	
14061	1	Skin tissue rearrangement	3	\$482	183	\$465	0.92	
14300		Skin tissue rearrangement	4	\$595 \$492	183	\$465 \$465	0.92	
14350	1	Skin tissue rearrangement	3 2	\$482 \$422	183	\$465 \$465	0.92	
15000 15050	1	Skin graft procedure Skin pinch graft procedure	2	\$422 \$422	183 183	\$465 \$465	0.92 0.92	
15050	1	Skin split graft procedure	2	\$422 \$422	183	\$465 \$465	0.92	
15100	1	Skin split graft procedure	3	\$482	183	\$465 \$465	0.92	
15120	1	Skin split graft procedure	2	\$422	183	\$465	0.92	
15121	1	Skin split graft procedure	3	\$482	183	\$465	0.92	
15200	1	Skin full graft procedure	3	\$482	183	\$465	0.92	
15201	1	Skin full graft procedure	2	\$422	183	\$465	0.92	
15220	1	Skin full graft procedure	2	\$422	183	\$465	0.92	
15221	1	Skin full graft procedure	2	\$422	183	\$465	0.92	i -

ADDENDUM A.-PROPOSED AMBULATORY SURGICAL CENTER (ASC) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION—Continued

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CPT 1/ HCPCS	ASC payment indicator	Description	Current payment group	Current payment rate	Proposed APC group	Proposed payment rate	Relative value factor	Add ² / Delete
15240	1	Skin full graft procedure	3	\$482	183	\$465	0.92	
15241	1	Skin full graft procedure	3	\$482	183	\$465	0.92	
15260	1	Skin full graft procedure	2	\$422	183	\$465	0.92	
15261	1	Skin full graft procedure	2	\$422	183	\$465	0.92	
15350	1	Skin homograft procedure	2	\$422	183	\$465	0.92	
15400	1	Skin heterograft procedure	2	\$422 \$482	183	\$465	0.92	
15570 15572	1	Form skin pedicle flap Form skin pedicle flap	3	\$482 \$482	183 183	\$465 \$465	0.92 0.92	
15574	1	Form skin pedicle flap	3	\$482	183	\$465	0.92	
15576	1	Form skin pedicle flap	3	\$482	183	\$465	0.92	
15580	1	Attach skin pedicle graft	3	\$482	183	\$465	0.92	
15600	1	Skin graft procedure	3	\$482	183	\$465	0.92	
15610	1	Skin graft procedure	3	\$482	183	\$465	0.92	
15620 15625	1	Skin graft procedure	4	\$595 \$482	183 183	\$465 \$465	0.92 0.92	
15630	1	Skin graft procedure Skin graft procedure	3	\$482	183	\$465	0.92	
15650	1	Transfer skin pedicle flap	5	\$678	183	\$465	0.92	
15732	1	Muscle-skin graft, head/neck	3	\$482	184	\$565	1.12	
15734	1	Muscle-skin graft, trunk	3	\$482	184	\$565	1.12	
15736	1	Muscle-skin graft, arm	3	\$482	184	\$565	1.12	
15738	1	Muscle-skin graft, leg	3	\$482	184	\$565	1.12	
15740	1	Island pedicle flap graft	2	\$422	184	\$565	1.12	
15750 15756	1	Neurovascular pedicle graft Free muscle flap, microvasc	2	\$422 \$482	184	\$565	1.12	Delete.
15756	3	Free skin flap, microvasc	3	\$482 \$482				Delete.
15758	3	Free fascial flap, microvasc	3	\$482				Delete.
15760	1	Composite skin graft	2	\$422	184	\$565	1.12	20.0101
15770	1	Derma-fat-fascia graft	3	\$482	184	\$565	1.12	
15775	7	Hair transplant punch grafts			183	\$465	0.92	Add.
15776	7	Hair transplant punch grafts			183	\$465	0.92	Add.
15780	1	Abrasion treatment of skin			163	\$449	0.89	Add.
15781 15782	1	Abrasion treatment of skin			163 163	\$449 \$449	0.89 0.89	Add. Add.
15782	5	Abrasion treatment of skin					0.09	Adu.
15786	5	Abrasion treatment of lesion						
15787	5	Abrasion, added skin lesions						
15788	5	Chemical peel, face, epiderm						
15789	5	Chemical peel, face, dermal						
15792	5	Chemical peel, nonfacial						
15793	5	Chemical peel, nonfacial						
15810 15811	5 1	Salabrasion				\$449	0.89	Add.
