

**MEDICARE CERTIFIED AMBULATORY SURGICAL CENTERS
CATARACT SURGERY COSTS AND RELATED ISSUES**



**OFFICE OF INSPECTOR GENERAL
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MEDICARE CERTIFIED AMBULATORY SURGICAL CENTERS

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**RICHARD P. KUSSEROW
INSPECTOR GENERAL**

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EXECUTIVE SUMMARY

PURPOSE: The inspection was designed to provide the Health Care Financing Administration (HCFA) with specific data and information concerning: (1) the cost of cataract surgery, (2) the provision of ancillary services and (3) the instances of aborted surgeries in ambulatory surgical centers (ASCs).

BACKGROUND: In March 1986, the Office of Inspector General (OIG) issued a report on Medicare cataract implant surgery. The report discussed the costs of cataract surgery in both inpatient and outpatient settings. To help HCFA determine appropriate ASC facility payment policy and rates for the July 1, 1988 payment update, the OIG conducted this followup inspection on the costs of cataract surgery in ASCs.

As of December 1987, 893 ASCs were certified to participate in the Medicare program. The Medicare law defines an ASC as a distinct entity that (1) operates exclusively for the purpose of providing surgical services to patients who do not require hospitalization, (2) has an agreement with HCFA to participate in the Medicare program as an ASC and (3) meets prescribed conditions for coverage.

Payment is made for facility services in ASCs on the basis of a prospectively determined rate for each covered procedure. All covered procedures are assigned to one of four payment groups. Each group is assigned a single reimbursement rate which is adjusted for geographic variations in labor costs. For multiple procedures, ASCs receive 100 percent of the highest applicable group rate and 50 percent of the group rate for the second procedure.

The Omnibus Budget Reconciliation Act of 1986 mandated that the Secretary of Health and Human Services review and update ASC payment rates by July 1, 1987. Because HCFA had not completed a survey and audit of the existing prospective payment rates, the 1987 update was based on a projected increase of 18.7 percent in the consumer price index. The July 1988 update will reflect the results of a survey and audit which were conducted during 1986 and 1987.

Cataract extraction with an intraocular lens (IOL) implant is considered a multiple procedure. Ambulatory surgical centers receive separate payment for the IOL. Separate payments may be made also for ancillary services which are not considered directly related to the provision of the cataract procedure. Laboratory tests that meet this criterion may be billed by the ASC if the ASC has been certified as an independent laboratory or if it has an arrangement with a certified independent laboratory.

Aborted surgery occurs when a medical crisis, on the scheduled day of surgery, prevents the procedure from being completed. The ASC has usually incurred some supply and staff expenses, but payment of the entire facility fee is not justified. A national payment policy has not been developed.

To gather information about current medical practices and the costs associated with cataract surgery in ASCs, the inspection team visited 29 facilities in 7 States and interviewed ASC administrators, ophthalmologists, representatives of trade associations and lens manufacturers.

MAJOR FINDINGS:

1. CATARACT EXTRACTION WITH IMPLANT IS NOT A MULTIPLE PROCEDURE. None of the ASCs reported any additional facility costs when the extraction and implant are done during the same operation.
2. DISCOUNTS, REBATES AND INCENTIVES ARE ROUTINELY OFFERED BY LENS MANUFACTURERS AND THEIR SALES REPRESENTATIVES. The problems regarding IOL payments that were discussed in the OIG March 1986 inspection report on Medicare cataract surgery have not been resolved. Manufacturers continue to offer discounts, incentives and rebates which are not reflected in the Medicare payments for IOLs.
3. FACILITY COSTS VARY SIGNIFICANTLY; SUPPLY AND EQUIPMENT COSTS CAN BE REDUCED BY GROUP BUYING AND COMPARISON SHOPPING. Some ASCs are unable to control costs, while others have successfully lowered their supply costs by joining buying groups and negotiating with vendors.
4. ASCs REQUIRE, BUT RARELY PROVIDE, ROUTINE LABORATORY TESTS FOR CATARACT SURGERY PATIENTS. Routine lab tests are required prior to cataract surgery. Normally, the patient is referred to his attending physician, a hospital or an independent laboratory for the tests. We found no instances where the ASC billed separately for lab services furnished in connection with cataract surgery. None of the sampled ASCs billed for lab services provided under contract with an independent laboratory.
5. ABORTED SURGERY WAS RARE IN ALL BUT ONE OF THE SAMPLED ASCs. In most instances, when a surgery is aborted, the ASC absorbs the cost instead of filing a claim. Frequent instances of aborted surgery may indicate a quality of care problem.

RECOMMENDATIONS:

1. THE HCFA SHOULD TREAT CATARACT EXTRACTION WITH IOL IMPLANT AS ONE PROCEDURE AND REIMBURSE IT AT 100 PERCENT OF THE APPROPRIATE FACILITY PAYMENT RATE EFFECTIVE JULY 1988.
2. THE HCFA SHOULD ESTABLISH A NATIONAL PART B REIMBURSEMENT CAP OF \$200, WITH A HANDLING FEE NOT TO EXCEED 10 PERCENT (\$20), FOR ANY IOL BILLED TO MEDICARE.
3. THE HCFA SHOULD BUNDLE THE IOL PAYMENT WITH THE ASC FACILITY FEE.
4. THE HCFA SHOULD (A) AUTHORIZE CARRIERS TO PAY ASCs THE FULL FACILITY FEE OR A PERCENTAGE OF THE FACILITY FEE WHEN SURGERY IS ABORTED, PROVIDED THAT AN OPERATIVE REPORT IS SUBMITTED WITH THE CLAIM AND (B) REQUIRE CARRIERS TO REPORT ALL CLAIMS FOR ABORTED SURGERY TO THE APPROPRIATE PEER REVIEW ORGANIZATION FOR QUALITY OF CARE REVIEW.

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INTRODUCTION

Ambulatory surgical centers (ASCs) are discrete entities operating exclusively for the purpose of furnishing outpatient surgical services to patients. Nearly 75 percent of all ASCs are independently owned.

