implications to warrant preparation of a Federalism Assessment.

**Environment**

The Coast Guard has reviewed the environmental impact of this proposed rule and concluded that under section 2.B.2e(32) of COMDTINST M16475.1B, this proposed change is categorically excluded from further environmental documentation because promulgation of changes to drawbridge regulations have been found not to have significant effect on the environment. A ''Categorical Exclusion Determination'' is available for inspection or copying where indicated under **ADDRESSES**.

**List of Subjects in 33 CFR Part 117**

Bridges.

**Regulation**

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

1. The authority citation for part 117 continues to read as follows:

**Authority:** 33 U.S.C. § 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.663 is revised to read as follows:

**§ 117.663 Minnesota River.**

The draws of bridges above LeSueur, MN need not be opened for the passage of vessels.

Dated: August 21, 1997.

**T.W. Josiah,**

*Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.*

[FR Doc. 97–23442 Filed 9–3–97; 8:45 am]

**BILLING CODE 4910–14–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

### 42 CFR Part 416

**[BPD–831–P]**

**RIN 0938–AH15**

## Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would establish in regulations a process under which interested parties may request, with respect to a class of new technology intraocular lenses (IOLs), a review of the appropriateness of the current payment amount for IOLs furnished by Medicare-participating ambulatory surgical centers.

The rule implements section 141(b) of the Social Security Act Amendments of 1994, which requires us to develop and implement this process.

**DATES:** Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 3, 1997.

**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–831–P, P.O. Box 26688, Baltimore, MD 21207–0488.

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.

Comments may also be submitted electronically to the following e-mail address: BPD831P@hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address below.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–831–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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**FOR FURTHER INFORMATION CONTACT:** Cathaleen Ahern, (410) 786–4515.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Payment for Ambulatory Surgical Center Facility Services*

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) provides that benefits under the Medicare supplementary medical insurance program (Part B) include services furnished in connection with surgical procedures that, under section 1833(i)(1)(A) of the Act, are specified by us and are performed on an inpatient basis in a hospital but that also can be performed safely on an ambulatory basis in an ambulatory surgical center (ASC) or in a hospital outpatient department. To participate in the Medicare program as an ASC, a facility must meet the standards specified under section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.25 (''Basic requirements''). Our regulations at 42 CFR part 416 contain the coverage and payment rules for services furnished by Medicare-participating ASCs.

Section 1833(i)(2)(A) of the Act authorizes us to pay ASCs a prospectively-determined rate for facility services. ''Facility services'' means services that are furnished in conjunction with covered surgical procedures performed in an ASC, or in a hospital on an outpatient basis. Section 416.61 sets forth included and excluded facility services. ASC facility services payment rates represent our

estimate of a fair fee that takes into account the costs incurred by ASCs generally in furnishing facility services in connection with performing a surgical procedure. ASC payment rates do not include physician fees and other medical items and services, such as laboratory services or prosthetic devices, for which separate payment may be authorized under other provisions of the Medicare program. However, an intraocular lens (IOL) is included as an ASC facility service under section 1833(i)(2)(A)(iii) of the Act.

Payment for ASC facility services is subject to the usual Medicare Part B deductible and coinsurance requirements. Therefore, participating ASCs are paid 80 percent of the prospectively-determined rate adjusted for regional wage variations. The beneficiary pays a coinsurance amount equal to 20 percent of the wage-adjusted ASC facility fee.

Currently, the Medicare program covers approximately 2,300 procedures performed in an ASC. We assign to each procedure one of eight standard payment rates. Collectively, the procedures assigned a particular payment rate constitute an ASC payment group. The current payment group rates follow:

Group 1—$312
Group 2—$419
Group 3—$479
Group 4—$591
Group 5—$674
Group 6—$785
Group 7—$935
Group 8—$923

All procedures within a payment group are paid the same rate, adjusted for geographic wage variation. (A detailed discussion of the ASC payment methodology and rate-setting procedures is set forth in the final notice published in the **Federal Register** on February 8, 1990, entitled ''Revision of Ambulatory Surgery Center Payment Rate Methodology'' (55 FR 4526).)

A ninth payment group allotted exclusively to extracorporeal shockwave lithotripsy services was established in the notice with comment period published December 31, 1991 (56 FR 67666). The decision in *American Lithotripsy Society* v. *Sullivan,* 785 F. Supp. 1034 (D.D.C. 1992), prohibits us from paying for these services under the ASC benefit at this time. Extracorporeal shockwave lithotripsy payment rates are the subject of a separate document, and a proposed notice was published October 1, 1993 (58 FR 51355).

*B. Payment for Intraocular Lenses Furnished in an Ambulatory Surgical Center*

At the inception of the ASC benefit on September 7, 1982, Medicare paid 80 percent of the reasonable charge for IOLs supplied for insertion concurrent with or following cataract surgery performed in an ASC. Section 4063(b) of the Omnibus Budget and Reconciliation Act of 1987 (OBRA 1987) (Pub. L. 100–203), enacted on December 22, 1987, amended section 1833(i)(2)(A) of the Act to mandate that we include payment for an IOL furnished by an ASC for insertion during or following cataract surgery as part of the ASC facility fee rather than paying for the IOL separately, in addition to the facility fee. Payment included in the facility fee for an IOL must be reasonable and related to the cost of acquiring the class of IOL involved.

Thus, for services furnished beginning March 12, 1990, which was the effective date of the final notice published in the **Federal Register** on February 8, 1990, entitled ''Revision of Ambulatory Surgery Center Payment Rate Methodology'' (55 FR 4526), Medicare included payment for an IOL in payment group 6 and payment group 8, the two payment groups that include IOL insertion procedures. The Physicians' Current Procedural Terminology (CPT) codes for groups 6 and 8 and their descriptors follow:

*Payment Group 6*

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

CPT code 66986—Exchange of intraocular lens. (This CPT code was first listed in CPT 1992; we added it to the ASC list effective January 30, 1992.)