15819	1	Plastic surgery, neck			183	\$465	0.00	Add.
15820	1	Revision of lower eyelid			183	\$465	0.92	Add.
15821	1	Revision of lower eyelid			183	\$465	0.92	Add.
15822	1	Revision of upper eyelid			183	\$465	0.92	Add.
15823	1	Revision of upper eyelid			183	\$465	0.92	Add.
15824	7	Removal of forehead wrinkles			184	\$565	1.12	Add.
15825 15826	7	Removal of neck wrinkles Removal of brow wrinkles			183 184	\$465 \$565	0.92	Add. Add.
15828	7	Removal of face wrinkles			184	\$565	1.12	Add.
15829	7	Removal of skin wrinkles			183	\$465	0.92	Add.
15831	1	Excise excessive skin tissue			184	\$565	1.12	Add.
15832	1	Excise excessive skin tissue			184	\$565	1.12	Add.
15833	1	Excise excessive skin tissue			184	\$565	1.12	Add.
15834	1	Excise excessive skin tissue			184	\$565	1.12	Add.
15835	1	Excise excessive skin tissue			183	\$465 \$565	0.92	Add.
15836 15837	1	Excise excessive skin tissue Excise excessive skin tissue			184 184	\$565 \$565	1.12 1.12	Add. Add.
15838	1	Excise excessive skin tissue			163	\$449	0.89	Add.
15839	1	Excise excessive skin tissue			184	\$565	1.12	Add.
15840	1	Graft for face nerve palsy	4	\$595	184	\$565	1.12	
15841	1	Graft for face nerve palsy	4	\$595	184	\$565	1.12	
15842	1	Graft for face nerve palsy	4	\$595	184	\$565	1.12	
15845	1	Skin and muscle repair, face	4	\$595	184	\$565	1.12	
15850	5 5	Removal of sutures						
15851 15852	5	Removal of sutures Dressing change,not for burn						
15860	1	Test for blood flow in graft			181	\$150	0.30	Add.
15876	7	Suction assisted lipectomy			184	\$565	1.12	Add.
15877	7	Suction assisted lipectomy			184	\$565	1.12	Add.
15878	7	Suction assisted lipectomy			184	\$565	1.12	Add.
15879	7	Suction assisted lipectomy			184	\$565	1.12	Add.
15920	1	Removal of tail bone ulcer	3	\$482	163	l \$449	0.89	I

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CPT 1/ HCPCS	ASC payment indicator	Description	Current payment group	Current payment rate	Proposed APC group	Proposed payment rate	Relative value factor	Add ² / Delete
15922	1	Removal of tail bone ulcer	4	\$595	184	\$565	1.12	
15931	1	Remove sacrum pressure sore	3	\$482	163	\$449	0.89	
15933	1	Remove sacrum pressure sore	3	\$482	163	\$449	0.89	
15934	1	Remove sacrum pressure sore	3	\$482	184	\$565	1.12	
15935	1	Remove sacrum pressure sore	4	\$595	184	\$565	1.12	
15936	1	Remove sacrum pressure sore	4	\$595	184	\$565	1.12	
15937	1	Remove sacrum pressure sore	4 3	\$595 \$482	184	\$565	1.12	
15940 15941	1	Removal of pressure sore Removal of pressure sore	3	\$482 \$482	163 163	\$449 \$449	0.89 0.89	
15944	1	Removal of pressure sore	3	\$482	184	\$565	1.12	
15945	1	Removal of pressure sore	4	\$595	184	\$565	1.12	
15946	1	Removal of pressure sore	4	\$595	184	\$565	1.12	
15950	1	Remove thigh pressure sore	3	\$482	163	\$449	0.89	
15951	1	Remove thigh pressure sore	4	\$595	163	\$449	0.89	
15952	1	Remove thigh pressure sore	3	\$482	184	\$565	1.12	
15953	1	Remove thigh pressure sore	4	\$595	184	\$565	1.12	
15956	1	Remove thigh pressure sore	3 4	\$482 \$505	184	\$565 \$565	1.12	
15958 15999	1	Remove thigh pressure sore	-	\$595	184	\$565	1.12	
16000	5	Removal of pressure sore Initial treatment of burn(s)						
16010	1	Treatment of burn(s)			152	\$213	0.42	Add.
16015	1	Treatment of burn(s)	2	\$422	152	\$213	0.42	, 1001
16020	5	Treatment of burn(s)		·····				
16025	5	Treatment of burn(s)						
16030	5	Treatment of burn(s)	1	\$314				Delete.