The first ASCs were established in 1970, but their numbers increased dramatically in the early 1980s. This growth was due in part to the Omnibus Budget Reconciliation Act of 1980 (OBRA) and the American College of Surgeons' approval of freestanding surgery centers in 1981. As of December 1987, 893 ASCs were certified to participate in the Medicare program.

The Health Care Financing Administration (HCFA) defines an ASC as a distinct entity that (1) operates exclusively for the purpose of providing surgical services to patients who do not require hospitalization, (2) has an agreement with HCFA to participate in the Medicare program as an ASC and (3) meets prescribed conditions for coverage.

The OBRA amended Title XVIII of the Social Security Act to authorize Medicare Part B coverage and routine waiver of the Part B deductible and coinsurance for facility services furnished in connection with certain surgical procedures performed in an ASC. The Secretary of Health and Human Services was required to develop conditions of participation, establish payment rates and specify the surgical procedures that could be performed safely in ASCs.

The Omnibus Budget Reconciliation Act of 1986 directed the Secretary to review and update payment rates for ASCs by July 1, 1987 and annually thereafter. The law also mandated that HCFA review and update the list of covered procedures by April 21, 1987 and every 2 years thereafter. The waiver of Medicare Part B deductible and coinsurance requirements for ASC facility services was repealed, and peer review organizations (PROs) were directed to conduct quality of care reviews of ASCs and hospital outpatient departments. These provisions also became effective on July 1, 1987.

The Medicare program reimburses ASCs for facility and physician services. Facility services include those services that would be covered otherwise under Medicare if furnished on an inpatient or outpatient basis in connection with a covered surgical procedure. ASC facility services include, but are not limited to:

1. nursing, technician and related services;
2. use of ASC facilities;

3. drugs, biologicals, surgical dressings, supplies, splints, casts and appliances and equipment directly related to the provision of surgical procedures;
4. diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;
5. administrative, recordkeeping, and housekeeping items and services;
6. materials for anesthesia; and
7. blood, blood plasma, platelets, etc., except for those to which the blood deductible applies.

Excluded from facility services are physician services and medical and other health services for which payment can be made under other Medicare provisions (primarily Part B). The HCFA regulations specifically exclude the following medical and other health services from ASC facility reimbursement:

1. laboratory, x-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure);
2. prosthetic devices;
3. ambulance services;
4. leg, arm, back and neck braces;
5. artificial limbs; and
6. durable medical equipment for use in the patient's home.

Payment is made for facility services on the basis of a prospectively determined rate, called a "standard overhead amount," determined by the Secretary of Health and Human Services for each covered procedure. In 1982, HCFA developed a four-group classification system for facility payment. All procedures within each group are reimbursed at a single rate, adjusted for geographic variations in labor costs. Between September 1982 and July 1987, the four groups were reimbursed as follows:

Group 1 - \$231
Group 2 - \$275
Group 3 - \$296
Group 4 - \$336

Group 1 covers the least complex procedures; Group 4 covers the most complex. For multiple procedures, ASCs receive 100 percent of the highest rate applicable and 50 percent of the rate for the second procedure.

Because an audit of the existing prospective payment rates had not been completed, HCFA based the 1987 ASC rates on a projected increase of 18.7 percent in the consumer price index for urban consumers. The new payment rates are:

Group 1 - \$274
Group 2 - \$326
Group 3 - \$351
Group 4 - \$399

Between May and August 1986, HCFA distributed the Ambulatory Surgical Center Payment Rate Survey Form (Form HCFA-452) to all Medicare-participating ASCs to determine facility overhead expenses and procedure-specific charges. In addition, in January and February 1987, HCFA conducted an audit of 97 ASCs to verify reported data. The July 1988 update will reflect the results of this survey and audit.

Almost 71 percent of the estimated 1.3 million cataract surgeries performed nationwide in 1987 were performed in hospital outpatient departments. Ambulatory surgical centers account for approximately 22 percent of the surgeries. The remaining surgeries were performed in doctors' offices and inpatient hospitals. We estimate that more than 138,000 of approximately 1 million Medicare cataract surgeries were performed in ASCs in 1986, and nearly 178,000 were performed in 1987. Cataract surgery is the most common Medicare-covered procedure performed in ASCs.

In March 1986, the Office of Inspector General issued a report describing trends in cataract surgery as well as the costs of the procedure in different surgical settings, including the ASC. The report, entitled "Medicare Cataract Implant Surgery," noted that Medicare reimbursement policy encouraged inflated prices for intraocular lenses (IOLs) and that discounts negotiated between providers and suppliers were not passed on to the Medicare program. The report recommended establishing a national cap for lens reimbursement.

Methodology

The inspection sample was drawn from a universe of 591 Medicare-certified ASCs that perform ophthalmic surgery. The team visited 29 facilities in 7 States (California, Arizona, North Carolina, Ohio, New Jersey, West Virginia and Nebraska) and collected information about the ASCs' costs and standard operating procedures. The team interviewed representatives of six carriers that process claims for the sampled ASCs, the Federated Ambulatory Surgical Association, other trade and professional associations and lens manufacturers. (See Appendix A for a detailed description of the methodology.)

FINDINGS

CATARACT EXTRACTION WITH IMPLANT IS NOT A MULTIPLE PROCEDURE

Since 1982, when HCFA began paying ASCs a facility fee, HCFA has treated cataract extraction with IOL implant as a multiple procedure and reimbursed it at 150 percent of the Group 4 payment rate, which covers the most complex procedures performed in ASCs. The Group 4 rate is currently \$399. This rate is adjusted for geographical variations in labor costs. The current allowances for cataract extraction with IOL implant range from approximately \$584 to \$659.

All of the sampled ASCs reported that, in nearly all Medicare cases, cataract extraction and insertion of the IOL are performed during the same operation. An IOL would not be implanted if the patient had certain health problems, such as uncontrolled diabetes or glaucoma. Secondary implants, or cases where a patient whose cataract was removed in a previous operation undergoes surgery for an IOL implant, account for very few cases in ASCs. Aside from the cost of the lens itself, which is reimbursed separately, facilities reported no additional costs attributable to inserting the lens during cataract surgery. Supply and labor costs are the same for an extraction with or without IOL implant.