*Payment Group 8*

CPT code 66983—Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure).

CPT code 66984—Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification).

Initially, we set the payment amount for IOLs at $200. We did not categorize IOLs into different classes for the reasons discussed below. The $200 allowance applied to any IOL furnished for surgical insertion by an ASC.

Our identification of $200 as the appropriate amount of payment for an IOL was influenced by the Office of Inspector General's (OIG's) finding that ASCs were able to negotiate an average IOL price of $200, and that discounts in unknown amounts were available to other ASCs. (See *Medicare Certified Ambulatory Surgical Centers, Cataract Surgery Costs and Related Issues,* OAI–09–88–00490, published March 1988. Copies can be obtained from the Office of Inspector General, Department of Health and Human Services, (415) 556–0675.)

In *Outpatient Ophthalmic Surgery Society, Inc.* v. *Shalala,* No. 90–0305 (D.D.C. January 31, 1994), the court rejected both arguments that were mounted in a challenge to the $200 IOL payment amount. The court deferred to our reliance on the OIG study as the basis for determining the IOL payment amount and upheld our determination that there is no medical justification to recognize different classes of IOLs.

Section 4151(c)(3) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508), enacted on November 5, 1990, froze the IOL payment amount at $200 for IOLs furnished by ASCs in conjunction with surgery performed during the period beginning November 5, 1990 and ending December 31, 1992. We continued paying an IOL allowance of $200 from January 1, 1993 through December 31, 1993.

Section 13533 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) (Pub. L. 103–66), enacted on August 10, 1993, mandated that payment for an IOL furnished by an ASC be equal to $150 beginning January 1, 1994 through December 31, 1998.

**II. Provisions of This Proposed Rule**

*A. Requirement for Review of Payment for New Technology Intraocular Lenses*

On October 31, 1994, the Congress passed the Social Security Act Amendments of 1994 (SSAA 1994) (Pub. L. 103–432). Section 141(b) of SSAA 1994 requires us, not later than 1 year after the date of enactment (that is, by October 31, 1995), to develop and implement a process under which interested parties may request, with respect to a class of new technology IOLs, a review of the appropriateness of the payment amount provided for IOLs furnished by ASCs under section 1833(i)(2)(A)(iii) of the Act. Since January 1, 1994, the payment amount for IOLs furnished by ASCs under section 1833(i)(2)(A)(iii) of the Act has been $150.

Section 141(b)(1) of SSAA 1994 stipulates that an IOL may not be treated as a new technology IOL unless it has been approved by the Food and Drug

Administration (FDA). Section 141(b)(2) of SSAA 1994 requires that, in determining whether to provide a payment adjustment, we take into account whether use of the IOL is likely to result in reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or any other comparable clinical advantages.

Section 141(b)(3) of SSAA 1994 requires that we publish at least annually a list of the requests received for review of the appropriateness of the IOL payment amount with respect to a new technology IOL. We must provide a 30-day comment period on the IOLs that are the subject of the requests for review. Within 90 days of the close of the comment period, we must publish a notice of the determinations made with respect to the appropriateness of the IOL payment amount for the IOLs for which a review was requested. Any adjustment of the IOL payment amount (or payment limit) for a particular IOL or class of IOLs that we determine is warranted would be effective not later than 30 days following publication of the final notice of our determination.

Implementation of section 141(b) of SSAA 1994 requires three principal policy decisions:

- Identification of a class or classes of new technology IOLs.
- Determination of whether the current IOL payment amount is appropriate for an IOL identified as belonging to a class of new technology IOLs.
- Identification of the payment adjustment to be applied if the current payment amount is found to be inappropriate.

In the sections that follow, we discuss the factors that led us to the process that is the subject of this proposed rule. We welcome comments on the options selected and rejected, and on potential alternatives not considered.

*B. Identification of a Class of New Technology Intraocular Lenses*

1. Distinguishing Among Classes of Intraocular Lenses

In order to prepare the final notice entitled ''Revision of Ambulatory Surgery Center Payment Rate Methodology'' (55 FR 4526) that was published in the **Federal Register** on February 8, 1990, we sought supporting documentation that would justify pricing IOLs according to IOL type or ''class,'' and that would establish the basis for distinguishing among different types of IOLs, such as placement of the IOL within the eye, either as anterior chamber or posterior chamber IOLs; or the style of the IOL, either single-piece or multi-piece; or characterization of the IOL as ''advanced technology.''

On February 22, 1989, the FDA advised us in a letter that its premarket approval review process determined whether IOLs were ''safe and effective'' not by comparing IOLs with one another, but by comparing them with a set of historical IOL data known collectively as the ''grid.'' The FDA noted that no additional labeling or advertising claims of the superiority of one IOL (or type of IOL) over another had been approved at that time; that is, medical benefits of one IOL or type of IOL over another had not been proven in the studies that were submitted to the FDA. There were no across-the-board differences in the indications and contraindications or in the warnings sections of the package insert that would imply across-the-board medical benefits for one IOL or type of IOL over another.

The studies that were submitted to HCFA at that time failed to yield conclusive evidence of specific clinical conditions or indications that required or influenced the use of one IOL over another, nor did HCFA find justification for a differentiated price structure based on IOL type. We therefore determined that a $200 payment amount was both reasonable and related to the costs incurred by ASCs to acquire IOLs available at that time. As noted above, a Federal court sustained this determination. (See *Outpatient Ophthalmic Surgery Society, Inc.* v. *Shalala,* No. 90–0305 (D.D.C. January 31, 1994).)