16035	1	Incision of burn scab	2	\$422	162	\$187	0.37	
16040	1	Burn wound excision			162	\$187	0.37	Add.
16041	1	Burn wound excision			162	\$187	0.37	Add.
16042 17000	1	Burn wound excision			162	\$187	0.37	Add.
17000	5	Destroy benign/premal lesion Destroy 2-14 lesions						
17003	5	Destroy 15 & more lesions						
17106	1	Destruction of skin lesions			152	\$213	0.42	Add.
17107	1	Destruction of skin lesions			152	\$213	0.42	Add.
17108	1	Destruction of skin lesions			152	\$213	0.42	Add.
17110	5	Destruct lesion, 1-14						
17111	5	Destruct lesion, 15 or more						
17250	5	Chemical cautery, tissue						
17260	5	Destruction of skin lesions						
17261	5 5	Destruction of skin lesions						
17262 17263	5	Destruction of skin lesions Destruction of skin lesions						
17264	5	Destruction of skin lesions						
17266	5	Destruction of skin lesions						
17270	5	Destruction of skin lesions						
17271	5	Destruction of skin lesions						
17272	5	Destruction of skin lesions						
17273	5	Destruction of skin lesions						
17274	5							
17276	5							
17280	5	Destruction of skin lesions Destruction of skin lesions						
17281 17282	5 5	Destruction of skin lesions						
17283	5	Destruction of skin lesions						
17284	5	Destruction of skin lesions						
17286	5	Destruction of skin lesions						
17304	1	Chemosurgery of skin lesion			162	\$187	0.37	Add.
17305	1	2nd stage chemosurgery			162	\$187	0.37	Add.
17306	1	3rd stage chemosurgery			162	\$187	0.37	Add.
17307	1	Followup skin lesion therapy			162	\$187	0.37	Add.
17310	1	Extensive skin chemosurgery			162	\$187	0.37	Add.
17340	5	Cryotherapy of skin						
17360 17380	5 5	Skin peel therapy Hair removal by electrolysis						
17380	5	Skin tissue procedure						
19000	5	Drainage of breast lesion						
19000	5	Drain added breast lesion						
19020	1	Incision of breast lesion	2	\$422	132	\$162	0.32	
19030	2	Injection for breast x-ray						
19100	1	Biopsy of breast	1	\$314	122	\$186	0.37	
19101	1	Biopsy of breast	2	\$422	197	\$411	0.81	
19110	1	Nipple exploration	2	\$422	197	\$411	0.81	
19112	1	Excise breast duct fistula	3	\$482	197	\$411	0.81	
19120	1	Removal of breast lesion	3	\$482	197	\$411	0.81	

ADDENDUM A.-PROPOSED AMBULATORY SURGICAL CENTER (ASC) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION—Continued

	ASC		Current	Current	Proposed	Proposed	Relative	
CPT 1/ HCPCS	payment indicator	Description	payment group	payment rate	APC group	payment rate	value factor	Add ² / Delete
19125	1	Excision, breast lesion	3	\$482	197	\$411	0.81	
19126	1	Excision, add'I breast lesion	3	\$482	197	\$411	0.81	
19140	1	Removal of breast tissue	4	\$595	197	\$411	0.81	
19160	1	Removal of breast tissue	3	\$482	198	\$596 \$506	1.18	
19162 19180	1	Remove breast tissue, nodes Removal of breast	4	\$941 \$595	198 198	\$596 \$596	1.18 1.18	
19182		Removal of breast	4	\$595	190	\$596	1.10	
19200	3	Removal of breast						
19220	3	Removal of breast						
19240	3	Removal of breast						
19260 19271	3	Removal of chest wall lesion Revision of chest wall	5	\$678				Delete.
19271	3	Extensive chest wall surgery						
19290	1	Place needle wire, breast	1	\$314	197	\$411	0.81	
19291	1	Place needle wire, breast	1	\$314	197	\$411	0.81	
19316	1	Suspension of breast			198	\$596	1.18	Add.
19318	1	Reduction of large breast	4	\$595	198	\$596 \$506	1.18	٨ ما ما
19324 19325	1	Enlarge breast Enlarge breast with implant			198 198	\$596 \$596	1.18 1.18	Add. Add.