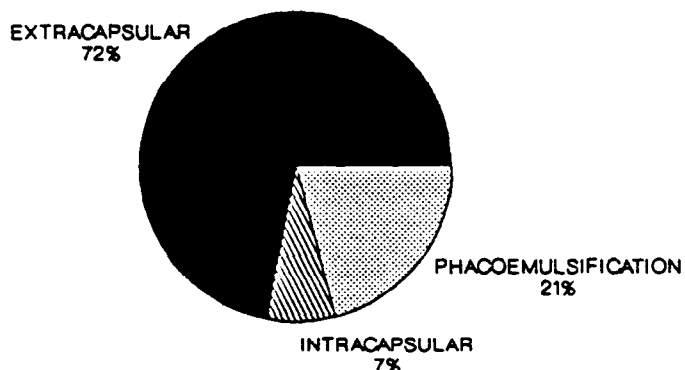
Extracapsular Cataract Extraction is the Method of Choice

Currently, there are three methods of cataract extraction--intracapsular, extracapsular and phacoemulsification. In an intracapsular extraction, the entire lens, including its surrounding capsule, is removed. This type of surgery is more invasive than the other two types because the incision is longer. During an extracapsular extraction, the surgeon makes a smaller incision, removes the anterior portion of the lens capsule and the lens cortex and nucleus, but leaves the posterior portion of the lens capsule intact. Many ophthalmologists believe that leaving the posterior portion of the capsule intact helps prevent damage to the retina and provides support for the intraocular lens implant. Regardless of which method of extraction is used, the surgeon must either use an air bubble or some other material, such as Healon, to cushion the cornea when inserting the IOL.

Phacoemulsification is a form of extracapsular extraction, because the posterior portion of the lens capsule is left intact. The key difference between this method and extracapsular extraction is that phacoemulsification involves the use of an ultrasonic needle to soften and liquify the cortex so that it can be aspirated through the hollow needle. During extracapsular extraction, the cortex is manually

expressed from the eye. Another difference is that the phacoemulsification technique requires a smaller incision than extracapsular extraction. Phacoemulsification may become more popular in the future because lens manufacturers are developing lenses that can be implanted through this smaller incision. Regardless of surgical setting, extracapsular cataract surgery is the procedure used in approximately 95 percent of surgeries. In the first half of 1987, surgeons used the phacoemulsification technique in 16 percent of all extracapsular surgeries. In the sampled ASCs, extracapsular cataract extraction is clearly the planned method for removing cataracts. If the capsule is damaged during surgery, however, intracapsular surgery must be performed.

METHODS OF CATARACT EXTRACTION IN SAMPLED ASCs

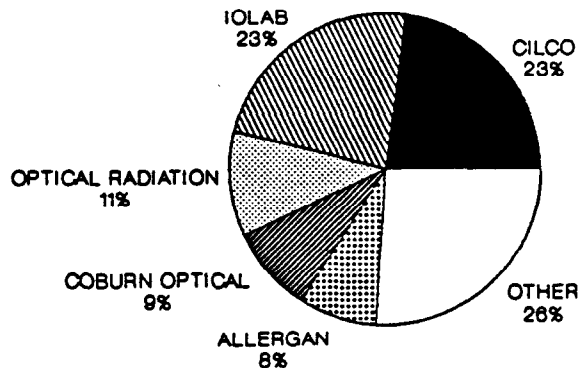


The choice between performing extracapsular extraction and phacoemulsification depends more on surgeons' preferences than on patients' needs. Surgeons in two of the sampled ASCs prefer phacoemulsification because they believe that patients heal more quickly after surgery. In contrast, the surgeon in another ASC does not use the phacoemulsification technique because he believes that it causes too much trauma to the lens capsule. The expense of the technique is also a consideration for surgeons and ASCs. Phacoemulsification can cost nearly \$100 per case for supplies alone. The cost of a phacoemulsification unit from one equipment manufacturer ranges from \$50,000 to \$70,000, and a repair contract for the machine can cost up to \$6,000 per year.

FIVE COMPANIES DOMINATE THE INTRAOCULAR LENS INDUSTRY

In 1986, an estimated 1.25 million lenses were sold in the United States. The intraocular lens industry is a \$265 million annual market dominated by five companies--Iolab, Cilco, Optical Radiation, Coburn and Allergan. Together these five companies accounted for 74 percent of the U.S. lens market during 1985-1986.

MARKET SHARE OF IOL COMPANIES



Three of the top lens companies are part of large medical and health care concerns. In 1980, most of the lens industry was controlled by small independent companies. Since then, large health care companies, attracted in part by healthy profit margins in the lens business, entered the market. Johnson & Johnson acquired Iolab in 1980 and recently bought another lens company, Precision-Cosmet. The Rorer Group acquired Cilco in 1981 and sold it to CooperVision in 1986. American Hospital Supply owned American Medical Optics until 1986, when it sold the company to SmithKline Beckman, which changed the name to Allergan Medical Optics. Johnson & Johnson and SmithKline Beckman rank first and seventh, respectively, among the top U.S. medical and health care companies in terms of annual revenues.

| <u>Parent Company</u> | <u>Operating Unit</u> | <u>Revenues*</u> |
|-----------------------|-----------------------|------------------|
| CooperVision, Inc. | Cilco | \$ 60M |
| Johnson & Johnson | Iolab | 60 |
| Optical Radiation | Optical Radiation | 30 |
| Revlon Group, Inc. | Coburn | 25 |
| SmithKline Beckman | Allergan | 20 |
| | | <u>\$195M</u> |

*Data reflect 1985 or 1986 domestic U.S. sales or the last year for which complete financial data are available.

All five companies manufacture and sell ophthalmic supplies and equipment as well as lenses:

| <u>Company</u> | <u>Other Ophthalmic Products</u> |
|--------------------|---------------------------------------------------------------------|
| CooperVision, Inc. | phacoemulsifier, irrigation/aspiration equipment, disposable packs* |
| Johnson & Johnson | diagnostic equipment, supplies and accessories |
| Optical Radiation | diagnostic equipment |
| Revlon Group, Inc. | ophthalmic lasers |
| SmithKline Beckman | ophthalmic lasers |

*A disposable pack is a package of accessories used during cataract surgery. Packs include tips to direct ultrasonic vibrations during surgery as well as tubing, irrigating solution and other items that the surgeon needs.