2. Criterion To Define a Class of New Technology Intraocular Lenses

There still is no universally accepted definition of what constitutes a ''class of new technology intraocular lenses.'' Section 141(b) of SSAA 1994 does not define new technology IOLs other than to specify that an IOL may not be treated as a new technology IOL unless it has been approved by the FDA. We must therefore first define the characteristics that distinguish a ''new technology'' IOL from other IOLs in order to comply with section 141(b) of SSAA 1994.

Section 141(b) of SSAA 1994 requires that we take clinical outcomes such as ''reduced risk of intraoperative or postoperative complication or trauma'' and ''reduced induced astigmatism'' into account in determining whether to provide a payment adjustment with respect to a particular IOL.

Because they are identified with such specificity, we infer that the clinical outcomes listed in the law are intended to characterize IOLs that belong to a ''class of new technology intraocular lenses,'' the use of which not only produces the specified clinical outcomes, but does so to a greater degree than other IOLs. We submit that the latter consideration is crucial because of the abundant evidence that demonstrates that IOLs have attained a level of technical sophistication, clinical success, and patient satisfaction that exceeds that of the more than 1 million IOLs implanted during clinical trials conducted between 1978 and 1982. (An analysis of the 1978 through 1982 clinical trial data forms the FDA's ''grid,'' the historical control group against which newer IOLs are measured.) To illustrate, 93 percent and 96.8 percent of patients in more recent trials of two IOLs that were approved in 1994 achieved visual acuity of 20/40 or better, compared to 88 percent of patients in the historical control group. The ''best cases,'' those without any preoperative ocular pathology or macular degeneration at any time, achieved visual acuity of 20/40 or better in 97 percent and 99.5 percent of the patients in the two newer trials, compared to 94 percent of the control group grid patients. The high level of improved vision and the low rate of adverse effects already attainable using currently available IOLs seem to leave little room for substantive improvements in the areas listed as desirable outcomes in SSAA 1994. At issue, then, is how to recognize IOLs that exceed the already superior levels of performance of IOLs readily accessible in the current market to such an extent that they warrant being recognized as belonging to a separate and distinct class of IOLs.

Determining if use of a particular IOL results in specific clinical outcomes, and the degree to which outcomes attainable by use of that IOL exceed what would be expected if a different IOL were used, requires an assessment of scientific data. We therefore considered convening an expert panel to evaluate claims of the clinical superiority of an IOL, or asking contractor medical directors to do so. Part of the FDA's responsibility is granting premarket approval of applications for new IOLs, through analysis by specialists such as ophthalmologists; chemical, biomedical, and mechanical engineers; microbiologists; and toxicologists. As part of the premarket approval process, an FDA group of experts evaluates

claims of safety and effectiveness, and approves the claims for the purposes of labeling and advertising. The FDA also has an advisory panel composed of practicing ophthalmologists and other clinicians who review clinical data and advise the FDA on the approvability of applications. This panel reviews any new device that presents new questions of safety and effectiveness.

Because the expertise and review process already exist within the Department of Health and Human Services, it would be duplicative for us to convene an expert panel for the purpose of evaluating claims of the clinical superiority of an IOL. Therefore, we propose that the criterion for identifying an IOL to be treated by us as a ''new technology'' IOL under the process proposed in this rule be that all claims of the IOL's specific clinical advantages and superiority over existing IOLs with respect to the factors listed in section 141(b) of SSAA 1994, for example, reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages, have been approved by the FDA for labeling and advertising purposes.

We asked the FDA if the premarket approval process would allow it to approve these claims for labeling and advertising purposes. The FDA responded on March 31, 1995 as follows:

> Intraocular lenses are regulated by the FDA as Class III, restricted devices that require premarket approval (PMA) prior to marketing in the United States. FDA's authority to regulate labeling can be found throughout the Federal Food, Drug and Cosmetic Act (FFDCA) (i.e., Sections 201, 301, 501, 502, 507, 519, 520, 701, 704). IOL labeling is reviewed and approved by the FDA as part of the PMA review process (Section 515(c)(1)(f) of the FFDCA). Any extraordinary labeling claims are similarly reviewed by the FDA as part of the PMA process. A device would be deemed to be misbranded if 'its labeling is false or misleading in any particular' (Section 502(a) of the FFDCA).
>
> As a restricted device, an intraocular lens would also be deemed to be misbranded if its advertising is false or misleading or lacks information required by the FFDCA, including intended uses (Sections 502(q) and (r) of the FFDCA). * * * Both clinical and bench testing could be used by firms to document additional claims, although clinical data would be needed if the clinical relevance or benefit of the ''high-tech'' feature were not well established.

In order to further define what distinguishes an IOL that would be treated as a ''new technology'' IOL under section 141(b) of SSAA 1994, we considered proposing as a second criterion the requirement that the IOL be appropriately characterized as a product of ''new technology.'' We would have expected a ''new technology'' IOL to embody materials, design, fabrication, or other features that are ''new,'' that is, original and generally recognized as a significant innovation relative to the materials, design, fabrication, or features of contemporary IOLs. However, any lens, whether new or previously approved, would have to demonstrate clinical advantages to the FDA's satisfaction in order to comply with the SSAA 1994 requirement of achieving clinical advantages. Thus, we hold the view that this definition of ''new'' is not required. We welcome comments on this issue.

Once we determine that an IOL satisfies the clinical criterion proposed above as the standard for treating an IOL as a ''new technology lens,'' that IOL will be considered as belonging to a ''class of new technology lenses'' for the purposes of implementing the payment review in accordance with section 141(b) of SSAA 1994 as described below.