19328		Removal of breast implant	1	\$314	190	\$596	1.10	Auu.
19330	1	Removal of implant material	1	\$314	198	\$596	1.18	
19340	1	Immediate breast prosthesis	2	\$422	198	\$596	1.18	
19342	1	Delayed breast prosthesis	3	\$482	198	\$596	1.18	
19350	1	Breast reconstruction	4	\$595	198	\$596	1.18	
19355	1	Correct inverted nipple(s) Breast reconstruction	5	\$678	198 198	\$596 \$596	1.18 1.18	Add.
19357 19361	3	Breast reconstruction	-	\$010	190	\$290	1.10	
19364	3	Breast reconstruction	5	\$678				Delete.
19366	1	Breast reconstruction	5	\$678	198	\$596	1.18	201010.
19367	3	Breast reconstruction						
19368	3	Breast reconstruction						
19369	3	Breast reconstruction						
19370	1	Surgery of breast capsule	4	\$595	198	\$596	1.18	
19371 19380	1	Removal of breast capsule Revise breast reconstruction	4	\$595 \$678	198 198	\$596 \$596	1.18 1.18	
19396	1	Design custom breast implant	-	ψ070	190	\$411	0.81	Add.
19499	3	Breast surgery procedure						
20000	5	Incision of abscess						
20005	1	Incision of deep abscess	2	\$422	251	\$504	1.00	
20100	3	Explore wound, neck						
20101 20102	3	Explore wound, chest Explore wound, abdomen						
20102	3	Explore wound, abdomen						
20150	3	Excise epiphyseal bar						
20200	1	Muscle biopsy	2	\$422	162	\$187	0.37	
20205	1	Deep muscle biopsy	3	\$482	162	\$187	0.37	
20206	1	Needle biopsy, muscle	1	\$314	122	\$186	0.37	
20220	1	Bone biopsy, trocar/needle	1	\$314	162	\$187	0.37	
20225 20240	1	Bone biopsy, trocar/needle Bone biopsy, excisional	2	\$422 \$422	162 163	\$187 \$449	0.37 0.89	
20240	1	Bone biopsy, excisional	3	\$482	163	\$449	0.89	
20250	1	Open bone biopsy	3	\$482	251	\$504	1.00	
20251	1	Open bone biopsy	3	\$482	251	\$504	1.00	
20500	1	Injection of sinus tract			181	\$150	0.30	Add.
20501	2	Inject sinus tract for x-ray						
20520 20525	5	Removal of foreign body Removal of foreign body		\$482		\$449	0.89	
20525	5	Inj tendon/ligament/cyst		\$40Z			0.09	
20500	5	Drain/inject joint/bursa						
20605	5	Drain/inject joint/bursa						
20610	5	Drain/inject joint/bursa						
20615	5	Treatment of bone cyst		 ¢ 400				
20650	1	Insert and remove bone pin	3	\$482 \$422	251	\$504	1.00	Delete.
20660 20661	3	Apply, remove fixation device Application of head brace	2	\$422 \$482				Delete.
20662	3	Application of pelvis brace	3	\$482				Delete.
20663	3	Application of thigh brace	3	\$482				Delete.
20664	3	Halo brace application						
20665	5	Removal of fixation device	1	\$314				Delete.
20670	1	Removal of support implant	1	\$314	162	\$187	0.37	
20680 20690	1	Removal of support implant Apply bone fixation device	3	\$482 \$422	163 252	\$449 \$574	0.89	
20690	1	Apply bone fixation device		\$422	252	\$574 \$574	1.14	Add.
20693					252	\$504		Add.
	'	.,			201	400 F	1.00	

CPT 1/ HCPCS	ASC payment	Description	Current payment	Current payment	Proposed APC	Proposed payment	Relative value	Add ² / Delete
псесо	indicator		group	rate	group	rate	factor	Delete
20694	1	Remove bone fixation device	1	\$314	251	\$504	1.00	
20802	3	Replantation, arm, complete						
20805 20808	3	Replant forearm, complete Replantation, hand, complete						
20816	3	Replantation digit, complete						
20822	3	Replantation digit, complete						
20824 20827	3	Replantation thumb, complete Replantation thumb, complete						
20838	3	Replantation, foot, complete						
20900	1	Removal of bone for graft	3	\$482	252	\$574	1.14	
20902 20910	1	Removal of bone for graft Remove cartilage for graft	4	\$595 \$482	252 183	\$574 \$465	1.14 0.92	
20912	1	Remove cartilage for graft	3	\$482	183	\$465	0.92	
20920	1	Removal of fascia for graft	4	\$595	183	\$465	0.92	
20922	1	Removal of fascia for graft	3	\$482	183	\$465	0.92	
20924 20926	1	Removal of tendon for graft Removal of tissue for graft	4	\$595 \$595	252 183	\$574 \$465	1.14 0.92	
20930	3	Spinal bone allograft				φ+00		
20931	3	Spinal bone allograft						
20936	3	Spinal bone autograft						
20937 20938	3	Spinal bone autograft Spinal bone autograft						
20950	1	Record fluid pressure,muscle			132	\$162	0.32	Add.