Three of these companies are entering the lucrative U.S. market for hyaluronic acid (a viscoelastic material, such as Healon). Annual sales of this product are estimated at \$70 million. Nearly 90 percent of all surgeons use viscoelastic material during cataract surgery to protect the cornea. Pharmacia Intermedics Ophthalmics, which manufactures Healon (made from the cockscombs of roosters), currently dominates the market, but competition is increasing. Another company developed a product called Occucoat and is exploring the possibility of packaging it with its lenses; the package would be called Oculens. Pharmacia Intermedics was the first company to package viscoelastic material with its lens. The package, called a Viscolens, consists of an intraocular lens and a 0.75 milliliter (ml) syringe of Healon. CooperVision's Cilco Division developed a viscoelastic material that has a lower molecular weight than Healon and is therefore less viscous. In January 1987, Optical Radiation Corporation received approval from the Food and Drug Administration (FDA) to begin limited clinical studies on Orcolon, a synthetic viscoelastic gel. The company anticipates full FDA approval by mid-1988.

Although all of the leading lens companies sell both IOLs and ophthalmic equipment, CooperVision was the first to adopt a marketing strategy specifically designed to increase sales to providers, such as ASCs, that are subject to prospective reimbursement. This strategy, known as cross-merchandising, involves marketing and selling multi-product packages with products from CooperVision's many eye care businesses in order to reduce customer costs. These businesses include the Cilco Division, which produces IOLs, CooperVision Pharmaceuticals, which manufactures ophthalmic drugs and CooperVision Surgical, which manufactures ophthalmic equipment and disposable supplies.

In 1984, CooperVision created a new unit, CooperVision Professional Resources, which is an umbrella organization for marketing products and services to ophthalmologists. Representatives of this unit market multi-product packages from CooperVision, help doctors and staff members design and select equipment for ASCs and advise them on such subjects as reimbursement and facility management. In its first 10 months of operation, the unit signed more than 50 long-term agreements with providers.

In the future, IOL companies may not be as attractive to large health care companies and investors as they have been in the past. While formerly regarded as a growth industry, the market has been reassessed, and the growth rate is now projected to be only 2 to 3 percent a year, a growth rate too low to attract investors. In September 1986, Ioptex, which manufactures and sells IOLs, tried to go public, but investor interest was absent. Investors did not believe that the company's large profit margins were sustainable (Ioptex reported a 22 percent profit for the 9-month period ending June 30, 1986). The prospectus for the stock offering cited government regulation as a risk factor that should be considered before buying stock and noted that future changes in reimbursement for cataract surgery could have an adverse effect on the growth and profitability of Ioptex' business and the IOL industry.

DISCOUNTS, REBATES AND INCENTIVES ARE ROUTINELY OFFERED BY LENS MANUFACTURERS AND THEIR SALES REPRESENTATIVES

In the March 1986 OIG report entitled "Medicare Cataract Implant Surgery," we noted that:

Lens and equipment manufacturers are competing aggressively for sales and market domination. Large discounts are common and include equipment rebates or credits.... Although these intense marketing activities have sometimes resulted in...reduced costs, the savings have not been passed on to the Federal government.

For the most part, these marketing practices have not changed.

The HCFA Medicare Carriers Manual instructs carriers to consider factors such as actual acquisition costs and nominal handling or dispensing fees to determine if the prevailing charges for IOLs are inherently reasonable. To calculate a lens payment price that is "inherently reasonable" is particularly difficult because of the different types of incentives that are offered in exchange for the purchase of lenses. While most, if not all, of the manufacturers' invoices contain a statement advising the purchaser that it must disclose discounts to Medicare, many of the arrangements are not easily quantified. For example, one lens company offers to create a custom videotape for the surgeon to use in his office or ASC, while another company offers to pay for training or attendance at a conference.

Lens companies that manufacture, or have a subsidiary or sister company that manufactures, ophthalmic equipment or supplies can usually offer equipment allowances or free supplies in exchange for a contract which obligates the ASC or ophthalmologist to buy a minimum number of lenses during a specified period of time. These offers are especially tempting given the cost of high-tech ophthalmic equipment and the fact that supplies are considered a part of the ASC facility rate and cannot be billed separately. By taking advantage of an equipment allowance, the purchaser can avoid the entire capital expenditure for phacoemulsification units, microscopes, lasers and/or irrigation and aspiration machines.

Specific equipment allowances and free supplies that have been accepted by the ASCs in our sample include:

1. microscopes and phacoemulsification machine valued at \$135,000 in exchange for purchasing 1,260 lenses;
2. a phacoemulsification machine and microscope worth \$94,000 in exchange for a 3-year contract to buy lenses;

3. a post-operative kit, sunglasses and eye drops with each lens;
4. viscoelastic material and syringe with each lens; and
5. lens discounts in exchange for agreement to purchase disposables.

The ASCs usually do not distinguish between the cost of the lens and the value of the free or discounted items when they bill Medicare. Also, the carriers that require invoices have not developed imputed values which are subtracted from the lens allowance when they process the ASC's or physician's claims. While many ASCs and ophthalmologists have taken advantage of manufacturer or sales representative incentives, others have not because they are under the impression that acceptance would be in violation of the Medicare law.

Volume discounts may be offered to one ASC while another ASC cannot, or has not tried to, negotiate a discount for the same lenses. Volume discounts are available for all lenses including those with special features such as ultraviolet blocker or laser ridge. Invoice prices from the five major lens manufacturers that have approximately 74 percent of the domestic market ranged from a low of \$150 per lens to a high of \$475 in the sampled facilities. These figures do not reflect any equipment credits or free supplies. Based on equipment credits and imputed values for free supplies, the lowest lens price from one of the five major manufacturers is \$85.

Of the six carriers in the OIG sample (representing seven States), two require invoices to determine the Medicare allowed amount, two have established ceilings that can only be exceeded if an invoice is submitted and two have established ceilings that cannot be exceeded even if an invoice accompanies the Medicare claim. The ceiling, in at least two cases, was determined by obtaining list prices from the major lens companies. Based on the previous OIG inspection and information that was obtained in this inspection, list prices do not reflect actual acquisition costs.