3. Five-Year Limit on Subsets of ''New Technology''

We propose to impose certain constraints on payment adjustments that result from the process that is the subject of this proposed rule to ensure that Medicare payments for IOLs furnished under section 1833(i)(2)(A)(iii) of the Act remain reasonable and related to their acquisition cost.

We do not believe that all IOLs that could satisfy the overall criteria of ''new technology'' proposed in this rule would necessarily be of the same type or category. Rather, based on our assessment of the kinds of IOLs that are currently in clinical trials, we believe ''new technology'' IOLs could logically be grouped into smaller subsets of ''new technology,'' each of which is defined or identified by a common salient feature or characteristic, such as fabrication from the same material, or being multifocal in design, or designed to correct astigmatism.

For payment purposes, after we accept an IOL as satisfying the criterion that we have proposed for belonging to a ''class of new technology lenses,'' we propose to assign that IOL to a subset of IOLs with which it shares a common feature that distinguishes it from other ''new technology'' IOLs. We further propose to set the lifespan of each subset of ''new technology'' IOLs at 5 years. That is, beginning the sixth year following our initial recognition of a ''new technology'' subset, the new technology attribute that the IOLs in the subset have in common would cease to be considered a characteristic of ''new technology,'' and the Medicare payment adjustment for IOLs in that subset would be discontinued. We would not consider for payment adjustment any other IOLs whose primary distinguishing feature was that attribute. For IOLs approved at the beginning of the fifth year of the subset term, Medicare would pay any ''new technology'' adjustment for 1 year only.

We are proposing a 5-year limit because defining a ''new technology'' characteristic as ''new'' for fewer than 5 years does not seem fair to manufacturers whose model(s) of the new technology IOL may receive FDA approval sometime after the original IOL that opened the subset within the class of ''new technology'' IOLs receives its premarket approval. But to define a ''new technology'' characteristic as ''new'' for more than 5 years seems to impose an unnecessary and unwarranted drain on the Medicare trust fund, given the natural course of market forces that have repeatedly succeeded in reducing IOL costs in a few years following introduction of a modification or innovation in design or material.

4. Impact of Memorandum of Understanding

On September 19, 1995, we published a final rule with comment period in the **Federal Register** entitled ''Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services'' (60 FR 48417). That regulation discussed a memorandum of understanding between the FDA and HCFA regarding extending Medicare coverage to certain investigational devices. Although the criteria to be used in the process described in the rule include determining whether or not a ''significant modification'' has been made to a device, that determination will not affect the process described in this proposed rule. We will consult with the FDA should issues arise concerning the classification of lenses.

*C. Appropriateness of Payment Amount*

SSAA 1994 requires us to review the appropriateness of the current IOL payment amount with respect to a class of new technology IOLs. Although SSAA 1994 itself does not provide explicit guidance on the standard for judging the appropriateness of the current IOL payment amount, section 1833(i)(2)(A)(iii) of the Act requires that the IOL payment amount included in

the ASC facility fee be reasonable and related to the cost of acquiring the class of IOL involved. Therefore, after we determine that an IOL meets the criterion that qualifies it to be treated as a new technology IOL under the process proposed in this rule, we must next determine if the current IOL payment amount is reasonable and related to the cost of acquiring that IOL.

At this time, the only method we are aware of for determining IOL acquisition costs is to survey purchasers and audit invoices. The OIG conducted such a survey in preparing its 1994 report entitled *Acquisition Costs of Prosthetic Intraocular Lenses*, OEI–05–92–01030. (Copies can be obtained from the Office of Inspector General, Department of Health and Human Services, (312) 353–4124.) The OIG found that when IOL payments were fixed at $200, ASCs could acquire and were acquiring IOLs for an average of $126 in 1991 and $112 in 1992. This does not take into account discounts available to the majority of purchasers because the financial arrangements took many forms, only a few of which were straightforward rebates or price reductions. The OIG also discovered that the newest type of IOL available at the time of its review (a foldable, ultraviolet-absorbing, silicone IOL) was obtainable within relatively the same price range as other IOLs in the study (from $75 to $475 for the foldable IOLs, compared to a range of $30 to $450 for rigid IOLs). The OIG determined that ASCs were buying foldable IOLs for $125 or less, at a time when the Medicare IOL payment amount was $200.

We are developing IOL cost data as part of the 1994 Medicare Ambulatory Surgical Center Payment Rate Survey of Facility Overhead and Procedure Specific Costs (Form HCFA–452B). Although that information is not yet available, we believe that the current payment amount of $150 continues to exceed the average cost to an ASC of acquiring an approved IOL.

We may find, however, that IOLs affected by this regulation will not have been in widespread use by ASCs at the time a review of the IOL is requested under the provisions of section 141(b) of SSAA 1994. Therefore, because actual acquisition cost information may be sparse, we propose also to take into account list price; manufacturing costs; selling costs; general and administrative overhead costs; research and development costs; manufacturer discount and rebate packages; and any other factors that may be relevant indicators that the current payment amount is not appropriate for the type of new technology IOL under review. We welcome comments on criteria that would facilitate an objective determination of what constitutes a payment that is both reasonable and related to acquisition cost with respect to ''new technology'' IOLs. The criteria should include the use of readily verifiable data, for example, studies published in peer-reviewed journals.