20955	3	Fibula bone graft, microvasc	4	\$595				Delete.
20956	3	Iliac bone graft, microvasc						
20957 20962	3	Mt bone graft, microvasc Other bone graft, microvasc	4	\$595				Delete.
20969	3	Bone/skin graft, microvasc	4	\$595				Delete.
20970	3	Bone/skin graft, iliac crest	4	\$595				Delete.
20972	3	Bone-skin graft, metatarsal	4	\$595 \$595				Delete.
20973 20974	3	Bone-skin graft, great toe Electrical bone stimulation	4	\$595				Delete.
20975	1	Electrical bone stimulation	2	\$422	251	\$504	1.00	
20999	3	Musculoskeletal surgery						
21010	1	Incision of jaw joint	2	\$422	232	\$814 \$437	1.62	۸dd
21015 21025	1	Resection of facial tumor Excision of bone, lower jaw	2	\$422	231 231	\$437	0.87 0.87	Add.
21026	1	Excision of facial bone(s)	2	\$422	231	\$437	0.87	
21029	1	Contour of face bone lesion			231	\$437	0.87	Add.
21030 21031	1	Removal of face bone lesion			231 231	\$437 \$437	0.87 0.87	Add. Add.
21031	1	Remove exostosis, mandible Remove exostosis, maxilla			231	\$437	0.87	Add. Add.
21034	1	Removal of face bone lesion	3	\$482	232	\$814	1.62	
21040	1	Removal of jaw bone lesion	2	\$422	231	\$437	0.87	
21041 21044	1	Removal of jaw bone lesion Removal of jaw bone lesion	2	\$422 \$422	231 232	\$437 \$814	0.87 1.62	
21044	3	Extensive jaw surgery		φ 4 22	2.52	φ014	1.02	
21050	1	Removal of jaw joint	3	\$482	232	\$814	1.62	
21060	1	Remove jaw joint cartilage	2	\$422	232	\$814	1.62	
21070 21076	1 6	Remove coronoid process Prepare face/oral prosthesis	3	\$482	232	\$814	1.62	
21070	6	Prepare face/oral prosthesis						
21079	6	Prepare face/oral prosthesis						
21080	6	Prepare face/oral prosthesis						
21081 21082	6	Prepare face/oral prosthesis Prepare face/oral prosthesis						
21083	6	Prepare face/oral prosthesis						
21084	6	Prepare face/oral prosthesis						
21085	6	Prepare face/oral prosthesis Prepare face/oral prosthesis						
21086 21087	6	Prepare face/oral prostnesis						
21088	6	Prepare face/oral prosthesis						
21089	3	Prepare face/oral prosthesis						
21100 21110	1	Maxillofacial fixation	2	\$422	231 231	\$437 \$437	0.87 0.87	Add.
21110 21116	2	Interdental fixation			231	φ43/	0.87	Auu.
21120	1	Reconstruction of chin			231	\$437	0.87	Add.
21121	1	Reconstruction of chin			232	\$814	1.62	Add.
21122 21123	1	Reconstruction of chin			232 232	\$814 \$814	1.62 1.62	Add.
21123	1	Augmentation lower jaw bone			232	\$814	0.87	Add. Add.
21127	1	Augmentation lower jaw bone			232	\$814	1.62	Add.
21137	3	Reduction of forehead						
21138	3	Reduction of forehead	l				I	

ADDENDUM A.-PROPOSED AMBULATORY SURGICAL CENTER (ASC) PAYMENT STATUS BY HCPCS CODE AND RELATED INFORMATION—Continued

CPT 1/ HCPCS	ASC payment	Description	Current payment	Current payment	Proposed APC	Proposed payment	Relative value	Add ² / Delete
	indicator		group	rate	group	rate	factor	
21139	3	Reduction of forehead						
21141	3	Reconstruct midface, lefort						
21142 21143	3	Reconstruct midface, lefort						
21145	3	Reconstruct midface, lefort						
21146	3	Reconstruct midface, lefort						
21147	3	Reconstruct midface, lefort						
21150	3	Reconstruct midface, lefort						
21151 21154	3	Reconstruct midface, lefort Reconstruct midface, lefort						
21154	3	Reconstruct midface, lefort						
21159	3	Reconstruct midface, lefort						
21160	3	Reconstruct midface, lefort						
21172	3	Reconstruct orbit/forehead						
21175	3	Reconstruct orbit/forehead						
21179 21180	3	Reconstruct entire forehead						
21180	1	Contour cranial bone lesion				\$814	1.62	Add.