For the sampled carriers, IOL payment ceilings ranged from \$275 to \$387.50. One of the carriers, whose ceiling without invoice is \$335, will allow up to \$500 with an invoice. Another carrier in the sample will pay a maximum of \$275 for a posterior chamber lens (the most popular lens) even with the submission of an invoice. None of the six carriers in the inspection sample allows separate charges for facility handling fees. Nationally, however, some carriers allow from \$10 to \$90. The sampled ASCs billed from \$0 to \$75. The Medicare Carriers Manual suggests that a nominal handling fee is appropriate.

To determine true acquisition costs, we obtained current discount prices which have been negotiated by some ASCs. We also deducted from the invoice price any equipment purchase allowances and the value of free supplies, if possible:

Equipment credits

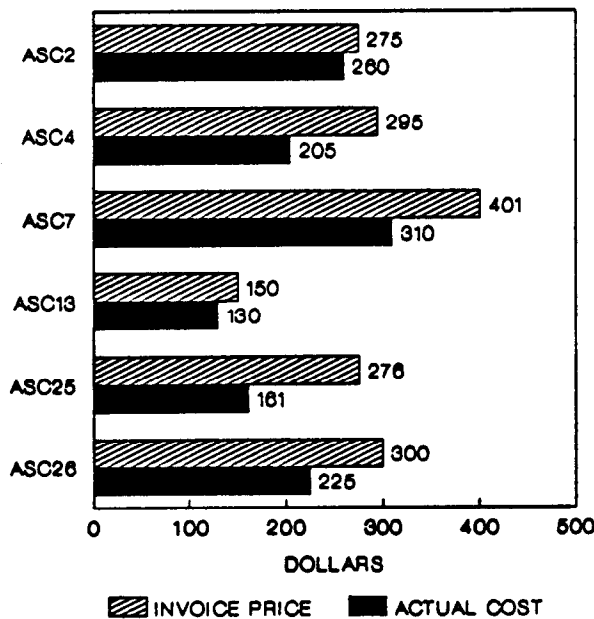
ASC #7 - \$91 per lens
 ASC #11 - (not determined)
 ASC #12 - (not determined)
 ASC #13 - \$20 per lens
 ASC #25 - (not determined)
 ASC #26 - \$75 per lens

Free supplies

ASC #2 - \$15 (post-op kit)
 ASC #4 - \$115 (.75 ml Healon)
 ASC #15 - \$115 (.75 ml Healon)
 ASC #25 - \$115 (.75 ml Healon)

In addition to the nine sampled ASCs that receive equipment credits or free supplies in exchange for purchasing lenses, six other sampled ASCs have negotiated discounts with lens manufacturers. The sample included 12 ASCs that have not attempted to negotiate prices and are paying as much as \$390 for each lens without receiving any free supplies or equipment allowance. The same lens that is costing one ASC \$390 is being purchased by another ASC for \$249. Another sampled ASC found that when it requested a discount, it was able to save 40 percent; the lens that has a list price of \$400 is now sold to the ASC for \$235.

IOL INVOICE PRICE COMPARED TO ACTUAL COST



Multispecialty ASCs often are unable to take advantage of discount arrangements because they rely on community physicians

to use the ASC and these physicians may have diverse lens preferences. The surgeons may bring their own lenses, or the ASC must stock a few lenses from several manufacturers to meet the surgeons' requirements.

Because HCFA has not required the carriers to limit their lens payments and the lens is not included in the ASC facility payment rate, there is no real incentive for providers to negotiate discounts. One respondent told us that when he requested a discount on IOLs from a sales representative, he was told: "Why not leave the lens price alone? We can negotiate on other things, and besides, Medicare pays the full non-discounted invoice price, so why are you concerned?"

The sampled ASCs pay an average price of \$254 per lens, regardless of manufacturer. The average price per lens for ASCs that do not negotiate any discounts, credits or free supplies is \$272, while the average price for those that negotiate is \$239. Nearly 75 percent of the facilities that negotiate pay under \$300; for these facilities, the average price per lens is \$200 (see Appendix B for details).

FACILITY COSTS VARY SIGNIFICANTLY; SUPPLY AND EQUIPMENT COSTS CAN BE REDUCED BY GROUP BUYING AND COMPARISON SHOPPING

The costs of cataract surgery in an ASC depend in large part on the surgeon performing the surgery. In multispecialty facilities, where more than one ophthalmologist performs cataract surgery, costs vary among surgeons. These ASCs are reluctant to dictate the drugs and supplies that a surgeon can use, because their financial success depends on attracting surgeons who are willing to perform surgery at an ASC rather than a hospital outpatient department.

For example, one sampled multispecialty facility reported that the supply costs associated with extracapsular cataract extraction ranged from \$158.61 to \$186.74 per case. In another multispecialty facility, supply costs ranged from \$127.54 to \$163.48 per case. Supply costs vary because surgeons prefer different drugs and supplies. In contrast, in single specialty facilities, which are frequently extensions of an ophthalmology practice, costs are determined by the preferences of the ophthalmologist who owns and operates the facility.

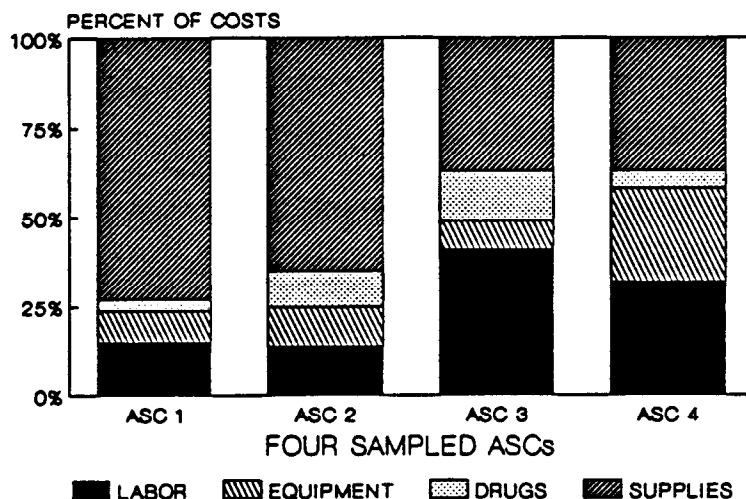
Since single specialty facilities are often extensions of an existing practice, they may not distinguish between ASC-related costs and revenues and office-related costs and revenues. Since the Medicare regulations governing ASCs do not prescribe cost accounting methods, single specialty facilities can commingle funds. One sampled single specialty ASC based its estimate of the cost per cataract surgery on the assumption that half the total expenses incurred by both the office and ASC portion of the practice were attributable to the ASC. The costs per case in 1986 were \$1,038.35, which includes \$87.77 for advertising and marketing, \$20.50 for legal and accounting services and \$10.50 for travel and entertainment.

