

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ACQUISITION COSTS OF PROSTHETIC
INTRAOCULAR LENSES**



MARCH 1994

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services' (HHS) programs as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by three OIG operating components: the Office of Audit Services, the Office of Investigations, and the Office of Evaluation and Inspections. The OIG also informs the Secretary of HHS of program and management problems and recommends courses to correct them.

OFFICE OF AUDIT SERVICES

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

OFFICE OF INVESTIGATIONS

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil money penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

OFFICE OF EVALUATION AND INSPECTIONS

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in these inspection reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs. This report was prepared in the Chicago regional office under the direction of William C. Moran, Regional Inspector General and Natalie A. Coen, Deputy Regional Inspector General. Project staff:

CHICAGO

John M. Traczyk, Project Leader
Suzanne G. Johnson
Thomas Komaniecki

BOSTON

Theodore T. Wall

SAN FRANCISCO

Paul Gottlobler
Don Loeb
Brian Pattison

HEADQUARTERS

Barbara R. Tedesco
W. Mark Krushat
Wayne A. Powell

DALLAS

Frank Almendarez

ATLANTA

Jacqueline Andrews
Chris Koehler

PHILADELPHIA

Joy Quill
Robert A. Vito
Nancy J. Molyneaux
Linda M. Ragone
Robert A. Baiocco
Robert A. Katz

NEW YORK

Joseph Corso
Alan Meyer
Lucille Cop
Joseph Benkoski

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ACQUISITION COSTS OF PROSTHETIC
INTRAOCULAR LENSES**



MARCH 1994 OEI-05-92-01030

FINDINGS

Intraocular lenses can be purchased for less than \$200.

On average, ASCs paid \$126 per IOL in 1991 and are paying \$112 for the same lenses today. The OPDs paid \$230 per IOL in 1991, over \$100 more than ASCs. Today's IOL acquisition costs for OPDs have decreased to an average of \$198 per lens, but this price is nearly \$86 more per IOL than that paid by ASCs.

The ability of purchasers to secure a low price for IOLs is not dependent on the number of IOLs purchased annually.

Contrary to expectations, our data show that the ability of purchasers to secure a low price for IOLs did not depend on the number of IOLs purchased annually, had no relationship to the type of lens technology purchased and did not depend on facility location or size.

Medicare's ability to obtain a fair price for IOLs under today's payment mechanisms is problematic, particularly in OPD settings.

In an effort to gain a competitive edge, many IOL vendors offer volume discounts, rebates, loans, customized packages of related cataract surgical supplies and other business arrangements. These incentives were equally distributed between the ASCs and OPDs in our sample. Since Medicare pays ASCs a fixed fee for IOLs, the prices ASCs pay and the business arrangements they have with IOL vendors have no immediate effect on Medicare expenditures. Medicare pays OPDs for the costs they incur. Therefore, Medicare is financially vulnerable to undisclosed business arrangements OPDs enter into with IOL vendors.

Beneficiary out-of-pocket expenses for cataract surgery with IOL implant are 2.5 to 3 times greater in OPDs than in ASCs.

Patient coinsurance for cataract extraction with IOL insertion averages \$195 in ASCs versus \$586 in OPDs. Patients pay coinsurance on the total charges they incur for services provided by an OPD. The amount of coinsurance an ASC can collect is limited to 20 percent of Medicare's allowed payment rate.

RECOMMENDATIONS

On June 18, 1993, the Principal Deputy Inspector General for the Office of Inspector General testified before the Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education and Related Agencies. At that hearing the Subcommittee was notified that this study was nearing completion and that the data collected for the study indicated that ASCs were paying about \$126 for IOLs while

Medicare was paying ASCs \$200 per lens. That testimony and the information in this report subsequently resulted in legislation reducing Medicare's \$200 fixed IOL payment to \$150.

At a \$150 fixed IOL payment rate, we project that reduced payments to ASCs would save the Medicare program over \$18 million annually, and more than \$90 million over 5 years. The change will also reduce beneficiary coinsurance payments to ASCs by \$10 per procedure or \$3.6 million annually.

We project \$9.7 million in OPD savings annually from this legislative change. We have reservations about whether these OPD savings would actually materialize. Complexities of the OPD cost reporting system coupled with opportunities for OPDs to shift costs or increase charges, may totally erode any potential savings. Unlike beneficiaries who have their cataract surgery with IOL implant performed in an ASC, patients of OPDs are unlikely to see any change in their out-of-pocket expenses.

COMMENTS TO THE DRAFT REPORT

This report has been modified and program savings adjusted to reflect the Health Care Financing Administration's (HCFA's) comments. The full text can be found in Appendix B.

The most significant change to the report involved the deletion of our recommendation that HCFA seek legislation that would enable them to establish a fixed payment level for cataract surgery performed in OPDs that would bring OPD payments more in line with ASC payments.

While we believe paying OPDs a fixed rate similar to ASCs to be the best interim solution, HCFA felt that this report in itself did not present enough evidence or make a convincing argument for such change. At this time, HCFA is continuing to pursue their ongoing work to determine the best method of calculation and reimbursement for an outpatient prospective payment system encompassing all outpatient procedures.

Should HCFA consider implementing an outpatient prospective payment system in stages, we would encourage them to include cataract surgery with IOL insertion in the first stage. Cataract surgery encompasses unique characteristics that distinguish it from other outpatient procedures. It is the number one outpatient procedure paid by Medicare. It is a procedure that is scheduled days or weeks in advance. It is essentially an elective procedure. The beneficiary has control over whether to have the procedure done and at what stage in the cataract development to have surgery. Access to facilities, ophthalmic surgeons and follow up care is widely available.