21182	3	Reconstruct cranial bone				ψ014	1.02	//00.
21183	3	Reconstruct cranial bone						
21184	3	Reconstruct cranial bone						
21188	3	Reconstruction of midface						
21193	3	Reconstruct lower jaw bone						
21194	3	Reconstruct lower jaw bone						
21195 21196	3	Reconstruct lower jaw bone Reconstruct lower jaw bone						
21198	3	Reconstruct lower jaw bone						
21206	1	Reconstruct upper jaw bone	5	\$678	232	\$814	1.62	
21208	1	Augmentation of facial bones	7	\$941	232	\$814	1.62	
21209	1	Reduction of facial bones	5	\$678	232	\$814	1.62	
21210	1	Face bone graft	7	\$941	232	\$814	1.62	
21215	1	Lower jaw bone graft	7	\$941	232	\$814	1.62	
21230 21235		Rib cartilage graft	7	\$941 \$941	232 232	\$814	1.62 1.62	
21235	1	Ear cartilage graft Reconstruction of jaw joint	4	\$595	232	\$814 \$814	1.62	
21240	1	Reconstruction of jaw joint	5	\$678	232	\$814	1.62	
21243	1	Reconstruction of jaw joint	5	\$678	218	\$730	1.45	
21244	1	Reconstruction of lower jaw	7	\$941	232	\$814	1.62	
21245	1	Reconstruction of jaw	7	\$941	232	\$814	1.62	
21246	1	Reconstruction of jaw	7	\$941	232	\$814	1.62	
21247 21248	3	Reconstruct lower jaw bone Reconstruction of jaw	7	 \$941		\$814	1.62	
21240	1	Reconstruction of jaw	7	\$941	232	\$814	1.62	
21255	3	Reconstruct lower jaw bone	-	φ υ +1		ψ014	1.02	
21256	3	Reconstruction of orbit						
21260	1	Revise eye sockets			232	\$814	1.62	Add.
21261	3	Revise eye sockets						
21263	3	Revise eye sockets						
21267	1	Revise eye sockets	7	\$941	232	\$814	1.62	
21268 21270	3	Revise eye sockets	5	 \$678		\$814	1.62	
21275	1	Revision orbitofacial bones	7	\$941	232	\$814	1.62	
21280	1	Revision of eyelid	5	\$678	231	\$437	0.87	
21282	1	Revision of eyelid	5	\$678	231	\$437	0.87	
21295	1	Revision of jaw muscle/bone			231	\$437	0.87	Add.
21296	1	Revision of jaw muscle/bone			231	\$437	0.87	Add.
21299 21300	3	Cranio/maxillofacial surgery Treatment of skull fracture	2	\$422	231	\$437	0.87	
21300		Treatment of skull fracture	2	\$422	231	\$437	0.87	
21315	1	Treatment of nose fracture	2	\$422	231	\$437	0.87	
21320	1	Treatment of nose fracture	2	\$422	231	\$437	0.87	
21325	1	Repair of nose fracture	4	\$595	231	\$437	0.87	
21330	1	Repair of nose fracture	5	\$678	232	\$814	1.62	
21335		Repair of nose fracture	7	\$941	232	\$814	1.62	Add
21336 21337	1	Repair nasal septal fracture Repair nasal septal fracture	2	 \$422	216 231	\$580 \$437	1.15 0.87	Add.
21337	1	Repair nasoethmoid fracture	4	\$595	231	\$814	1.62	
21339	1	Repair nasoethmoid fracture	5	\$678	232	\$814	1.62	
21340	1	Repair of nose fracture	4	\$595	232	\$814	1.62	
21343	1	Repair of sinus fracture	5	\$678	232	\$814	1.62	
21344	3	Repair of sinus fracture						
21345	1	Repair of nose/jaw fracture			232	\$814	1.62	Add.
21346 21347	3	Repair of nose/jaw fracture Repair of nose/jaw fracture						
2104/	- 3 	1 100 pair of 11000 jaw Iraciare	• •••••				• • • • • • • • • • • • • • • • • • • •	