Ophthalmologists often open an ASC not to make money, but to remain competitive with other ophthalmologists and hospital outpatient departments as well as to avoid the operating room scheduling problems that they have in a hospital setting. In fact, ophthalmologists in four sampled ASCs reported that the facility fee does not cover all their costs; two of the surgeons noted that their professional fees subsidize the ASC. Two other ASCs commented that they "break even."

ASCs Can Reduce the Costs of Cataract Surgery by Joining Buying Groups, Substituting Supplies and Comparison Shopping

Drugs and surgical supplies for cataract surgery can account for more than 50 percent of an ASC's total costs per case.

FOUR COMPONENTS OF ASC COSTS



Since ASCs receive a fixed fee for performing the surgery and cannot bill separately for drugs and supplies, facilities have an incentive to find ways to lower the costs of these two items. One way is to join a buying group. By paying monthly dues, the ASC can take advantage of the lower prices that the buying group negotiates with suppliers. One sampled ASC that belongs to a national buying group saves 30 percent when it buys a 0.75 ml syringe of Healon. The manufacturer's list price for Healon is \$65 for a 0.4 ml syringe and \$115 for a 0.75 ml syringe. The ASC pays \$83 instead of \$115.

Another way to lower supply costs is to buy less expensive supplies. For example, two sampled facilities use Amvisc instead of Healon to save money. One of these facilities previously used Healon, which cost \$90 per surgery, but switched to Amvisc and saved \$35 per surgery. The surgeons in two other sampled ASCs do not incur any costs for viscoelastic material, because they inject an air bubble into the eye to protect the cornea during cataract surgery.

Eight facilities found they could obtain lower prices by comparison shopping among suppliers. They saved more money than if they purchased supplies through buying groups. One sampled facility annually solicits bids for surgical supplies to find out which companies offer the lowest prices, while another ASC decreased its costs by 67 percent for balanced salt solution (an irrigating solution) and by 25 percent for Amvisc by negotiating reductions with its suppliers.

ASCs REQUIRE, BUT RARELY PROVIDE, ROUTINE DIAGNOSTIC TESTS FOR CATARACT SURGERY PATIENTS

Medicare regulations specify that ASCs can receive reimbursement for simple tests provided only on the day of surgery, primarily urinalysis and blood hemoglobin or hematocrit, which must be included in their facility charges. Medicare will not reimburse an ASC for other diagnostic tests, such as an electrocardiogram (EKG), chest x-ray or a complete blood count (CBC), unless the ASC is certified as an independent laboratory.

As the following table illustrates, the sampled ASCs' policies on the diagnostic tests required prior to cataract surgery are not uniform:

| <u>Diagnostic Test(s)</u> | <u># of ASCs Where Required</u> |
|---------------------------|---------------------------------|
| CBC | 19 |
| EKG | 17 |
| CBC and EKG | 15 |
| Chest x-ray | 5 |
| CBC, EKG and chest x-ray | 4 |

Most of the sampled ASCs reported that they require patients to undergo a history and physical exam prior to surgery. However, the ASCs have no standard set of diagnostic tests that they require before surgery. Sixty-six percent of the ASCs require a CBC, 59 percent require an EKG and 17 percent require a chest x-ray. Normally, the ASC refers patients to their attending physicians, a hospital or an independent laboratory for the tests. Ten percent of the facilities reported that the required services depend on the results of the history and physical.

There is far more uniformity among ASCs concerning the tests that are performed on the day of surgery. Nearly 80 percent of the sampled facilities perform either no laboratory tests at all or only simple tests, consisting of a hematocrit and urinalysis. About half of the ASCs perform these tests at a combined cost not exceeding \$2.00. There is no separate charge for these tests; the costs are incorporated in the facility fee. None of the sampled ASCs had sophisticated diagnostic equipment on the premises that would enable them to perform tests other than a hematocrit and urinalysis.

ABORTED SURGERY IS RARE IN ALL BUT ONE OF THE SAMPLED ASCs

Sometimes ASCs must cancel or abort surgery. The ASCs must cancel surgery if a patient is ill or eats after midnight on the day of surgery. ASCs must abort surgery if a patient develops complications during preparation for surgery or

during the procedure itself. Common medical indications that surgery should be aborted include an increase in pressure in the eye, elevated blood pressure and cardiac or respiratory arrest. In the event of cardiac or respiratory arrest, the ASC would transfer the patient to a local hospital.

Aborted surgery is rare because facilities screen their patients before surgery and require patients to undergo certain diagnostic tests to determine if they are good candidates for outpatient surgery. Nearly 90 percent of the sampled ASCs reported 8 or fewer cases of aborted surgery since opening. Forty-one percent of the ASCs reported no cases of aborted surgery. In one sampled facility, aborted surgery was more common. According to that ASC's administrator, the aborted surgeries occurred because the facility's preoperative screening procedures were inadequate. Reportedly, procedures have been changed, and instances of aborted surgery have declined.

In most instances, ASCs absorb any costs incurred in connection with a case of aborted surgery instead of filing a claim. These costs could include any preoperative supplies, such as drapes, gowns and medications, and the staff time spent admitting and preparing the patient for surgery. Three of the six carriers for the ASCs in the sample reported receiving no claims for reimbursement for aborted surgery. Another carrier estimated that claims for reimbursement totaled only 10 a year. Three carriers noted that they would reimburse facilities for aborted surgery after reviewing their claims. Two of these carriers reported that if a claim were approved, the facility would receive a percentage of its usual rate.

