Board of Governors of the Federal Reserve System, October 2, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24885 Filed 10–5–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Committee on Vital and Health Statistics Meeting

Pursuant to Pub. L. 92–463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS).

Times and Dates: 9 a.m.–5 p.m., October 24, 1995; 9 a.m.–5 p.m., October 25, 1995; 9 a.m.–5 p.m., October 26, 1995.

Place: Room 703A, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, D.C. 20201.

Status: Open.

Purpose: The purpose of this meeting is for the Committee to plan for the upcoming special meetings on the Core Data Elements Project; to discuss the Committee's work plan for the coming year; to consider reports from each NCVHS subcommittee; to receive reports from offices of the Department of Health and Human Services and department-wide Data Council; and to address new business as appropriate.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each meeting day either between 8:30 and 9:00 a.m. or 12:30 and 1:00 p.m. so they can be escorted to the meeting. Entrance to the meeting at other times during the day cannot be assured.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Dated: September 29, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–24898 Filed 10–5–95; 8:45 am]

BILLING CODE 4163–18–M

Health Care Financing Administration

[BPD–797–PN]

RIN 0938–AG65

Medicare Program; Limitations on Medicare Coverage of Cataract Surgery

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

ACTION: Proposed notice.

SUMMARY: This notice announces the Medicare program's proposal to define medical necessity with respect to Medicare coverage of preoperative testing for cataracts, cataract surgery, and Nd:YAG capsulotomy.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 5, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–797–PN, P.O. Box 26688, Baltimore, MD 21207.

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

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

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

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–797–PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to: Allison Herron Eydt, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 10235, New Executive Office Building, Washington, DC 20503.

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

FOR FURTHER INFORMATION CONTACT: Karen McVearry, (410) 786–4643.

SUPPLEMENTARY INFORMATION:

I. Background

A. Medicare Program Description

The Medicare program was established by the Congress in 1965 through the enactment of title XVIII of the Social Security Act (the Act). This program provides payment for certain medical services and supplies for persons 65 years of age and over, certain disabled persons, and beneficiaries with end-stage renal disease.

While Medicare does cover many health care costs, the program was not designed to pay for every type of medical care for its beneficiaries. Section 1862(a)(1)(A) of the Act prohibits Medicare payment for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.

Longstanding Medicare policy has interpreted the term ''reasonable and necessary'' to mean that an item or service is safe and effective, not experimental or investigational, and generally accepted in the medical community. We have used various methods for seeking medical and scientific opinion in determining whether a health care technology is reasonable and necessary. These methods have included, at one time or another, the use of the Office of Health Technology Assessment (OHTA), a unit of the Agency for Health Care Policy and Research (AHCPR) within the Public Health Service (PHS), and various forms of consultation and liaison with national medical associations and groups along with carrier medical directors, our central office staff physicians, and PHS representatives.

In developing this proposal for a national coverage policy concerning preoperative testing, cataract removal surgery, and postoperative issues, we

carefully considered cataract practice guidelines developed by a private-sector panel of experts under the auspices of AHCPR (referenced in this notice as the ''Expert Panel'') as well as findings from several other studies discussed in this notice.

The following studies are those that we considered:

- Cataract Management Guideline Panel, *Cataract in Adults: Management of Functional Impairment,* Clinical Practice Guideline Number 4, Rockville, MD, U.S. Department of Health and Human Services, PHS, AHCPR, AHCPR Publication Number 93–0542, February 1993. (Throughout this notice, this study will be referred to as the *Clinical Practice Guideline*). In addition to the *Clinical Practice Guideline,* AHCPR also published as companion pieces a *Patient's Guide* (AHCPR Publication Number 93–0544) and *Management of Cataracts in Adults,* Quick Reference Guide for Clinicians Number 4 (AHCPR Publication Number 93–0543). (Copies of the guidelines may be obtained from the AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907; its toll free telephone number is 1–800–358–9295.)
- American College of Eye Surgeons, Outpatient Ophthalmic Surgery Society, Society for Excellence in Eye Care, and Society for Geriatric Ophthalmology, *Guidelines for Cataract Practice,* Bellevue, WA, McIntyre Eye Clinic and Surgical Center, February 1993. (Copies of the guidelines may be obtained from the McIntyre Eye Clinic and Surgical Center, 1920–116th Avenue NE., Bellevue, WA 98004; its toll free telephone number is 1–800–822–0199. Its fax number is 1–206–646–5914.)
- General Accounting Office (GAO), Program Evaluation and Methodology Division, *Cataract Surgery,* (GAO/PEMD–93–14 Cataract Surgery, B–239626, April 20, 1993. (Copies of the GAO study may be obtained from the following address: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. The telephone number is 1–202–512–1800. The fax number is 1–202–512–2250.)
- U.S. Department of Health and Human Services, Office of Inspector General (OIG), *Outpatient Surgery—Medical Necessity and Quality of Care* (OEI–09–88–01000, 1991). (Copies of the OIG study may be obtained from the following address: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. The telephone number is 1–202–512–1800. The fax number is 1–202–512–2250.)