TABLE OF CONTENTS

	PAGE
EXECUTIVE SUMMARY	i
INTRODUCTION	1
FINDINGS	3
• Intraocular lenses can be purchased for less than \$200	3
• The ability of purchasers to secure a low price for IOLs is not dependent on the number of IOLs purchased annually	4
• Medicare's ability to obtain a fair price for IOLs under today's payment mechanisms is problematic, particularly in OPD settings	4
• Medicare beneficiary copayments for cataract extraction with IOL insertion are almost 2.5 to 3 times greater in OPDs than in ASCs	6
RECOMMENDATIONS	8
APPENDICES:	
A: Expanded Methodology and Statistical Information	
B: Health Care Financing Administration Comments	

INTRODUCTION

PURPOSE

This study evaluates whether Medicare's current payment policy for prosthetic intraocular lenses (IOLs) is prudent.

BACKGROUND

Cataract extraction with IOL insertion is the most frequently performed procedure paid by Medicare and accounts for approximately 6 to 8 percent of the Medicare outpatient budget. The number of IOLs implanted in Medicare beneficiaries has increased steadily over the last decade. In 1991, the Medicare program paid for an estimated 1.14 million IOLs. Hospital outpatient departments (OPDs) account for two out of three of the IOLs implanted in Medicare beneficiaries. Ambulatory surgical centers (ASCs) account for most of the remaining IOL implants and about 2 percent of the implants were performed in hospital inpatient or physician office settings.

In March 1986, the Office of Inspector General (OIG) issued a report which concluded that Medicare payment policies encouraged inflated IOL prices. Discounts negotiated by purchasers were not passed on to the Medicare program resulting in Medicare paying double or triple the actual IOL purchase price.

In June 1990, the OIG conducted a follow-up study on Medicare's reimbursement for IOLs and, like the previous report, found that IOLs were widely available well below Medicare payment level. Both reports concluded that a national cap for IOL payment was needed to bring Medicare payment more in line with actual procurement costs.

The Consolidated Omnibus Budget Reconciliation Act of 1985 and the Omnibus Budget Reconciliation Act of 1986 sought to correct the inequities fostered by Medicare payment policies. These Acts reduced cataract surgery fees, limited IOL payment and attempted to address Medicare payment inequities to ASCs and OPDs.

In an effort to control expenditures for IOL acquisition costs, Medicare's current policy limits IOL payment in ASCs. After beneficiaries meet their annual deductible, Medicare pays 80 percent of the \$200 fixed fee, established by the Health Care Financing Administration (HCFA), to cover ASC IOL acquisition costs. Payment for the IOL is included in Medicare's ASC facility payment and is not an itemized charge on ASC claims.

Hospital OPDs are paid on a cost basis. Payment for cataract surgery includes the IOL and is based on the lower of: (1) charges, (2) cost, or (3) the blended rate. The blended rate is equivalent to 58 percent of the ASC cataract surgery rate less deductible and

coinsurance, plus 42 percent of the costs the OPD incurred less deductible and coinsurance. Medicare pays for OPD services using interim payments and then reconciles these interim payments with actual costs at the end of the cost reporting period.

Payment for IOLs implanted during hospital inpatient cataract surgery is included in the hospital's DRG payment. Physicians who perform cataract surgery in their office are paid for IOLs based on reasonable charge. The reasonable charge may not exceed the actual acquisition cost for the IOL plus up to a 5 percent handling fee.

SCOPE and METHODOLOGY

A random sample of 361 Medicare patients was drawn from a 1 percent sample of the 1991 Medicare Part B Common Working File. A total of 326 IOL purchasers responded to our survey.

An effort was made to contact each of the ophthalmic surgeons who operated on the 361 beneficiaries in the sample. The surgeons were asked to identify the IOL manufacturer and model number. When the surgeon did not purchase the IOL, we contacted the OPD, ASC or other purchaser for IOL cost and procurement information.

All respondents were asked to provide information about their business transactions with IOL vendors. In addition to specific information about the IOL implanted in our sampled Medicare beneficiary, IOL purchasers were asked to provide cost information about all of the IOL models they purchased in 1991 and 1992. They were also asked to provide information about the cost of IOLs they purchased and intended to purchase in 1993.

Respondents were contacted in person, through mail surveys or over the telephone. In some cases, the ophthalmologist had died or the facility or practice had been sold and the medical records pertaining to the beneficiary in our sample could not be located. Some surgeons and facilities chose not to participate in our study; others were not contacted because they were under investigation for fraud or abuse. A total of 35 potential IOL purchasers were dropped from the study for one or more of the above reasons.

Survey responses and information collected from surgeons and facilities on the beneficiary sample and for IOL purchases in 1991 and 1992 were entered into a data base. This information was subsequently prepared for analysis by merging it with information obtained from the Food and Drug Administration (FDA) on IOL manufacturers suppliers and distributors, model numbers, and FDA approval dates.

A more complete discussion of the methodology used for this study can be found in Appendix A. Appendix A also contains more detailed information on how the data and projections presented in this report were determined.