### *D. Payment Adjustment When Current Payment Amount Is Inappropriate*

The final step in the process that is the subject of this proposed rule involves determining the amount of a payment adjustment if we find that the current IOL payment amount is inappropriate. Among the factors that we propose to take into account in order to determine the amount of the adjustment to be made if the current IOL allowance is found to be inappropriate with respect to the acquisition cost of the particular IOL are the following:

- Market projections based on anticipated clinical indications of need for the IOL and the percent of the Medicare population expected to present that need on an annual basis.
- Additional incremental costs incurred to manufacture a new technology IOL relative to the cost of manufacturing other IOLs, such as the cost attributable to using a more sophisticated piece of machinery or the cost of fabricating a new IOL material.
- Additional costs incurred to conduct clinical trials that document for FDA approval the clinical superiority of the IOL relative to the costs incurred to conduct clinical trials for other IOLs.
- Research and development costs incurred that exceed those associated with other IOLs approved by the FDA.
- Current and historical pricing, sales volume, and revenues.
- A reasonable rate of return and profit based on the manufacturer's investment in the IOL.

We considered other options for determining the amount of an adjustment to be made if the current payment amount was found to be inappropriate for an IOL being reviewed under the provisions proposed in this rule including—

- Application of a single flat, across-the-board percentage increase to the IOL payment amount for every IOL that we determined satisfied the criteria defining a ''new technology'' IOL;
- The percent of the IOL industry's investment in research and development that ultimately leads to innovations in IOLs; and
- The percentage of sales attributable to an IOL for which a review was requested.

We rejected these options, however, primarily because they are inconsistent with the overall statutory mandate that payment be reasonable and related to the cost of acquiring an IOL.

### *E. Implementation of the Payment Adjustment*

#### 1. Two-Year Limit on Payment Adjustment

A related issue pertains to the appropriate length of time the adjusted payment amount would be allowed by Medicare for a particular ''new technology'' IOL. We propose to allow a single IOL the benefit of any payment adjustment determined to be appropriate for a period of 2 years following the review process proposed in this rule. At the conclusion of the 2-year payment adjustment period, Medicare payment for the IOL would then revert to the payment rate for IOLs furnished by an ASC that is in effect at that time.

Supporting a 2-year payment limit is the OIG's 1994 report (*Acquisition Costs of Prosthetic Intraocular Lenses*, OEI–05–92–01030), which found a decrease in IOL prices generally over a 2-year period ranging from 11 to 14 percent in various settings. We assume this decrease is attributable to technology diffusion and the associated development of similar lenses by competing firms. We believe a desirable new technology IOL with demonstrated clinical superiority would be subject to equivalent conditions, and thus experience a similar drop in acquisition cost over a 2-year period.

#### 2. Operational Payment Principles

The payment adjustments we publish in the **Federal Register** would be implemented prospectively, effective 30 days from the date of their publication. This implementation date of a payment adjustment is required under section 141(b) of SSAA 1994.

We propose to apply the same payment adjustment amount established for the first IOL or IOLs approved within a new technology subset to all IOLs that we subsequently accept as satisfying the criteria for ''new technology'' that are assigned to the same subset. If a new technology IOL were to qualify under more than one subset of technology, and the subsets had different payment rates, the IOL would be paid for at the higher (or highest) applicable rate.

We expect that more than one manufacturer would be working to develop IOLs that rely on the same or similar technology that defines ''new technology'' under the provisions of this

rule. If we were to make a payment adjustment under the provisions proposed in this rule, the payment adjustment amount would be based on information regarding IOL production, acquisition costs, and IOL benefits that is submitted by the manufacturer or manufacturers that first request review for a particular type of new technology IOLs. Manufacturers would have 3 years during which to submit requests for review of equivalent IOLs approved by the FDA that were in a ''new technology'' subset already approved by us and still benefit from the full 2-year payment adjustment term. Requests for review of an IOL submitted during the third year of a technology's designation as ''new'' would only have the benefit of a payment adjustment for 1 year.

If an interested party wants an IOL to be considered for a payment adjustment under section 141(b) of SSAA 1994, that interested party must request a review in accordance with the process proposed in this rule, which request would be approved and published in a final rule and codified in the Code of Federal Regulations. In accordance with section 141(b) of SSAA 1994, we would adhere to a yearly cycle of receiving requests for review, publishing those requests, reviewing comments on the requests, reviewing the requests, and publishing our determinations. We would not make determinations or provide for payment adjustments outside this schedule, although interested parties may submit requests for review as soon as FDA grants its approval. We would compile these requests for publication in the next applicable **Federal Register** notice.

We propose to assign codes to be used to bill for IOLs that qualify for the payment adjustment. The list of these IOLs, with the appropriate billing code, would be published annually in the **Federal Register**. Billing for any other IOLs using ''new technology'' billing codes would constitute fraud.

We invite comments on the suitability of these proposals and solicit suggestions for alternative approaches for determining how to identify IOLs as ''new technology''; for evaluating the appropriateness of the current IOL allowance; for calculating the amount of an adjustment to be made in the event the current IOL payment amount is found to be inappropriate with respect to a particular IOL; and for defining the period of time during which the payment adjustment would be in effect. We believe that any adjustment amount should be modest, since the high quality, readily accessible IOLs currently on the market leave only marginal room for improvement. We do not believe that an upward adjustment is warranted unless the new technology IOLs, as a group, cost more to produce, are appreciably superior clinically, and successfully fulfill a need unmet before that time in an innovative manner.

*F. Review and Adjustment Process*

In this section, we describe the process that we propose to implement annually in order to determine the appropriateness of IOL pricing as required under section 141(b) of SSAA 1994.

1. **Federal Register** Notice Inaugurates Annual Cycle

The process, which is designed to be repeated annually on a 365-day cycle, would be initiated by publication of a **Federal Register** notice that would serve a threefold purpose.