B. Medicare Coverage of Cataract Surgery

A cataract is an opacification, or clouding, of the eye's lens that usually occurs as a part of the aging process. This condition affects about 50 percent of Americans between the ages of 65 and 75, and approximately 70 percent of people over 75. Not all cataracts require surgical removal. The presence of a cataract does not always produce a noticeable or functional impairment. Thus, cataract surgery is generally considered to be elective.

When cataract surgery is performed, the opacified lens is removed from the eye. Extracapsular extraction and phacoemulsification are cataract removal procedures. The extracapsular procedure is done by making an incision in the eye and removing the anterior portion of the capsule. In addition, the nucleus and lens cortex are also extracted, leaving behind the posterior capsule. Phacoemulsification cataract removal is a modification of the extracapsular procedure. In phacoemulsification, the nucleus of the cataract is fragmented by a probe through ultrasonic frequency while simultaneously aspirating the fragments from the eye. In most cases, an intraocular lens is then implanted in the treated eye. The Expert Panel reviewed medical literature and prepared guidelines based on that review, which revealed that these surgeries appear to be equally effective in restoring vision. Adequate data are not available to determine if one technique is more effective than the other in reducing or eliminating functional impairment due to the cataract.

Section 35–9 of the Medicare Coverage Issues Manual (HCFA–Pub. 6), ''Phacoemulsification Procedure—Cataract Extraction,'' states that phacoemulsification is an acceptable procedure for the removal of cataracts. Therefore, the Medicare program covers reasonable and necessary services furnished in connection with this procedure, as well as for extracapsular extractions.

Although Medicare presently does not have a national coverage policy that specifies the exact parameters for determining coverage of cataract surgery, there are guidelines for the coverage of presurgery cataract diagnostic evaluations in Medicare Coverage Issues Manual section 35–44, ''Use of Visual Tests Prior to and General Anesthesia in Cataract Surgery.'' Medicare currently covers one comprehensive eye examination and an A-scan and, if medically justified, a B-scan. (These scans use sonar to study structures that are not directly visible. They are used to determine the appropriate pseudophakic power of the intraocular lens. For most cases involving a simple cataract, a diagnostic ultrasound A-scan is used. For patients with a dense cataract, a diagnostic ultrasound B-scan may be used.) These ultrasound scans are billed and paid for separately from the comprehensive eye examination because they are separate procedures with their own Physicians' Current Procedural Terminology (CPT) codes. (Tests performed that have separate CPT codes are not included as part of the service reported under ''evaluation and management'' codes. Thus, A-scans and B-scans cannot be included in the payment for the comprehensive eye examination.)

Section 50–38 of the Medicare Coverage Issues Manual sets forth Medicare's current policy on endothelial cell photography. This test is used to determine the endothelial cell count, which is a predictor of success of ocular surgery or certain other ocular procedures. Section 50–38 states that this test may be covered in certain circumstances but that, if the test is performed as part of a presurgical examination for cataract surgery, coverage for the test is available only as part of the comprehensive eye examination. In this circumstance, therefore, separate payment is not made.

This notice proposes to continue this policy of limiting coverage of diagnostic testing performed before cataract surgery to a comprehensive eye examination, an A-scan, and, if medically necessary, a B-scan. Thus, Medicare's policy of not providing additional or separate coverage for other preoperative tests unless there is another diagnosis in addition to cataracts would be continued.

Currently, Medicare does not have a national coverage policy that specifically addresses the following tests:

- Contrast sensitivity testing, which is designed to measure the amount of contrast required to detect a specific stimulus.
- Glare testing, which attempts to reproduce the symptom of glare in cataract patients and to quantify the amount of visual impairment it causes by comparing acuity with and without a bright light source directed by the eye.
- Potential vision testing, which is designed to determine whether patients with obviously impaired vision have the potential to see well following cataract surgery.

C. Rationale for This Notice: Clinical Studies and Other Evaluations

In reviewing Medicare's cataract removal policy, we have reviewed the Expert Panel's *Clinical Practice Guideline* as well as the findings of the *Guidelines for Cataract Practice*, the GAO study, and the OIG study.

1. Findings From the Expert Panel

Through the sponsorship of AHCPR in PHS, the *Clinical Practice Guideline* was published in February 1993. In sponsoring development of this guideline, AHCPR convened an interdisciplinary panel of private-sector experts made up of ophthalmologists, nurses, optometrists, internists, a family physician, a psychiatrist, an anesthesiologist, a clinical social worker, and a patient representative. The panel first undertook an extensive and comprehensive interdisciplinary review of the field to define the existing knowledge base and to evaluate critically the assumptions and common wisdom in the field of cataract care. Next, the panel developed and initiated a peer review of the guideline drafts and field reviews with intended users in clinical sites. Finally, comments from these reviews were assessed and used in the development of the final guidelines.

The Expert Panel included the following findings concerning preoperative testing, cataract removal surgery, and postoperative issues in its guidelines.

a. Preoperative Testing. The *Clinical Practice Guideline* found inadequate scientific evidence to support the use of most preoperative tests in deciding whether cataract surgery is medically appropriate. These preoperative tests include contrast sensitivity testing, glare testing, potential vision testing, and specular photographic microscopy (referred to in this proposed notice as endothelial cell photography).