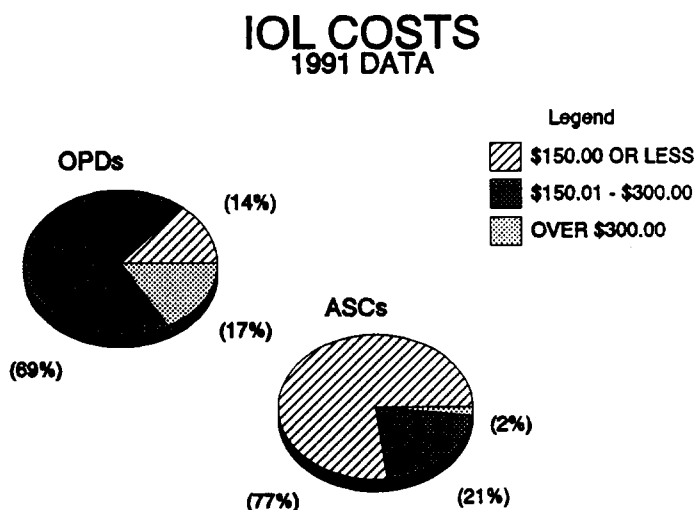
FINDINGS

Finding #1: Intraocular lenses can be purchased for less than \$200.

The surgeons and facilities purchasing IOLs reported that they spent between \$30 and \$450 to secure the lenses implanted in our sampled beneficiaries. In 1991, the average price paid was \$198.

Considerable difference exists in the price paid by ASCs and OPDs. The ASCs in our sample paid, on average, \$126 to secure the IOL implanted in our sampled beneficiary. The OPDs paid considerably more, averaging \$230 per IOL.

According to survey responses, nearly 9 out of 10 respondents still purchase the same IOL model they implanted in 1991 in 1993. The same IOLs that cost on average \$198 in 1991 are being purchased in 1993 for an average price of \$172. As the table below illustrates, OPDs are paying less in 1993 than in 1991, but, on average, OPDs pay nearly \$86 more per IOL than ASCs.



**AVERAGE IOL PURCHASE PRICE
MEDICARE BENEFICIARY SAMPLE DATA**

1991	PURCHASER	1993
\$230	OPD	\$198
\$126	ASC	\$112
\$104	Difference in Mean Price (OPD-ASC)	\$ 86
\$30-450	Purchase Price Range	\$40-410

Table 1

Finding #2: The ability of purchasers to secure a low price for IOLs is not dependent on the number of IOLs purchased annually.

Contrary to expectations, our data show that the ability of purchasers to secure a low price for IOLs did not depend on the number of IOLs purchased annually. When we analyzed the data on all of the lenses our respondents purchased in 1991 and 1992, we found that less than 3 percent of the variance in IOL prices can be explained by the volume of lenses purchased.

When we analyzed our data on lens purchases, we found that OPDs affiliated with hospitals having 100 beds or less had no problem securing IOLs at competitive prices. As with our analysis of volume versus price, we found little correlation between bed size and IOL prices.

Analysis of data and information provided by respondents show that the price negotiated between purchaser and vendor was usually valid for all similar, if not all, IOL models in the vendor's product line. For example, a single price would be negotiated for all poly(methyl methacrylate) or PMMA IOLs, all posterior chamber IOLs or all IOLs except specific models.

The same data and information indicate that surgeons tended to use the same posterior chamber IOL model for all of their patients. Surgeons deviated from their IOL of choice only when an anterior chamber IOL was needed, when experimenting with trial lenses or when the surgeon's preferred IOL was contraindicated. Some surgeons changed their IOL preference when the lens they used was no longer offered by the vendor.

We also expected that newer lenses would be more costly than older model IOLs. When we examined the acquisition costs of foldable ultraviolet absorbing silicone lenses we found that they were available in prices ranging from \$75 to \$475. Our data also showed that this IOL, which many consider to be the newest technology available, was being purchased by ASCs for \$125 or less.

Examination of the data on all IOLs purchased in 1991 and 1992 shows that vendors charged purchasers whatever the market would bear for a particular model. For example, one vendor sold a particular model for \$100 to one purchaser and for \$410 to another purchaser. Of the seven purchasers of this IOL model, five paid more than \$100 but less than \$410. All of the purchasers bought at least 500 units of this particular model in 1991 and 1992. The price paid for this IOL had no apparent correlation to the volume of other products purchased from the vendor.

Finding #3: Medicare's ability to obtain a fair price for IOLs under today's payment mechanisms is problematic, particularly in OPD settings.

In an effort to gain a competitive edge, many IOL vendors offer volume discounts, rebates, loans, customized packages of related cataract surgical supplies and other

business arrangements. When we examined invoices, contracts, agreements and other documents provided by our respondents, we found evidence to establish that 52 percent of the IOL purchasers had one or more of the following included in their IOL purchase:

- Customized package deals in which other cataract related supplies and pharmaceuticals are included at no cost or provided at greatly reduced cost.
- Discounted microscopes and other surgical equipment and supplies.
- Volume discounts based on minimum purchase commitments.
- Free IOLs or further price reductions after meeting certain volume level commitments.
- Loans, some of which appear to have been forgiven in later years.
- Frequent buyer points good toward the purchase of the vendor's other product lines.
- Free equipment and trial IOLs.
- Cash rebates on total IOL purchases.

IOL PURCHASERS RECEIVE

Free

- surgical supplies
- viscoelastic
- pharmaceuticals
- IOLs

Discounted

- microscopes
- surgical equipment
- surgical blades

Incentives

- loans
 - cash rebates
 - frequent buyer points
-

The actual number of purchasers with a quid pro quo business arrangement with their IOL vendor is probably closer to 75 or 80 percent. We believe the higher number to be correct after examining all of the invoices and other documents submitted.