RECOMMENDATIONS

RECOMMENDATION #1--THE ASC PAYMENT RATE FOR CATARACT SURGERY

FINDING: None of the sampled ASCs incurs additional facility costs when cataract extraction and IOL implant are done during the same operation.

RECOMMENDATION: The HCFA should discontinue regarding cataract extraction with implant as a multiple procedure. Reimbursement should be 100 percent of the appropriate facility payment rate effective July 1988.

IMPACT: Medicare reimbursement for cataract surgery would reflect current medical practice. Program savings cannot be projected until the 1988 update rates are established.

HCFA RESPONSE: The HCFA will implement this recommendation when the ASC payment rates are updated.

RECOMMENDATION #2--LENS REIMBURSEMENT

FINDING: The problems regarding lens payments that were discussed in the OIG March 1986 inspection report on Medicare cataract surgery have not been resolved. Manufacturers continue to offer discounts, incentives and rebates that are not passed on to the Medicare program. Current reimbursement policy does not provide an incentive for providers to be prudent buyers.

RECOMMENDATION: The HCFA should establish a national Part B reimbursement cap of \$200, with a handling fee not to exceed 10 percent (\$20), for any intraocular lens billed to Medicare.

IMPACT: As a result of this recommendation, which was contained in our draft report, the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) mandated that payment for IOLs be limited to the acquisition cost, taking into account any discount, plus a handling fee not to exceed 5 percent of that cost.

We estimate that more than \$14 million in ASC payments alone could be saved annually if HCFA established a cap of \$200. The savings per IOL would be \$107. Assuming that 71 percent of cataract surgeries (approximately 710,000 Medicare surgeries) are performed in outpatient departments of hospitals, applying the cap would yield additional annual program savings of more than \$75 million in payments to hospitals.

HCFA RESPONSE: The HCFA will study the OIG data base for purposes of proposing a national cap for IOL reimbursement.

RECOMMENDATION #3--BUNDLED LENS PAYMENTS

FINDING: Prospective payment rates encourage ASCs to be prudent buyers. Through negotiations and comparison shopping, some ASCs have realized significant savings for supplies.

RECOMMENDATION: The capped lens payment should be bundled with the ASC facility prospective payment rate for cataract extraction with IOL implant.

IMPACT: The OBRA 1987 has incorporated this recommendation by requiring that HCFA bundle the IOL payment with the facility fee. This will encourage the ASCs to negotiate lower lens prices. In addition, bundling will reduce carrier administrative costs by eliminating the need for separate payment determinations for IOLs.

HCFA RESPONSE: The HCFA intends to implement this recommendation when the ASC payment rates are updated.

RECOMMENDATION #4--ABORTED SURGERY

FINDING: Aborted surgery was rare in all but one of the sampled ASCs. In most instances, when surgery is aborted, the ASC absorbs the cost instead of filing a claim. Frequent instances of aborted surgery may indicate a quality of care problem.

RECOMMENDATION: The HCFA should (a) authorize carriers to pay ASCs the full facility fee or a percentage of the fee when surgery is aborted, provided that an operative report is submitted with the claim to justify the payment amount and (b) require carriers to report all claims for aborted surgery to the appropriate peer review organization (PRO) for quality of care review.

IMPACT: A uniform national policy would allow ASCs to receive reimbursement for legitimate costs that have been incurred. In addition, PROs could determine if the aborted surgery indicates a quality of care problem that warrants disciplinary action.

HCFA RESPONSE: The HCFA agrees that there should be a uniform national policy with respect to payment for aborted surgery. The HCFA also agrees that information on aborted procedures should be furnished to the PROs.

METHODOLOGY

The inspection team used a two-stage cluster sample with stratification at the second stage to identify ASCs for data collection. Using a list of all ASCs currently certified to provide Medicare services, we identified a universe of 591 facilities that met the following conditions:

1. the facility provided ophthalmology services,
2. the facility's service date was prior to January 1, 1987 and
3. the facility had not been terminated as of September 30, 1987, when the facilities were selected.

At the first stage, we selected States with probability proportional to size with replacement. The size of each State was determined by the number of ASCs in each State that met the three conditions. We selected seven States in this manner and selected one State, California, three times. Within each State, the ASCs were arrayed by location (urban versus rural). Where possible, we selected one rural and three urban ASCs in each State. If there were fewer than four ASCs meeting the three conditions in a given State, all of the ASCs were selected for the sample. Three States--Ohio, New Jersey and Nebraska--did not have any rural ASCs certified by HCFA. Three separate subsamples were selected in California. The following table lists the States selected along with the number of urban and rural ASCs in each:

| <u>State</u> | <u># of ASCs</u> | | <u>Total</u> | <u>Percent of Universe</u> |
|----------------|------------------|--------------|--------------|----------------------------|
| | <u>Urban</u> | <u>Rural</u> | | |
| California | 115 | 5 | 120 | 20.3 |
| Arizona | 27 | 10 | 37 | 6.3 |
| North Carolina | 15 | 5 | 20 | 3.4 |
| Ohio | 15 | 0 | 15 | 2.5 |
| New Jersey | 15 | 0 | 15 | 2.5 |
| West Virginia | 1 | 2 | 3 | 0.5 |
| Nebraska | 2 | 0 | 2 | 0.3 |
| TOTAL | 190 | 22 | 212 | 35.8 |
| # sampled | 26 | 7 | 33 | 5.6 |

Of the 33 ASCs selected for the sample, 5 were found not to perform cataract surgery. We substituted one facility for one of the excluded ASCs, because it is located nearby and is owned by the same party. Of the 29 facilities visited, two were unable to supply data on the costs of intraocular lenses because the surgeons bring their own lenses and bill for them under their individual provider numbers.