- Contrast Sensitivity Testing

The guidelines state that, at this time, there is inadequate evidence that contrast sensitivity testing provides information, beyond the information obtained through a patient's history and an ocular examination, that is useful for the determination of whether a patient would benefit from cataract surgery.

- Glare Testing

The report of the Expert Panel indicates that there is inadequate evidence that glare testing provides useful information beyond that found in a patient's history and an eye examination. This testing, however, may be useful for corroborating glare symptoms in a small percentage of cataract patients who complain of glare, yet measure good Snellen acuity (a standard method of measuring visual accuracy during an eye examination) in office testing. Even in these patients, a positive glare test does not determine whether surgery should be recommended.

- Potential Vision Testing

Regarding potential vision testing (PVT), the Expert Panel found that adequate evidence is lacking as to whether PVT can assist the ophthalmologist in predicting the outcome of cataract surgery.

- Endothelial Cell Photography

The Expert Panel found that there is currently no evidence or rationale to support the use of endothelial cell photography on all patients who have cataracts in order to predict the response of the cornea to cataract surgery.

- Other Preoperative Tests

Other preoperative tests were also reviewed by the Expert Panel. The panel concluded that the following tests are not indicated as part of the preoperative workup for cataract surgery unless specific circumstances justify them and unless the justification is documented in the patient's chart:

—Formal visual fields, which refers to the entire area that can be seen without shifting the gaze.
—Fluorescein angiography, which is a process in which dye is used to assess adequate circulation in the blood vessels of the eye.
—External photography, which is a photograph of the external portion of the eye and lens.
—Corneal pachymetry, which is a procedure that quantifies and monitors changes in the thickness of the central cornea.
—B-scan ultrasonography, defined earlier in this notice.
—Specialized color vision tests, which are done to determine the functional ability of the macula and optic nerve.
—Tonography, which records changes in intraocular pressure produced by the constant application of a known weight on the globe of the eye, reflecting the facility of outflow of the aqueous humor from the anterior chamber.
—Electrophysiologic tests, which test the organic functions of the eye by means of electrical current.

The Expert Panel's report indicates that most of the preoperative tests reviewed by the panel provide inadequate scientific evidence to support the need for surgery. Thus, the Expert Panel concluded that these tests do not predict the benefits a patient may experience from the surgery or negative outcomes of the surgery. The Expert Panel found inadequate evidence to support the use of these tests in most cases to determine the need for cataract removal surgery. The Expert Panel also found that ''special circumstances'' often necessitate the use of these preoperative tests.

b. Cataract Removal Surgery. The guidelines also found that surgery usually is not necessary solely because a cataract is present. The Expert Panel found that the decision to have cataract surgery should be based on several factors, such as a complete patient history and an ocular examination, and an evaluation of the effect of the cataract on the patient's visual and overall function, after assessing the patient's visual needs, and after a thorough consideration of the potential risks associated with the surgery. The Expert Panel believes that cataract surgery should be considered if—

- The individual is afflicted with visual disability that results in functional impairment, taking into special consideration the circumstances of the one-eyed patient;
- The individual suffers from a lens-induced disease (such as phacomorphic glaucoma or phacolytic glaucoma); or
- The individual has an ocular condition that requires cataract extraction in order to be adequately diagnosed or treated.

Functional impairment means that the cataract causes a reduction in visual function that significantly interferes with the person's ability to participate in everyday activities and infringes on the person's autonomy. Management of the cataract should be determined primarily on the basis of the patient's overall visual function and needs, a complete medical history, an eye examination, and the person's understanding of the risks and benefits of cataract surgery. The Expert Panel concluded that cataract surgery performed solely for improving vision should not be performed if the patient does not want surgery; if glasses or visual aids provide satisfactory functional vision; if the patient's lifestyle is not compromised; or if the patient is medically unfit for cataract removal surgery. Whether the patient's lifestyle is compromised because of the cataract is a decision made by the patient and reached through subjective criteria. In addition, the physician should assist in assessing the patient's visual needs as well as informing the patient of the potential risks associated with the cataract removal surgery. The

patient must decide whether the cataract infringes on his or her ability to carry out needed or desired activities. Therefore, it is the patient along with the physician who must determine whether the visual disability caused by the cataract is significant enough to warrant surgery.

The panel reviewed situations in which cataract surgery is indicated for both eyes. The panel concluded that indications for cataract removal surgery are the same as those for the first eye. Therefore, the same subjective and objective criteria used to determine the need for cataract removal in the first eye should also be used in the evaluation of the second eye. According to the panel, visual acuity, stereopsis, and visual field are all enhanced by binocular vision. These facts strongly support the potential benefit of cataract removal surgery on the second eye.

At this time, there appear to be no scientific data indicating the optimal time interval for surgically removing a cataract in the second eye. The panel strongly emphasized, however, that cataract removal surgery not be performed on both eyes at the same time. The panel warned that surgery on both eyes during the same procedure runs the risk of catastrophic consequences if there are unrecognized problems with unsterile instruments or materials used during the procedure.