*a. Deadline for submission of a request for review. The publication date of the* **Federal Register** notice announcing the deadline by which any interested parties would have to submit requests in order for us to review the appropriateness of the Medicare payment allowance under section 1833(i)(2)(A)(iii) of the Act with respect to a particular IOL would be established as ''Day 1'' of the 365-day annual review cycle. The ''Day 1'' **Federal Register** notice would include the deadline for submission of requests to review (the date of publication of the **Federal Register** notice plus 125 days); the requirements to be satisfied in order for an IOL to be treated as a ''new technology'' IOL under section 141(b) of SSAA 1994; the specific information that must accompany a request for review as well as the format in which that information is to be submitted; the address to which the request is to be sent; the factors that we would take into account in determining whether the current IOL payment amount is appropriate; the factors that we would take into account in determining the payment adjustment to be made; and any other information that we believe is relevant and necessary.

*b. List of intraocular lenses for payment adjustment.* The **Federal Register** notice published on ''Day 1'' of the 365-day cycle, in addition to announcing the deadline for submission of requests to review for the forthcoming year, would list those IOLs, identified as new technology IOLs, for which we had found a payment adjustment to be appropriate during the prior year's review. The ''Day 1'' notice would also include information on the amount of any payment adjustment determined for a particular IOL; the subset of ''new technology'' under which each IOL would be classified; the beginning date of the period when the payment adjustment would be effective (''Day 1,'' the date of publication of the **Federal Register** notice, plus 30 days); the code(s) to be used to bill for the IOL; the expiration date of the period during which the payment adjustment would be allowed (2 years from the date of publication of the **Federal Register** notice); and, the expiration date of the IOL's ''new technology'' designation (5 years from the date of publication of the **Federal Register** notice). Because ASC rates are prospectively set, we would make payment adjustments prospectively.

*c. Summary of previous year's determinations.* The ''Day 1'' **Federal Register** notice would list any other IOLs to which a payment adjustment still applied as the result of reviews in earlier years; the type of ''new technology'' under which each IOL had been classified whether or not it qualified for a payment adjustment; the amount of the payment adjustment allowed for each type of IOL; the code(s) to be used to bill; and the dates when the ''new technology'' designation of the IOL and the applicable payment adjustment would expire.

2. Publication of Requests for Review

We would provide that we must receive requests for review no later than 125 days from the date of publication of the ''Day 1'' **Federal Register** notice inviting requests for review. We would compile a list of any requests for review that we received timely. The list, including the manufacturer's name and the model number of the IOL to be reviewed, would be published in a **Federal Register** notice with comment period. This second notice would be published no later than 245 days from the publication date of the first **Federal Register** notice that initiated the annual review cycle by inviting requests for review. The public would have 30 days to comment on the IOLs included in the list of those for which a payment review had been requested.

3. Our Review and Publication of Determinations

We would review any comments that were submitted regarding the list of IOLs published in the **Federal Register** along with the information submitted with the request to review to decide whether an adjustment of the current IOL payment amount was appropriate with respect to each IOL on the list. Because of the rigid time frame for this process, the applicant must submit sufficient information in a timely manner to allow for review. At our

discretion, we may request additional information. If an initial submission is incomplete, however, we would make a determination based on the information submitted.

As described in an earlier section, we propose to take the following factors into account in determining whether to provide a payment adjustment:

- The IOL meets the definition of a ''new technology IOL'' in § 416.180 (''Definitions'').
- The extent to which the current IOL payment amount is reasonable and reflects the acquisition cost of the IOL under review.

No later than 90 days after the close of the public comment period, we would publish in the **Federal Register** a notice announcing our determinations with respect to the requests for review that had been published 120 days previously announcing the amount of any new payment adjustments; announcing the deadline for submission of the upcoming year's requests for review 125 days from that time; and summarizing payment adjustments made previously that were still in effect. With publication of this notice, the annual cycle would be repeated with a new ''Day 1'' date.

The following table summarizes the key events in the annual review cycle that is the subject of this proposed rule:

| Event | Timeframe |
|---|---|
| Publication of a FEDERAL REGISTER notice inviting requests for review, announcing our determinations of adjustments to be made to ''new technology'' IOL payment amounts, and summarizing adjustments from prior years that are still in effect. | Date of publication of this notice constitutes ''Day 1'' of the annual review cycle. |
| Effective date for any payment adjustments that we determine are appropriate as published in the FEDERAL REGISTER on ''Day 1.''. | ''Day 1'' date plus 30 days. |
| Deadline for receipt of the IOL review requests for our consideration | ''Day 1'' date plus 125 days. |
| Publication in the FEDERAL REGISTER of the list of requests for review | ''Day 1'' date plus 245 days. |
| End of 30-day public comment period regarding the list of requests for review | ''Day 1'' date plus 275 days. |
| Publication of a FEDERAL REGISTER notice inviting requests for review, announcing our determinations of adjustments to be made to ''new technology'' IOL payment amounts, and summarizing adjustments from prior years that are still in effect. | ''Day 1'' date plus 365 days; cycle starts over with new ''Day 1.'' |

To summarize the process that we propose in this rule, in order for us to treat an IOL as a new technology IOL under the provisions of SSAA 1994, the IOL must have obtained FDA approval to include in labeling and advertising claims of superior clinical advantages over other IOLs. If we find that the IOL for which a review is requested meets this criterion and if we determine that the current payment amount for IOLs furnished by ASCs is inappropriate with respect to the IOL, that is, the current IOL payment amount is not reasonable and is not related to the cost of acquiring the IOL, we would adjust the payment amount for the IOL. In determining the amount of adjustment, we propose to take into account development and manufacturing costs and sales projections as elements of cost with respect to the IOL under review, both alone and relative to other IOLs.