The following projections were calculated using the appropriate weighting based on the sampling design described above. All averages reported are weighted averages and appropriate to the universe of 591 facilities. We calculated savings under three scenarios. The first scenario assumes that reimbursement is capped at \$200 per IOL. The second scenario assumes a \$200 cap and a handling fee of \$25. The third scenario assumes a \$200 cap and a handling fee of \$15. The expected expenditures under current pricing are based on the allowed amounts reported by the carriers serving the universe of 591 ASCs. The following tables show projected surgeries and savings under the three scenarios:

PROJECTED SURGERIES

| <u>Estimated Number of Cataract Surgeries</u> | <u>90% Conf. Interval</u> | | <u>P*</u> |
|-----------------------------------------------|---------------------------|--------------|-----------|
| | <u>Lower</u> | <u>Upper</u> | |
| 138,527 (1986) | 92,557 | 184,497 | 20.2% |
| 177,985 (1987) | 141,147 | 213,823 | 12.6% |

PROJECTED EXPENDITURES AND SAVINGS (\$ in 000s)

| | <u>Expenditures/ Savings</u> | <u>90% Conf. Interval</u> | | <u>P*</u> |
|--------------------------|----------------------------------|---------------------------|--------------|-----------|
| | | <u>Lower</u> | <u>Upper</u> | |
| <u>Expenditures:</u> | | | | |
| o under Current Pricing | \$54,043 | \$42,413 | \$65,672 | 13.1% |
| o under Cap of \$200 | 35,597 | 28,229 | 42,964 | 12.3% |
| o with \$25 handling fee | 40,047 | 31,758 | 48,335 | 12.6% |
| o with \$15 handling fee | 39,867 | 31,544 | 48,208 | 12.7% |
| <u>Savings:</u> | | | | |
| o under Cap of \$200 | \$18,446 | \$12,001 | \$24,890 | 21.2% |
| o with \$25 handling fee | 13,996 | 7,877 | 20,116 | 26.6% |
| o with \$15 handling fee | 14,167 | 7,989 | 20,344 | 26.5% |

*Precision of the estimate.

Based on the above data, the average savings per ASC is \$34,800 with a \$200 cap, \$26,400 if a \$25 handling fee is allowed and \$26,700 if a \$15 handling fee is allowed. The savings per IOL, assuming the cap is \$200, is \$107 if no handling fee is paid (90% confidence interval, \$73 to \$141), \$84 if the fee is \$25 (90% confidence interval, \$51 to \$116) and \$93 if the fee is \$15 (90% confidence interval, \$60 to \$126).

INTRAOCULAR LENS DETAILS

We collected information on the types and costs of intraocular lenses used in the 29 sampled facilities. We obtained usable data from 27 ASCs because in two facilities (#5 and #18), the lenses are not supplied or billed by the ASCs and no specific lens information was available. Both facilities are multispecialty ASCs that are used by community ophthalmologists. In another multispecialty ASC, the lenses are provided by the surgeon but are billed to Medicare by the ASC. For this reason, data from the facility was included in the calculations.

Some of the sampled ASCs are extensions of an ophthalmologist's office, and the IOLs are billed using the physician's provider number rather than the ASC's. For these ASCs, the carriers were able to obtain the data we needed by accessing the physician's provider number profile.

We found that 15 ASCs negotiated lower lens prices or received equipment credits or supplies from the lens manufacturers:

| <u>ASC</u> | <u>Invoice price¹</u> | <u>Actual price²</u> |
|------------|----------------------------------|----------------------------------------|
| #2 | \$275 | \$260 |
| #3 | 213 | 213 |
| #4 | 295 | 205 |
| #7 | 401 | 310 |
| #11 | 380 | 380 less undetermined equipment credit |
| #12 | 380 | 380 less undetermined equipment credit |
| #13 | 150 | 130 |
| #15 | 175 | 85 |
| #16 | 235 | 235 |
| #20 | 300 | 300 |
| #22 | 235 | 235 |
| #23 | 205 | 205 |
| #24 | 250 | 250 |
| #25 | 276 | 161 |
| #26 | 300 | 225 |

Six of these facilities negotiated lower prices. The remaining nine ASCs received either equipment credits or free supplies, but

¹The lowest invoice price for any lens used in the ASC.

²The invoice price less any discount, equipment allowance or free supply (of a known value) that had not been subtracted by the lens company from the invoice price for each IOL.

the invoices did not reflect actual acquisition costs because the company did not deduct the value of the credit or supplies from the price shown. Twelve ASCs did not obtain any discounts and did not mention any equipment credits or free supplies:

| <u>ASC</u> | <u>Invoice price</u> |
|------------|----------------------|
| #1 | \$275 |
| #6 | 290 |
| #8 | 280 |
| #9 | 195 |
| #10 | 195 |
| #14 | 294 |
| #17 | 390 |
| #19 | 205 |
| #21 | 375 |
| #27 | 265 |
| #28 | 255 |
| #29 | 240 |

Eleven of the 15 ASCs (73.3 percent) that negotiated lower lens prices or receive equipment credits/free supplies pay less than \$300 per lens. The average lens acquisition cost for these 11 ASCs is \$200. The four ASCs that pay \$300 or more are considered to be paying inflated lens prices for the following reasons:

| <u>ASC</u> | <u>Reason</u> |
|------------|---------------|
|------------|---------------|

- | | |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| #7 | This ASC received a phacoemulsification machine and two microscopes worth at least \$135,000 from a lens company in exchange for a contract to purchase lenses. For each lens purchased, the ASC receives a \$91 equipment credit which is mentioned at the top of the invoice but is not subtracted from the prices shown for the itemized lenses. |
| #11 | This ASC received a phacoemulsification machine and a microscope from a lens company in exchange for an agreement to purchase lenses. The ASC receives an equipment credit which is not shown on the invoice. |
| #12 | This ASC received a phacoemulsification machine and a microscope valued at \$94,000 in exchange for an agreement to purchase lenses. The ASC receives an equipment credit which is not shown on the invoice. |
| #20 | This ASC is receiving a discount price of \$300 for a lens that lists for \$370. Another ASC in our sample is paying \$213 for a comparable lens from the same manufacturer. |

Since nearly 75 percent of the ASCs that negotiated lower prices or receive equipment credits/free supplies pay an average price of \$200 per lens and since the remaining 25 percent pay what we consider inflated lens prices, we believe that a cap of \$200 is reasonable and appropriate.