In summary, the Expert Panel believes the goal of cataract treatment is to maintain or restore autonomy through appropriate treatment in order to remove the disability. In addition, the panel also asserts that the purpose of cataract surgery is to reduce and, ideally, alleviate functional impairment caused by the cataract. If a patient does not have to compromise everyday activities because of the cataract, the surgery is usually unnecessary. The panel considers surgery necessary only when the cataract has progressed to the point that the person's vision is functionally impaired to a level that infringes on the person's lifestyle.

c. Postoperative Issues. Opacification of the posterior, or back, lens capsule is a consequence of modern cataract surgery. As the cloudiness increases, the patient's vision is adversely affected. This opacification can lead to functional impairment. The most common technique for treating posterior capsular opacification (PCO) is Nd:YAG capsulotomy, also referred to as YAG or laser capsulotomy. This technique uses a laser to make a hole in the central part of the posterior lens to improve vision.

The Expert Panel lists indications for Nd:YAG capsulotomy in its *Clinical Practice Guideline* that include subjective, objective, and educational criteria. Nd:YAG capsulotomy is considered appropriate and justified when the ability to carry out needed and desired activities is impaired. The eye examination confirms the diagnosis of PCO and excludes other ocular causes of functional impairment, and also confirms that the patient has been educated about the risks and benefits of laser surgery to the posterior capsule.

The Expert Panel found no justification for Nd:YAG capsulotomy to be scheduled at the same time the patient is scheduled for cataract removal surgery, or when the cataract removal is performed. The Expert Panel noted that Nd:YAG capsulotomy should never be performed prophylactically because there is no predictable time at which this procedure may be necessary. The *Clinical Practice Guideline* reports that Nd:YAG capsulotomy is seldom needed before 3 months have elapsed following cataract surgery, and that Nd:YAG capsulotomy carries its own risks. Although PCO is common, it varies in severity and does not always necessitate surgery. It is rare that opacification is severe enough to require Nd:YAG capsulotomy within 3 months of cataract surgery, and it is uncommon within the first 6 months after cataract surgery. The Expert Panel asserts that less than 25 percent of those having cataract surgery have Nd:YAG capsulotomy done within 2 years of surgery. The Expert Panel found Nd:YAG capsulotomy to be a highly successful procedure. However, justification for Nd:YAG capsulotomy should be well documented in the patient's record.

2. Findings From the Guidelines for Cataract Practice

Another study on cataract removal was issued at approximately the same time that the AHCPR-sponsored *Clinical Practice Guideline* was published. The additional study is entitled *Guidelines for Cataract Practice* and was completed by a cooperative committee composed of members of the leadership of several clinical ophthalmic surgeon organizations. These guidelines represent a consensus of highly experienced surgeons who have been personally involved in the development of cataract surgical removal techniques, the treatment of patients, and the education of other ophthalmic surgeons.

a. Preoperative Testing. The *Guidelines for Cataract Practice,* like the *Clinical Practice Guideline,* states that before the decision to have cataract surgery is made, full information regarding the correct diagnosis of the cataract and the prognosis for return of visual function following the anticipated treatment must be obtained. The patient's medical history should be carefully evaluated including how the cataract presently affects the patient's ability to function normally. In other words, these guidelines support the Expert Panel's findings that functional impairment of the patient should be weighed heavily before deciding whether to have cataract removal surgery.

In addition, the *Guidelines for Cataract Practice* states that preoperative testing may be of some use in determining the presence of a cataract, as well as the presence of other ocular diseases. Several preoperative tests that are discussed in the Expert Panel's findings are also addressed in the *Guidelines for Cataract Practice.* Three specific tests are discussed in detail by both studies. These tests are contrast sensitivity testing, glare testing, and endothelial cell photography.

- *Contrast Sensitivity Testing*

Contrast sensitivity is a measure of the contrast level required for detection of a specified size of a test object. This test quantitatively reveals decreased perception of low contrast objects. Although the *Guidelines for Cataract Practice* indicates that contrast sensitivity has been shown to be an indication of the need of recognition of visual targets for those dealing with rapidly moving test targets, the Expert Panel's guidelines state only that there is inadequate evidence as to whether this test will indicate either the presence or severity of a cataract or a prognosis for improvement following cataract removal surgery.

- *Glare Testing*

Glare testing measures the effect of simulated glare on vision function. Disabling glare is often an indication that a cataract has developed. But, the *Guidelines for Cataract Practice* found that using glare testing as a diagnostic tool may be effective only if the patient complains of glare in situations when visual function would otherwise be considered satisfactory. If visual function is decreased in normal lighting conditions, glare testing adds little to the diagnostic evaluation. Although glare testing may indicate the presence of a cataract, the test does not measure the severity of the cataract or the prognosis for improvement after cataract surgery. Thus, this test does not show that cataract removal surgery is medically necessary.