Some respondents did not provide conclusive evidence acknowledging their business arrangement with their IOL vendor; the information they did provide fit the pattern of business arrangements established from files with more complete information. For example, some respondents did not acknowledge in our survey that they had made equipment purchases through their IOL vendor. No documentation to establish conclusively that an equipment purchase was included in the IOL purchase price was submitted. However, the IOL price reflected on invoices or other documents provided fits the pattern of business established by IOL vendors. When complete information was provided, this vendor's pattern of business established that the purchaser's IOL acquisition cost included payment for more than the IOL itself.

While providers are required by law to disclose discounts and other incentives that affect the costs they claim; discounts and other incentives have not always been passed on to the Medicare program. We are concerned because the complexities of cost reporting still leave the Medicare program vulnerable to financial harm from undisclosed business arrangements OPDs enter into with IOL vendors.

Perhaps the most abusive practice we found involved IOLs purchased by an OPD that were delivered to physicians who, in turn, resold them to the OPD at even higher prices. Another, involved wasteful and unnecessary next day freight charges that the OPD

insisted upon and routinely paid. Most cataract surgeries are scheduled days if not weeks in advance. The IOLs used are taken from stock on hand. There is no reason to pay next day shipping charges for routine restocking. The most prevalent practices involved inflated IOL prices in exchange for discounts on other vendor products and unbundling of items included with the IOL purchase.

According to HCFA, very few OPDs are subjected to full scale audits of the costs they claim to have incurred to provide cataract extraction with IOL insertions. Fiscal intermediaries complain of complex and often conflicting laws, regulations and rules that make indepth audits time consuming and not cost effective. Providers voice the same complaints. Cost reporting forms have not been changed to enable fiscal intermediaries to effectively track the lesser of charges, costs or the blended rate for OPD cataract surgery.

Vendor business arrangements with purchasers are customized to meet the buyer's needs. The arrangement may be purely financial such as a loan to purchase a piece of equipment or to establish an operating suite. It may involve bundled cataract surgery products from a single source or from multiple sources. The vendor's stated value of any item can vary considerably. The list price for equipment, supplies, IOLs and other items is readily available but very few items offered by vendors are actually sold at list. The cost to produce an IOL and the other items needed to perform cataract surgery is unknown. Determining cost becomes more difficult as distributors and other third parties add their profit margins to actual production costs. Eleven of our respondents reported that the value of items they received with each IOL exceeded their IOL acquisition cost.

Arrangements may be one time events, short term (less than a year) or long term (one or more years). They may be limited to IOL purchases or applied to other surgical or facility supplies. They may be straight forward or backdoor arrangements such as rebates paid to corporate offices or other third parties. Overall, they reflect business practices common in the American economy. Attempts by Medicare to quantify the value of these arrangements is extremely difficult, if not impossible.

Finding #4: Medicare beneficiary copayments for cataract extraction with IOL insertion are 2.5 to 3 times greater in OPDs than in ASCs.

After a beneficiary's annual cash deductible has been satisfied, Medicare pays 80 percent of the ASC prospective payment rate established by HCFA for cataract extraction with IOL insertion. The beneficiary, or as is often the case the beneficiary's secondary insurance, is responsible for paying the remaining 20 percent. The beneficiary copayment for services provided in ASCs is limited to the difference between the Medicare payment and the total ASC fixed rate calculated by the carrier paying the claim. The fixed rate calculation uses national payment rates established by HCFA to approximate the cost incurred by ASCs in providing covered services. Each carrier adjusts the national payment rate using the wage index value for the geographical area in which the ASC is located. Areas with high wage levels receive a higher payment than ASCs located in

areas with lower wage levels. Based on our sample, the average prospective rate established by HCFA for ASC cataract extraction with IOL insertion in 1991 was \$975. On average, patients paid \$195 in coinsurance to ASCs and the Medicare program paid the remaining \$780.

Hospital OPDs are not under the same billing constraints as ASCs. Patients pay coinsurance on the total charges they incur. Our sample establishes that the average charge for OPD cataract extraction with IOL insertion in 1991 was \$2,928. On average, OPD patients paid \$586 in coinsurance in 1991, which amounts to \$390 more than ASC patients paid in the same year.

Medicare payments to OPDs are affected by the amount of coinsurance OPDs collect. The greater the OPD charge to the patient the greater the patient coinsurance and the lower the Medicare payment. Our data established that the average OPD charge to patients for cataract surgery with IOL implant in 1991 was \$2,928. The difference between an OPD's charges to patients and the actual costs they incur in providing OPD services establishes the cost to charge ratio. Assuming the average cost to charge ratio for OPDs to be 50 percent, we calculated that the average cost of providing cataract surgery in OPDs in 1991 was approximately \$1,464.

Our data shows that on average, patients paid OPDs \$586 in coinsurance for OPD cataract surgery. This payment is deducted from the costs recognized by the program. After the \$586 coinsurance has been deducted from the \$1,464 cost, Medicare paid, on average, \$878 per OPD procedure.

Currently, IOL costs are not paid separately from total cataract surgery costs. Nor is the beneficiary copayment for the IOL calculated separately. If IOLs were paid separately, the coinsurance on the IOL would be \$40 in ASCs. In OPDs, the IOL coinsurance is 20 percent of the OPD charge for the lens. In our sample, OPDs charged beneficiaries an average of \$580 for an IOL. The beneficiary coinsurance on IOLs provided by OPDs in 1991, averaged \$116, nearly 3 times greater than ASCs.