*G. Requirements for Content of a Request To Review*

We propose to require interested parties seeking a review of the IOL allowance under section 141(b) of the SSAA 1994 to submit certain information that we regard as critical if we are to make a fair and objective determination that the payment amount for an IOL paid under section 1833(i)(2)(A)(iii) of the Act is or is not appropriate. Interested parties requesting a review of the IOL payment amount with respect to a particular IOL would be required to submit the following: identification of the individual IOL under consideration as a ''new technology'' IOL for which a payment review is requested, including the name of the manufacturer, model number, trade name, and the date the FDA granted premarket approval for the IOL; a copy of the FDA's summary of safety and effectiveness; a copy of the labeling claims of specific clinical advantages approved by the FDA; reports of modifications made after FDA approval; development and manufacturing costs of the ''new technology'' IOL relative to the costs of manufacturing other approved IOLs; the costs of conducting clinical trials for the IOL in question relative to the costs of conducting clinical trials for other approved IOLs; indications and contraindications for use; epidemiological data indicating demand for the IOL; sales price, sales history, and revenues, and prices and projected revenues during the period of the payment adjustment; names of purchasers; and other information we consider appropriate for making a determination. We cannot be all-inclusive in this list since we may need information that we cannot foresee at this time. We may modify our requests for information as changes in technology dictate. We may request supplemental information from individual interested parties during the review process. The interested party would be responsible for demonstrating to our satisfaction that a payment adjustment for the IOL under review is warranted, especially given the widespread availability of high quality IOLs at a cost equal to or less than the current Medicare IOL allowance. The burden of proof would be on the interested party to show that the current IOL payment amount is inappropriate for the new technology IOL for which a review is requested.

Interested parties should be aware that 45 CFR 5.65(c) provides that a submitter of information may designate all or part of the information as being exempt from mandatory disclosure under Exemption 4 of the Freedom of Information Act.

## III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

## IV. 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.

## V. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act

(RFA) (5. U.S.C. 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all manufacturers of IOLs, ASCs, hospital outpatient departments, and physicians who perform IOL insertion surgery to be small entities. Individuals and States are not included in the definition of a small entity. We are not preparing a regulatory flexibility analysis because we have determined, and the Secretary certifies, that this proposed regulation would not have a significant economic impact on a substantial number of small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed rule would 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. We are not preparing a rural hospital impact statement because we have determined, and the Secretary certifies, that this proposed regulation would not have a significant impact on the operations of a substantial number of small rural hospitals.

Although this proposed rule is not an ''economically significant'' rule under Executive Order 12866, we present below a voluntary analysis of the effects of this proposed rule because many beneficiaries who undergo IOL insertion surgery following a cataract extraction could be affected.

We believe that the fiscal impact of this rule would be negligible. We do not expect that making this payment adjustment would have an impact on the availability or prices of other IOLs. We do not expect that it would affect competition, employment, or investment. The ocular implant industry is mature, with a successful product readily available to purchasers. Our data suggest that we pay, under the Medicare program, more than the acquisition cost for most of the IOLs used today. New technology IOLs would achieve improvements in only small segments of the industry, since the majority of IOLs function superbly. The IOLs under development that we are aware of would substitute for spectacles in some cases, and in others would allow the patient to wear a single vision prescription rather than bifocals. The desirability of this feature to the Medicare population is not known.

There would be no significant program savings, even if the use of these IOLs reduced expenditures for spectacles or eliminated the need for follow-up treatment. The complexities of claims processing for an additional payment on top of a bundled, fixed payment would be considerable. Manual claims processing or a significant reconfiguration of claims processing software would be required. The payment method for ASC-type procedures performed in hospital outpatient departments requires that we use a blend of 42 percent of the hospital's costs or charges and 58 percent of the ASC rate as a basis for payment. The addition of an adjustment to two of the ASC rates would complicate hospital payment. The review process to determine which IOLs qualify for a payment adjustment would be costly in terms of staff hours and **Federal Register** publication costs. We would have to develop new codes to identify specific IOLs, which creates the possibility of ''upcoding,'' or using those codes for IOLs not eligible for the adjustment. We would also have to undertake an extensive educational effort, to explain the use of the new codes to the provider community and to our contractors. This would involve manual issuances and program memoranda. These direct and indirect costs more than outweigh the marginal benefit available to a few manufacturers.

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

**List of Subjects in 42 CFR Part 416**

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

For the reasons set forth in the preamble, 42 CFR part 416 would be amended as follows:

## PART 416—AMBULATORY SURGICAL SERVICES

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

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

2. A new subpart F, consisting of §§ 416.180, 416.185, 416.190, 416.195, and 416.200, is added to read as follows:

**Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses**

Secs.



### Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses

#### § 416.180 Definitions.

As used in this subpart, the following definitions apply:

Class of new technology intraocular lenses (IOLs) means all of the IOLs, collectively, that HCFA determines to have met the definition of ''new technology IOL'' under the provisions of this subpart.

Interested party means any individual, partnership, corporation, association, society, scientific or academic establishment, professional or trade organization, or any other legal entity.

New technology IOL means an IOL that HCFA determines to have met the following criterion: The FDA has approved for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

New technology subset means a group of IOLs that HCFA determines to meet the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs. For example, all new technology IOLs that are made of a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another.

#### § 416.185 Payment review process.

(a) HCFA publishes a **Federal Register** notice announcing the deadline and requirements for submitting a request for HCFA to review payment for an IOL.

(b) HCFA receives requests for review of payment for an IOL.

(c) HCFA compiles a list of the requests it receives timely and identifies the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(d) HCFA publishes the list of requests in a **Federal Register** notice with comment period, giving the public 30 days to comment on the IOLs for which review was requested.