• *Endothelial Cell Photography*

Endothelial cell photography may be done before an intraocular operation because the corneal endothelium is particularly sensitive to the trauma of the surgery. This test is used to measure and record the evaluation of corneal endothelial cells. Patients with a preoperative reduction of their endothelial cell density are unusually sensitive to the trauma of surgery and may not maintain adequate visual functions following surgery. The *Guidelines for Cataract Practice* found that endothelial cell photography is useful in these cases to predict unusual surgical risks because low endothelial cell density may not be accurately predicted by patient history or examination. However, the *Guidelines for Cataract Practice* also found that many patients of low endothelial cell density can be identified through the patient's medical history and clinical examination.

• *Other Tests*

In addition to contrast sensitivity, glare testing, and endothelial cell photography, the *Guidelines for Cataract Practice* discusses other preoperative tests. The *Guidelines for Cataract Practice* states that these additional tests may be of some use in the diagnosis and prognosis of cataract removal. The *Guidelines for Cataract Practice* suggests that patients with ocular diseases other than cataracts would benefit from additional preoperative testing because these tests would protect the patient from disappointing results if the cataract is not the major cause of visual impairment. Some of these additional tests are also discussed in AHCPR-sponsored *Clinical Practice Guideline*. In addition to the tests previously mentioned, both studies discuss B-scan ultrasonography, corneal pachymetry, the electrophysiological test, external photography, fluorescein angiography, formal visual fields, the specialized color vision test, and tonography.

b. Cataract Surgery. Regarding the treatment of cataracts, the findings from the *Guidelines for Cataract Practice* are similar to those in the Expert Panel's guidelines. The *Guidelines for Cataract Practice* agrees with the Expert Panel's guidelines, which state that the goal of cataract removal surgery for the purpose of functional rehabilitation is improvement of visual function. Surgery should be performed for the purpose of reducing or eliminating functional impairment caused by the cataract.

The *Guidelines for Cataract Practice* concurs with the Expert Panel's findings that surgery generally is not necessary solely because the cataract is present. Both guidelines list similar reasons why a patient may choose not to have surgery. These reasons include:

- The patient does not desire surgery.
- Glasses or visual aids provide functional vision satisfactory to the patient's needs and desires.
- The patient's lifestyle is not compromised.
- The patient is known to be medically unfit for safe surgical intervention.

The *Guidelines for Cataract Practice* generally supports the Expert Panel's findings regarding surgical removal of a cataract in the second eye. The guidelines concludes that surgery on the second eye is justified in order to restore binocular vision. In addition, the subjective and objective criteria used to determine the necessity of cataract removal for the first eye must also be fulfilled before performing the same procedure on the second eye.

While the *Guidelines for Cataract Practice* agrees that cataract removal generally should not be performed on both eyes during the same procedure, additional findings contend that some clinical circumstances may exist that would require consideration of operating on both eyes simultaneously. For example, a patient who has poor general health and multiple medical conditions may be a candidate for dual cataract removal because of the high risk involved in anesthetizing the patient twice. It is suggested that whenever possible, however, cataract removal surgery be performed on each eye separately and that sufficient time be allowed for the first eye to heal before the second cataract removal is performed.

The Expert Panel's guidelines and the *Guidelines for Cataract Practice* both agree that the decision to have cataract surgery should be left to the patient after all appropriate counseling has been provided.

c. Postoperative Issues. The *Guidelines for Cataract Practice*, like the Expert Panel's findings, indicates that PCO frequently occurs after cataract removal surgery. Nd:YAG laser capsulotomy was found to be the most commonly performed procedure to relieve PCO. Management of functional impairment due to PCO is similar to the management of the procedure that removes the cataract. Findings from the *Guidelines for Cataract Practice* also are consistent with the Expert Panel's guidelines that Nd:YAG capsulotomy should not be performed or scheduled at the same time cataract removal is performed. Both studies assert that routine or prophylactic posterior capsulotomy is not appropriate.

3. Findings from GAO

In April 1993, GAO issued a report on cataract surgery. GAO's findings support the Expert Panel's assertion that the mere presence of a cataract does not necessitate the surgical removal of the cataract. GAO set up a study to determine how many cataract surgeries were performed unnecessarily. GAO hypothesized that the four States (California, Massachusetts, Pennsylvania, and Texas) from their survey on eye symptoms and functional impairment before and after surgery were not unrepresentative of current practice and applied the permissive criterion that surgery is considered inappropriate if the patient reported no functional impairment. The study revealed that by using the criterion of functional impairment, 6 percent of the respondents' surgeries were inappropriate. GAO further calculated that every 1 percent of cataract surgeries represented approximately $34 million in expenditures for Medicare. Under this scenario, GAO concluded that Medicare spent $204 million in 1991 for inappropriate cataract surgery. This is a conservative estimate considering that, in that same year, 1.35 million cataract surgeries were performed for which the Medicare program alone spent $3.4 billion. GAO theorized that if the number of inappropriate surgeries could be reduced, Medicare would not only save a great deal of money, but the quality of care for individuals with cataracts would improve.