RECOMMENDATIONS

On June 18, 1993, the Principal Deputy Inspector General for the Office of Inspector General testified before the Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education and Related Agencies. At that hearing the Subcommittee was notified that this study was nearing completion and that the data collected for the study indicated that ASCs were paying about \$126 for IOLs while Medicare was paying ASCs \$200 per lens. That testimony and the information in this report resulted in legislation to reduce Medicare's \$200 fixed IOL payment to \$150. We encourage HCFA to broaden the scope of that legislation by seeking an amendment to the statute and regulations that would extend the \$150 limit on IOLs to physicians who perform cataract surgery in their office.

At a \$150 fixed IOL payment rate, we project that reduced payments to ASCs would save the Medicare program over \$18 million annually, and more than \$90 million over 5 years. The change will also reduce beneficiary coinsurance payments to ASCs by \$10 per procedure or \$3.6 million annually.

We project \$9.7 million in OPD savings annually from this legislative change. We have reservations about whether these savings would actually materialize. Complexities of the OPD cost reporting system coupled with opportunities for OPDs to shift costs or increase charges, may totally erode any potential savings. Unlike beneficiaries who have their cataract surgery with IOL implant performed in an ASC, patients of OPDs are unlikely to see any change in their out-of-pocket expenses.

COMMENTS TO THE DRAFT REPORT

The Health Care Financing Administration (HCFA) commented on our draft report. The report has been modified and program savings adjusted to reflect HCFA's comments. The full text can be found in Appendix B.

The most significant change to the report involved the deletion of our recommendation that HCFA seek legislation that would enable them to establish a fixed payment level for cataract surgery performed in OPDs that would bring OPD payments more in line with ASC payments.

Until a comprehensive outpatient system can be developed we believe paying OPDs a fixed payment rate similar to the rate paid to ASCs to be the best interim solution. The HCFA felt that this report in itself did not present enough evidence or make a convincing argument for such change. At this time, HCFA is continuing to pursue their ongoing work to determine the best method of calculation and reimbursement for an outpatient prospective payment system encompassing all outpatient procedures.

If HCFA should consider implementing a prospective payment system for outpatient

services in stages, we would encourage them to include cataract surgery with IOL in the first stage. Cataract surgery encompasses unique characteristics that distinguish it from other outpatient procedures. It is the number one outpatient procedure paid by Medicare. It is a procedure that is scheduled days or weeks in advance. It is essentially an elective procedure. The beneficiary has control over whether to have the procedure done and at what stage in the cataract development to have surgery. Access to facilities, ophthalmic surgeons and follow up care is widely available.

APPENDIX A

Expanded Methodology and Statistical Information

METHODOLOGY

A random sample of 361 Medicare beneficiaries who had cataract surgery with IOL insertion performed in 1991 was drawn from a 1 percent sample of the Medicare Part B Common Working File (CWF). Using CWF information, we identified the ophthalmic surgeon for each patient in the sample.

An effort was made to contact each surgeon either in person, through the mail or over the telephone.

We did not receive information from 8 ophthalmic surgeons:

- Five surgeons did not respond to our requests,
- Two were under investigation and were not contacted at the request of the Office of Investigations, and
- One could not be located.

A total of 353 ophthalmic surgeons (nearly 98 percent of the sample) responded to our request for information.

Three beneficiaries were dropped from the sample for the following reasons reported by the ophthalmic surgeon:

- The cataract procedure with IOL implant had actually been performed in 1990,
- One patient died and surgery was aborted before lens implant, and
- One patient had a cataract removed but no lens was implanted.

Overall, we were able to identify, from surgeon records: (1) the IOL purchaser, (2) the IOL manufacturer, (3) the IOL model number, and (4) the IOL serial number for 350 of the 361 patients in our sample.

Using the information gained from surgeon records, we attempted to contact each IOL purchaser (ASC, OPD or physician) to ascertain the cost of the IOL implant. We were unable to secure a response to our request for information from 27 IOL purchasers:

- Twenty-one purchasers did not respond to our request for information,
- Three were under investigation and at the request of the Office of Investigations were not contact,
- Three could not be identified (the ophthalmic surgeon did not respond and information on hand was insufficient to identify the purchaser).

Information was received from 326 IOL purchasers, representing 90 percent of the sample. The information presented in this study was derived from the information we received from these 326 IOL purchasers.

Each purchaser was asked to disclose the cost they incurred to procure the IOL implanted in our sampled patient. They were also asked to provide a copy of the invoice showing: (1) the IOL manufacturer, (2) the IOL model number, and (3) the IOL serial number. **Accuracy of reported IOL acquisition costs were verified by comparing reported acquisition costs with the purchase prices shown on the purchase invoices.** Discrepancies between survey responses and the invoice price were documented for analysis.

Finding #1

The IOL cost incurred by the 326 purchasers responding to our request for information was entered into a data base for analysis. Arraying the data established that the IOLs implanted in our sampled beneficiaries ranged in price from \$30 to \$450. The average price paid was \$198.

Analysis of IOL acquisition cost data by type of purchaser revealed that OPDs paid significantly more for their IOLs than did the ASCs in our sample. On average, OPDs paid \$230 for each lens they implanted during 1991. The ASCs paid an average \$126 per lens during the same period.

Nine out of 10 (299 of 326) purchasers indicated that they were still purchasing the same IOL model implanted in our sampled Medicare beneficiary. Information provided by these purchasers established that the average price they paid for IOLs had decreased between 1991 and 1993. The average cost of an IOL fell from \$198 per lens in 1991 to \$172 per lens in 1993. The lowest price paid for an IOL in 1993 was \$40 and the highest price \$450. The average price paid by ASCs declined from \$126 to \$112, while the average price paid by OPDs declined from \$230 to \$198 per lens.