4. Findings from OIG

The OIG's study, *Outpatient Surgery—Medical Necessity and Quality of Care* (OEI–09–88–01000, 1991), found that high-volume ophthalmologists (those who earn at least $1 million annually) are more likely to perform medically unnecessary surgeries and provide poor or questionable care than non-high-volume ophthalmologists.

II. Provisions of the Proposed Notice

The findings from the Expert Panel regarding cataract surgery and postoperative issues are supported by information found in the *Guidelines for Cataract Practice*. The GAO study concluded that there are substantial numbers of inappropriate cataract surgeries, while the OIG study found that high-volume ophthalmologists are more likely to perform medically unnecessary surgeries and provide poor or questionable care than non-high-volume ophthalmologists.

After evaluating these findings, we are proposing to adopt the following policies:

- Medicare would maintain its policy of paying only for a comprehensive eye examination or brief/intermediate examination as well as an A-scan and, if medically necessary, a B-scan before cataract surgery if the patient's only diagnosis is cataracts. We believe coverage of the B-scan is justified because this is a necessary diagnostic test for a patient who has a dense cataract rather than a simple cataract, which can be tested with an A-scan.

Thus, Medicare would include payment for tests such as contrast sensitivity, glare testing, and potential vision testing in the payment for the comprehensive eye examination performed before cataract surgery if the patient's only diagnosis is cataracts. Additional or separate payment for these tests would not be allowed if the only diagnosis is cataracts. Also, when there is a diagnosis in addition to cataracts, we would require that the medical need for these tests be documented in the patient's medical record whenever they are performed.

- Medicare would cover cataract surgery only for individuals who desire the surgery; who are medically fit for the surgery; and whose lifestyle is compromised by functional impairment because of the cataract, as documented in the patient's medical record. Medicare would not consider cataract surgery reasonable and necessary if glasses could satisfactorily correct the condition; if the patient's lifestyle was not compromised; or, if surgery was performed solely because a cataract was present. Medicare would also cover cataract surgery for individuals who suffer from lens-induced disease and ocular conditions requiring clear media.
- The Expert Panel's guidelines strongly emphasized that clinical studies have revealed that there is the potential for great risk if cataract removal is performed on both eyes during the same procedure. As a result, the Expert Panel found that cataract removal be performed on each eye during separate procedures and sufficient time be allowed for the first eye to heal before cataract removal is performed on the second eye. If extraordinary medical circumstances exist in which it may be dangerous or life-threatening for the patient to undergo anesthesia twice, a single procedure may be considered. Medicare coverage extends to both sets of circumstances.
- Medicare would cover Nd:YAG capsulotomy only if this procedure is performed subsequent to cataract surgery and is found to be medically necessary. Namely, Nd:YAG capsulotomy would be covered when it is reasonable and medically necessary to remedy functional impairment due to opacification following cataract surgery, as documented in detail in the patient's record. Medicare would not cover Nd:YAG capsulotomy if this procedure is performed or scheduled concurrently with cataract removal surgery.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Collection of Information Requirements

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

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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

The information collection requirements concern written documentation in the patient's medical record of the necessity of cataract surgery. The record must state that the individual desires the surgery, is medically fit for the surgery, and the lifestyle of the individual is compromised by functional impairment because of the cataract; or, the individual suffers from lens-induced disease and ocular conditions requiring clear media. The information collection requirements also concern written documentation in the patient's medical record of the necessity of Nd:YAG capsulotomy. The record must state that this procedure is performed subsequent to cataract surgery and is found to be medically necessary to remedy a documented functional impairment because of opacification following cataract surgery. Physicians, specifically ophthalmologists, would provide the information. Public reporting burden for this collection of information is estimated to be 166,666 hours per year based on an average of 5 minutes per service for a total of approximately 2 million services furnished in 1994.

These reporting and recordkeeping requirements are not effective until they have been approved by OMB. A notice will be published in the Federal Register when approval is obtained.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to HCFA, OFHR, MPAS, C2–27–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850 and to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

V. Regulatory Impact Analysis

A. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a notice would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all ophthalmologists, ambulatory surgical centers (ASCs), and hospitals are considered to be small entities.

We are preparing a regulatory impact analysis because we anticipate that a majority of the ophthalmologists who perform cataract surgery would be affected by recommendations contained in this notice. The following discussion describes what we know about the impact of this proposed notice on affected entities and is intended to fulfill the requirements of the RFA.

1. Background

The effect of a cataract on vision can range from minimal to catastrophic. In most cases, surgical removal of the obscured natural lens, usually combined with the insertion of an artificial lens implant, is the only treatment option available. In recent years, the vast majority of these operations have been performed either in a hospital outpatient department or in a Medicare-

certified ASC. The GAO report, *Cataract Surgery*, discussed earlier in this notice, mentions that the Medicare program paid for more than 1.8 million outpatient cataract surgeries in 1991. Our payment data indicate that these surgeries cost the Medicare program in excess of $3.4 billion.

The information in the GAO report, issued in April 1993, was based on a random sample survey of 1,964 Medicare patients living in four States who had undergone cataract surgery. Usable responses were obtained from 76 percent of the sample. About 75 percent of the responding Medicare patients reported one or more substantial functional impairments affecting their ability to drive, read, or watch television before their cataract surgery. If the criterion for surgery is that any level of problem with either symptoms or functions (even those the patient considers slight) is sufficient to warrant surgery, responses to the GAO survey show that few surgeries (2.5 percent) were inappropriate. If the criterion is functional impairment, then 6 percent of the respondents' surgeries could be considered inappropriate.

The GAO report stated that the data from the four States did not allow them to make generalizations regarding the likely levels of questionable cataract surgery in the nation as a whole. However, to get some sense of the financial importance reducing this surgery could have, GAO: (1) Hypothesized that the four States in the survey were not unrepresentative of current practice; (2) applied the permissive criterion that, for the surgery to be considered inappropriate, a patient must have reported no functional impairment; and (3) calculated that every 1 percent of cataract surgeries represented approximately $34 million in expenditures for the Medicare program as a whole. Under the outlined scenario, GAO reported that Medicare spent approximately $200 million in 1991 for inappropriate cataract surgery.

2. Effects on Expenditures

We believe that the provisions of this notice would facilitate savings. First, by reaffirming existing coverage for preoperative tests, we eliminate or reduce any confusion about this matter. Medicare would continue to pay for a comprehensive eye examination and an A-scan and, if medically necessary, a B-scan if the patient's only diagnosis is cataracts. Payment for additional preoperative tests would be considered as part of the payment for the comprehensive eye examination. Additional or separate payment would not be allowed for tests other than the comprehensive eye examination, A-scan, and, if medically necessary, a B-scan if the patient's only diagnosis is cataracts.

Second, we believe that savings would result from a reduction of unnecessary cataract-removal surgeries. We do not have our own estimate determining to what degree cataract surgery is performed inappropriately or the effect this notice would have on reducing inappropriate cataract surgery. However, the GAO report estimated that 6 percent of the respondents' surgeries could be considered inappropriate.

Medicare would cover cataract removal surgery only if specific indications for the surgery are fulfilled. The group that may be most affected by the inclusion of these indications would be high-volume ophthalmologists. In its 1991 report, as discussed earlier in this notice, OIG stated that high-volume ophthalmologists (those who earn at least $1 million annually) perform almost twice the rate of medically unnecessary surgery and questionable care as non-high-volume ophthalmologists.

Third, we believe there would be a decline overall in the number of Nd:YAG capsulotomies performed as a result of requiring physicians to document in the patient's medical record that the patient suffers from functional impairment due to PCO before performing or scheduling the surgery. Since we are proposing to redefine what constitutes medical necessity for Nd:YAG capsulotomy, we believe the frequency the procedure is performed prophylactically (sometimes within 3 months following cataract surgery) would be drastically reduced, resulting in additional savings.

We cannot estimate the value of any savings we anticipate as a result of this notice because we lack information. Savings would depend upon our ability to generate payment edits that would help us enforce the proposed coverage policy.

3. Effects on Providers

Cataract surgery performed to redress functional impairment due to cataract in the adult is the most common surgical procedure performed on Americans age 65 and over. As a result, cataract surgery is a significant item in the Medicare budget. The extent that ophthalmologists would be affected by this notice would depend upon the extent that they perform cataract surgery on Medicare beneficiaries that would not conform to the medical necessity criteria proposed in this notice. All ophthalmologists who treat Medicare beneficiaries, especially those who perform a high volume of cataract procedures, would be required to review their methods of evaluating patients before surgery. Also, ophthalmologists would be required to review their criteria for performing surgery to ensure that they perform surgery only on those Medicare patients who have a functional impairment resulting from the effect of the cataract that compromises the patient's lifestyle and for whom glasses do not satisfactorily correct the condition. Under the provisions of this notice, the ophthalmologists must document in the patient's record any impairment requiring cataract surgery.

Because the policies we are proposing reflect some of the findings stated in the guidelines, which were developed by an interdisciplinary private sector Expert Panel under the sponsorship of AHCPR, we anticipate that the guidelines would be acceptable to those physicians furnishing services to Medicare beneficiaries. Most ophthalmologists are already documenting to some extent the need for cataract surgery in patients' records; however, this notice would impose additional requirements on ophthalmologists. We believe that any decrease in the number of tests and procedures that would result due to a change in Medicare policy would primarily affect ophthalmologists performing a high volume of cataract-related procedures on Medicare beneficiaries. The GAO findings describe a situation in which Medicare expenditures could be reduced and the quality of services furnished by ophthalmologists could be enhanced at the same time.

In recent years, the vast majority of cataract surgery procedures have been performed either in a hospital outpatient department or in a free-standing ASC. Cataract procedures are performed approximately twice as often in a hospital outpatient department as in an ASC. A facility that specializes in eye procedures would be affected to a greater extent if the number of cataract surgery procedures is reduced than a facility that handles a wider range of surgical procedures.

B. Rural Hospital Impact Statement

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of

a Metropolitan Statistical Area and has fewer than 50 beds.

This notice would have little direct effect on payments to rural hospitals since this rule would recommend coverage changes that would affect primarily ophthalmologists, ASCs, and hospital outpatient surgery departments. Very few small rural hospitals would have an outpatient surgery department.