Finding #2

In addition to information about the IOL implanted in our sampled Medicare beneficiary, all purchasers were asked to provide volume and cost data on all of the IOLs they acquired in calendar years 1991 and 1992. **Invoices and contracts provided by our respondents were used to validate the accuracy of the reported costs.** The information provided was entered into a data base for analysis. Discrepancies between invoices/contracts and reported data were documented and analyzed.

The 326 purchasers in our sample bought a total of 213,745 IOLs in 1991 and a total of 233,036 lenses in 1992. We calculated the mean and median for all lenses purchased in 1991 and 1992. The analysis of the 213,745 lenses purchased in calendar 1991 produced

a mean of \$121 for ASCs compared to our sample mean of \$126. The same data set produced a mean of \$219 for OPDs compared to our sample mean of \$230. Analysis of the 233,036 IOLs purchased in 1992 revealed that the average IOL acquisition cost had declined from 1991 levels for both ASCs and OPDs. This finding was consistent with the results of our initial sample which showed that the average price paid to acquire an IOL had fallen between 1991 and 1993 from \$198 in 1991 to \$173 in 1993.

Neither ASC or OPD variance in IOL prices was explained by the volume of lenses purchased. We analyzed the data on all lenses purchased in 1991 and 1992 to determine if a correlation existed between the volume of lenses purchased and acquisition cost. Correlation analysis indicated that overall less than 3 percent (1991 R-square = 0.0289, 1992 R-square = 0.0274) of the variance in IOL prices was explained by the volume of lenses purchased.

Analysis of the OPD data for 1991 and 1992 produced R-squares slightly higher than the overall sample. R-squares for OPDs were 0.0566 for 1991 and 0.0483 for 1992 indicating again little of the variance in IOL prices paid by OPDs was explained by the volume of lenses they purchased. Additional analysis of the 1991 and 1992 OPD data revealed that no correlation existed between the price OPDs paid for IOLs and the size of the purchasing institution.

The data on all lenses purchased in 1991 and 1992 was further analyzed by merging it with a data base containing Food and Drug Administration (FDA) approved IOLs. The FDA data base contained information on all IOL model numbers approved by the FDA for each manufacturer/distributor and the year in which the IOL model received FDA approval.¹ Analysis of this data revealed the price paid for a particular lens model varied significantly and that neither the attributes of the lens (PMMA, hepatics etc.) nor the number of years the lens had been on the market affected the price of the lens.

Finding #3

Providers are required by law to disclose discounts and other incentives that might affect the costs they claim and the providers subsequent reimbursement from the Medicare program. Several prior studies have attempted to make adjustments to the IOL costs claimed by respondents by taking into account the value of free or discounted services and supplies provided by IOL manufacturers and distributors. We made no such adjustments to IOL acquisition costs reported by our respondents.

¹ As of August 8, 1989 manufacturers could make certain model additions without FDA approval. These new model numbers did not require FDA approval because they were essentially the same lens already approved by the FDA. Likewise, manufacturers and distributors were not required to report new model numbers assigned lenses already approved by the FDA.

We found evidence to establish that 169, or 52 percent, of our study respondents clearly had business arrangements with IOL manufacturers, distributors and others that arguably could have inflated the IOL acquisition price they reported to us. A number (76) of respondents did not provide complete copies of their financial agreements with their IOL vendors. The invoices and other information that these 76 respondents did provide indicated that they might have business arrangements with IOL vendors similar to the 169 respondents who disclosed such arrangements. Overall, we concluded that 75 percent our respondents had business arrangements with one or more of their IOL suppliers that might artificially inflate the cost they incurred in procuring IOLs. The number climbs to nearly 80 percent when arrangements involving third parties are taken into consideration.

Finding # 4

All of coinsurance amounts reported in this study were derived from the actual bills submitted to the Medicare program by the OPDs and ASCs in our sample.

The ASC billing and payment information was readily obtained from the Part B history contained in the common working file (CWF) from which we drew our sample. The ASC patient deductibles and coinsurance were determined by subtracting program payments from the recognized ASC facility charge shown on the CWF.

The ASC data in the CWF indicated that the average ASC allowed charge for the beneficiaries in our sample was \$975. The data also established that beneficiaries paid, on average, \$195 in coinsurance to ASCs. On average the Medicare program paid \$780 to ASCs for each cataract procedure performed in 1991.

To determine what OPDs were charging patients for cataract surgery with IOL implant we used information that we obtained from the OPDs that responded to our survey. All of the HOPDs in our sample were asked to provide a copy of the itemized bill they provided to the Medicare patient in our sample. They were also asked to provide a copy of the bill that they submitted to Medicare for payment. This information was entered into a data and when analyzed revealed that on average:

- 1) OPDs charged \$2,928 for cataract surgery with IOL implant in 1991, and
- 2) Medicare beneficiaries paid, on average, \$586 in coinsurance.

SAVINGS PROJECTIONS

Our sampling of the CWF indicated that approximately 1.14 million cataract procedures with IOL implant were performed in calendar year 1991. Of the 361 beneficiaries in our sample, 238 (66 percent) had cataract surgery performed in an OPD; 114 (32 percent) had surgery in an ASC. The remaining 9 beneficiaries (2 percent) were classified as

"other or unknown" and includes beneficiaries who had surgery performed while hospital inpatients or in a physician's office.

Medicare Program Savings From Changes to ASC Payments

The legislation enacted by Congress would not change the current method used by Medicare to pay ASCs for cataract extraction with IOL implant. The ASC payment method adds the maximum allowable amount for an IOL to the geographically adjusted standard overhead amount or payment group. In 1991, \$200 (the maximum allowable for an IOL) was added to the payment group (adjusted standard overhead) determined for each ASC. The legislation enacted by Congress lowered this amount from \$200 to \$150.

One out of every 3 (32 percent) cataract procedures with IOL implant was performed in an ASC. This equates to 360,000 of the 1.14 million procedures performed in 1991. The change enacted by Congress will lower the amount Medicare allows for IOL acquisition costs by \$50 per procedure and produce savings of over \$18 million per year (360,000 procedures x \$50). Over 5 years these savings will amount to more than \$90M. Calculations may vary slightly due to rounding.

Beneficiary Savings

As previously mentioned, we used the CWF to determine the average coinsurance paid by Medicare beneficiaries to ASCs. The change in the amount recognized for an IOL will have a direct impact on the amount of coinsurance that will be paid by beneficiaries electing to have their cataract surgery with IOL implant performed in an ASC. Beneficiary coinsurance liability will decrease by \$10 for each cataract procedure with IOL insertion performed at an ASC. Overall, the 360,000 beneficiaries who use ASCs each year will save a more than \$3.6 million annually (360,000 x \$10).

Medicare Program Savings From Changes to OPD Payments

Using the billing information provided by the OPDs our sample, we determined approximately how much Medicare might have paid each of them for the claim they submitted on our sampled beneficiary. To do this we determined how much Medicare would have paid each OPD using cost reimbursement, the blended rate and actual charge. The lowest payment amount was then used in all calculations.

Our first calculation established the likely Medicare payment if the OPD in our sample had been paid using cost reimbursement. To arrive at a Medicare payment amount based on cost, we used an average cost to charge ratio of 50 percent. The 50 percent figure was taken from a HCFA draft report concerning outpatient services.

For each OPD in our sample we took 50 percent of the total charges indicated on the bill (UB82 or other) submitted to Medicare for payment. From this amount (total billed charges x 0.50) we subtracted the actual amount of coinsurance the patient was required to pay (20 percent of the total charges shown on the bill). This gave us the approximate Medicare payment if the claim was paid using cost reimbursement.

OPD COST REIMBURSEMENT CALCULATION	
Total bill submitted to Medicare	\$3000.00
cost (using 50% cost to charge ratio)	\$1500.00
less coinsurance to be paid by beneficiary	<u>600.00</u>
Medicare payment (cost - coinsurance)	\$ 900.00

Our second calculation established Medicare's payment to each OPD in the sample using the blended rate. To establish a potential Medicare payment amount using the blended rate it was necessary for us to determine the ASC and OPD portion of the blend.

The ASC portion of the blend was determined using data from the CWF. The average ASC payment rate for 1991 (\$975) was adjusted to reflect the average coinsurance (\$195) paid by beneficiaries. This gave us the average net amount paid by Medicare to ASCs or \$780 (\$975 - 195). The net amount paid to ASCs was then adjusted by 58 percent to arrive at the ASC portion of the blend (\$780 x 0.58 or \$452.40).

The OPD portion of the blended rate was determined by taking 42 percent of the cost determined under the cost reimbursement method described above.

OPD REIMBURSEMENT USING BLENDED METHOD	
<i>ASC Portion of the Blend</i>	
Average ASC payment rate in 1991	\$ 975.00
less patient coinsurance (\$975 x 0.20)	<u>195.00</u>
Subtotal	\$ 780.00
Portion of ASC payment rate included in blend	<u>0.58</u>
ASC PORTION OF BLEND	\$ 452.40
<i>OPD Portion of Blend</i>	
Total bill submitted to Medicare	\$3000.00
cost (using 50% cost to charge ratio)	\$1500.00
less patient coinsurance (\$3000 x 0.20)	<u>600.00</u>
Subtotal	\$ 900.00
OPD specific portion of blend	<u>0.42</u>
OPD PORTION OF BLEND	\$ 378.00
Medicare payment using blended rate (ASC portion + OPD portion)	\$830.40

The Medicare payment amount determined from each method (cost reimbursement and blended rate) described above was compared to actual amount billed. The lowest of the three numbers was established as Medicare's likely payment amount for each OPD in our sample.

Savings from the change in IOL reimbursement were derived by changing the blend calculation to reflect the lower ASC portion resulting from legislative change. This new blended rate was compared to the lowest rate established in the above calculations. If the new blended rate was lower than the previously established payment rate, savings would accrue to the Medicare program.

We calculated that the ASC portion of the blend would decline from \$452.40 to \$429.20. Using the lower ASC portion of the blend we recalculated the blended rates for each OPD in the sample. The revised blended rates were compared to the lowest payment we calculated for the OPD bill submitted to Medicare in 1991. When the revised blended rate was lower than the amount paid in 1991 savings would accrue to the Medicare program. We added up these individual OPD savings and determined \$12.90 to be the average savings per OPD procedure.

Of the 1.14 million cataract procedures with IOL implant, approximately 66 percent, or 752,000 procedures, were performed in OPDs. Savings of \$12.90 per procedure are projected to yield savings of \$9.7 million annually or \$48.5 million over 5 years.

APPENDIX B

Comments

of

Of the 1.17 million cataract procedures with IOL implants, approximately 65 percent, or 752,000 procedures, were performed in OPDs. Savings of \$12.90 per procedure are projected to yield savings of \$9.7 million annually or \$48.5 million over 5 years.