We are not preparing an analysis for section 1102(b) of the Act since we have determined, and the Secretary certifies, that this notice would not result in a significant impact on the operations of a substantial number of small rural hospitals.

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

(Sections 1861 and 1862 of the Social Security Act (42 U.S.C. 1395x and 1395y))

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare Supplementary Medical Insurance)

Dated: May 7, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: June 30, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–24835 Filed 10–5–95; 8:45 am]

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Office of the Secretary

Assistant Secretary for Management and Budget; Statement of Organization, Functions, and Delegations of Authority

Part A (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (DHHS), Chapter AH ''Office of the Assistant Secretary for Personnel Administration,'' as last amended at 57 FR 7391; and Chapter AM ''Office of the Assistant Secretary for Management and Budget,'' as last amended at 57 FR 8334 is being amended. The reorganization will abolish the Office of the Assistant Secretary for Personnel Administration and transfer the remaining functions to the HHS Office of Management and Budget. It will also establish the Departmental Appeals Board as a component within the Office of the Secretary. The Specific amendments to Part A are:

I. Make the following changes to Chapter AA ''Office of the Secretary,'' paragraph AA.10 Organization: Delete the Office of the Assistant Secretary for Personnel Administration and insert the Departmental Appeals Board.

II. Under Chapter AH, beginning with paragraph Section AH.00 Mission delete the remaining functions within the Office of the Assistant Secretary for Personnel Administration in its entirety.

III. Make the following changes to Chapter AM:

A. Section AM.00 Mission. Delete in its entirety and replace with the following:

AM.00 Mission. The mission of the HHS Management and Budget Office is to provide advice and guidance to the Secretary on administrative, budget, financial management, equal employment opportunity, and personnel, and to provide for the direction and coordination of these activities throughout the Department.

B. Section AM.10 Organization. Delete in its entirety and replace with the following:

AM.10 Organization. The HHS Management and Budget Office is headed by the Assistant Secretary for Management and Budget (ASMB). The ASMB is the Departmental Chief Financial Officer (CFO), and reports to the Secretary. The ASMB also serves as the Director for Equal Employment Opportunity for the Department. The office consists of the following organizations:

Immediate Office (AM)
Office of Grants and Acquisition Management (AMG)
Office of Budget (AML)
Office of Information Resources Management (AMM)
Office of Finance (AMN)
Administrative Services Center (AMQ)
Office of Human Resources (AMP)

C. Section AM.20 Functions is amended to add paragraph G, Office of Human Resources.

G. Office of Human Resources (AMP) advises and supports the Secretary and the Assistant Secretary for Management and Budget/CFO in the development and assessment of human resource programs and personnel policies. In coordination with the Operating Divisions (OPDIVs), formulates HHS policies pertaining to employment, compensation, position classification, employee benefits, performance management, employee development, and employee and labor relations. On behalf of the Department's Director of Equal Employment Opportunity (EEO), adjudicates complaints of discrimination. Serves as Departmental liaison to central management agencies exercising jurisdiction over personnel and EEO matters.

D. Establish a new Chapter AMP. The Office of Human Resources.

AMP.00 Mission. The Office of Human Resources (OHR) Provides leadership in the planning and development of personnel policies and human resource programs that support and enhance the Department's mission. Provides technical assistance to the Operating Divisions (OPDIVs) in building the capacity to evaluate the effectiveness of their human resource programs and policies. Serves as the Departmental liaison to central management agencies on topics relating to EEO and personnel matters.

AMP.10 Organization. The Office of Human Resources (OHR), headed by a Deputy Assistant Secretary for Human Resources who reports to the Assistant Secretary for Management and Budget, consists of the following components:

Immediate Office (AMP)
Policy Coordination Staff (AMP–1)
Personnel Programs Group (AMP–2)
Equal Employment Opportunity Programs Group (AMP–3)

AMP.20 Function. 1. The Immediate Office of Human Resources (OHR), provides leadership to the development and assessment of the Department's human resources programs and policies. In coordination with the Operating Divisions, designs human resource programs that support and enhance the HHS missions. Provides technical assistance to the OPDIVs in building the capacity to evaluate the effectiveness of their human resource programs and policies, including the development of performance standards. On behalf of the Department's Director of Equal Employment Opportunity, adjudicates complaints of discrimination. Serves as Departmental liaison to central management agencies exercising jurisdiction over personnel and EEO matters.

2. Policy Coordination Staff. Provides a variety of program support services to the components of the Office of Human Resources and to the OPDIVs. Coordinates the design of the evaluation capabilities and systems for use by the OPDIVs in determining the effectiveness of their personnel and EEO programs. Analyzes workforce data and trends to support program evaluation and strategic planning efforts, both at the departmental and OPDIV levels. Coordinates the development, approval, and dissemination of Departmental human resource policies.

3. Personnel Programs Group. Provides leadership to the planning and development of personnel policies and programs that support and enhance the Department's mission. In coordination with the OPDIVs, formulates HHS policies pertaining to employment, compensation, position classification,