Memorandum

Date **NOV 22 1993**

From **Bruce C. Vladeck**
Administrator *Bruce Vladeck*

Subject **Office of Inspector General (OIG) Draft Report: "Intraocular Lens (IOL) Implant Acquisition Costs," (OEI-05-92-01030)**

To **June Gibbs Brown**
Inspector General

We reviewed the subject draft report which examines IOL acquisition costs.

HCFA concurs with Option 1 presented in the report. A provision included in the Omnibus Budget Reconciliation Act of 1993 reduces the IOL payment rate for ambulatory surgical centers to \$150. Our detailed comments are attached for your consideration.

Thank you for the opportunity to review and comment on this report. Please advise us if you would like to discuss our position on the report recommendation at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on the Office of Inspector General (OIG) Draft Report:
"Intraocular Lens (IOLs) Implant Acquisition Costs,"
(OEI-05-92-01030)

OIG Recommendation

HCFA should establish a fixed payment level for cataract surgery performed in hospital outpatient departments (OPDs) that would bring Medicare reimbursement to OPDs more in line with ambulatory surgical centers (ASCs) payments.

If this is not achievable, we suggest HCFA consider our options for addressing lens acquisition costs.

- Option 1 - Reduce the \$200 fixed IOL payment, without changing current policies for determining payment.

- Option 2 -
 - A - Establish a fixed program payment for IOLs and a fixed beneficiary copayment for each IOL. Payment for IOLs at \$150, and beneficiary copayment at 1991 levels: \$40 for ASCs and \$116 for OPDs.

 - B - Establish a fixed program payment for IOLs and a fixed beneficiary copayment for IOLs. Payment for IOLs at \$150, and beneficiary copayment set at \$92 for both ASCs and OPDs.

 - C - Establish a fixed program payment for IOLs and a fixed beneficiary copayment for IOLs, with beneficiary copayment set at 20 percent of the payment rate for both ASCs and OPDs.

HCFA Response

HCFA concurs with option 1 and has taken action. We have already received legislation through the Omnibus Budget Reconciliation Act (OBRA) of 1993, signed on August 10, 1993, to reduce the IOL payment rate for ASCs to \$150 for the period January 1, 1994, through December 31, 1998. We suggest that in the final report this option include a more detailed description of what implementation would accomplish. For example, in addition to the direct savings realized in ASCs, there will be some indirect savings in OPDs as the payment level used in the blended payment amount would also decrease. (The blended payment amount includes 58 percent of the ASC rate.)

Each segment of option 2 represents a piecemeal approach to payment and coinsurance reform, and each contains inherent problems, both in the calculation of savings and in implementation. Options 2A and 2B would increase the beneficiary share of total payment for IOLs in ASCs from 20 percent to 27 percent and 61 percent, respectively. In addition, although option 2B decreases the coinsurance paid in OPDs for IOLs by \$18 million, at the same time it increases actual beneficiary payments by the same amount in ASCs.

The report shows option 2C as saving the program ~~\$24 million~~ if IOL rates were set at \$150. We believe that this option would actually prove a cost to the program, as beneficiary coinsurance for the IOL would decrease more than would the total payment.

A technical appendix to the report would be indispensable. This should describe the sampling methodology in greater detail than presented in the report, clarifying such questions as how survey information was "merged with information obtained from the Food and Drug Administration" and the relationship between IOL costs and procedure costs.

It is not clear how OIG derived their program savings in OPD payments. There are discrepancies between the OIG's estimates and our own estimates which suggest a systematic difference in the way these figures are calculated. Based on information contained in the report, it appears to us that the program savings are greatly overstated. We suggest that all savings calculation be presented in detail, either at relevant places in the text or as part of a technical appendix.

Refer to the attached markup of the draft report for other suggested changes.

In addition to supporting the reduction in Medicare IOL allowance to the \$150 level in ASCs, we also support an amendment to the statute and regulations that would apply that level to IOL payments made to physicians who perform cataract surgery in their office. Although these changes could possibly be made through ordinary notice and comment procedures, we believe that legislation would more expediently achieve these ends.

Regarding the report's primary recommendation, OBRA of 1986 requires HCFA to develop a prospective payment approach for hospital outpatient services. Toward this end, the Office of Research and Demonstrations is funding a study to assist in implementing such an approach. The study will produce a national data base of outpatient facility resource costs that can be used as input to formulate an outpatient prospective payment system. The study will cover 400 procedures including the resource use and costs for cataract removal and IOL implants in both the hospital OPD and the ASC setting.

The study is not complete at this time. The final report is expected to be completed in early 1994. Upon completion, it is expected that data from over 70 OPDs and ASCs will have been analyzed, comprising an estimated 25,000 cataract procedures. The preliminary data indicate that the average cost of the IOLs is below \$200 (in the range of \$175), although some were purchased at a cost of over \$400. The method for calculating the cost for the IOLs will be expanded beyond the existing methodology, which determines an average cost across all sites, to also include a weighted analysis of the number and range of costs for IOLs purchased at each site.

General Comments

Descriptions of OPD payment in the Background sections of the Executive Summary and Introduction are not completely accurate. Twenty percent of the ASC rate is netted out in the ASC portion of the blend, rather than actual coinsurance.

We suggest that the term "blended payment amount" be used instead of "blended rate" as "rate" implies an amount determined in advance based on a blended payment methodology.

The primary recommendation in the report; i.e., establish a fixed rate for OPDs approximating ASC payment levels, does not flow from the findings in the report.

The first option does not specifically address coinsurance; however, the report does indicate that beneficiaries would save \$1.7 billion from this recommendation. What generates these savings? Who pays the \$1.7 billion if not Medicare?