(e) HCFA reviews the information submitted with the request to review, any timely comments that are submitted regarding the list of IOLs published in the **Federal Register**, and any other timely information that HCFA deems relevant to decide whether to provide a payment adjustment. Factors that HCFA takes into account in determining whether the IOL payment amount provided under section 1833(i)(A)(2)(iii) of the Act is appropriate with respect to an IOL for which a review was requested include, but are not limited to, the following:

(1) Whether the IOL meets the definition of a ''new-technology IOL'' in § 416.180.

(2) What it costs ASCs to acquire IOLs in the new technology subset to which the IOL under review belongs.

(3) Whether the current IOL payment allowance is reasonable with regard to the IOL under review.

(f) If HCFA determines that the current IOL payment allowance is not appropriate for the IOL under review, HCFA establishes a payment adjustment that takes into account the following factors:

(1) IOL manufacturing costs.

(2) The IOL manufacturer's selling costs and general and administrative overhead costs.

(3) Research and development costs attributable to the IOL.

(4) Manufacturer discount and rebate packages.

(5) Other information that HCFA considers appropriate in determining a payment adjustment.

(g) Within 90 days of the end of the comment period following the **Federal Register** notice identified in paragraph (d) of this section that lists IOLs for which a review was requested, HCFA publishes its determinations with regard to payment adjustments in the **Federal Register**. In the same **Federal Register** notice, HCFA also announces the deadline and requirements for submitting requests for the next annual cycle of reviews.

(h) Payment adjustments are effective beginning 30 days after the publication of HCFA's determinations in the **Federal Register**.

**§ 416.190 Who may request a review.**

Any party who is able to furnish the information required in § 416.195 may request that HCFA review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the definition of a new technology IOL in § 416.180.

**§ 416.195 Content of a request to review.**

The interested party requesting a review of the IOL payment amount must timely furnish convincing evidence that the payment amount provided under section 1833(i)(2)(A)(iii) of the Act is not appropriate for a new technology IOL and that a payment adjustment is reasonable and warranted.

(a) Requirements for a request to review the appropriateness of the IOL payment amount for a new technology IOL. In order for HCFA to consider a request to review the IOL payment amount with regard to a particular IOL, the request must meet all of the following requirements:

(1) Identification of an IOL. The interested party must provide the following information:

(i) The name of the manufacturer, the model number, and the trade name of the IOL.

(ii) A copy of the FDA's summary of the IOL's safety and effectiveness.

(iii) A copy of the labeling claims of specific clinical advantages approved by the FDA for the IOL.

(iv) A copy of the IOL's original FDA approval notification.

(v) Reports of modifications made subsequent to original FDA approval.

(vi) Indications and contraindications for use of the IOL.

(vii) Epidemiological data indicating demand for the IOL.

(viii) Other information that HCFA finds necessary for identification of the IOL.

(2) IOL costs. To enable HCFA to review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with regard to the IOL, the following documented evidence of the cost of the IOL and the manufacturer's investment in the IOL is required:

(i) The manufacturer's current list price for the IOL and a history of the IOL's pricing since FDA approval was obtained.

(ii) Manufacturing costs of the IOL relative to the costs of manufacturing other approved IOLs.

(iii) Research and development costs incurred to create the IOL, using research and development costs of other FDA-approved IOLs for purposes of comparison.

(iv) Costs incurred to conduct clinical trials for the purpose of demonstrating for FDA approval the clinical superiority of the IOL relative to the costs incurred to conduct clinical trials for other approved IOLs.

(v) Sales and revenue history of the IOL, and sales and revenues projected for the IOL if a payment adjustment were approved by HCFA.

(vi) Names of purchasers of the IOL.

(vii) Other information HCFA finds necessary for making a determination.

(b) Confidential information. To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade secret or as privileged or confidential commercial or financial information, Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905), allow HCFA to maintain the confidentiality of the information and to protect it from disclosure not otherwise authorized or required by Federal law.

**§ 416.200 Application of the payment adjustment.**

(a) New technology subset. (1) HCFA designates a predominant characteristic of a new technology IOL that both sets it apart from other IOLs and links it with other similar IOLs with the same characteristic to establish within the ''class of new technology IOLs'' a specific subset of new technology.

(2) Each subset is recognized for purposes of this subpart as belonging to the class of new technology IOLs for a period of 5 years, effective beginning the date that the first IOL that defines the subset is identified.

(3) During the fifth year following the date that the first IOL is designated as belonging to the subset, requests to review IOLs that would be considered part of the subset that expires at the end of the year are not considered.

(4) Beginning on the sixth anniversary date of the effective date of the recognition of a subset, payment adjustments applicable to IOLs in that subset cease for all IOLs in that subset and payment reverts to the payment rate in effect at that time for IOLs under section 1833(i)(2)(A)(iii) of the Act.

(b) Duration of payment adjustment. (1) Any single model of IOL for which HCFA determines that a payment adjustment is appropriate receives the payment adjustment for a period of 2 years.

(2) On the second anniversary date of implementation of a payment adjustment approved for the IOL under the provisions of this subpart, payment for the IOL reverts to the IOL payment rate in effect at that time under section 1833(i)(2)(A)(iii) of the Act.

(c) Similarity of payment adjustment. All IOLs included in the same subset of new technology IOLs and for which HCFA determines a payment adjustment is appropriate receive the same payment adjustment.

(d) Basis for payment. (1) In order for HCFA to consider an IOL for a payment

adjustment under this subpart, an interested party must submit timely a request for review prepared in accordance with the requirements in § 416.195, and the IOL must be included in the list of requests for review that is published annually in the **Federal Register** in accordance with the process described in § 416.185.

(2) In order for HCFA to make an IOL payment adjustment under this subpart, the IOL for which the adjustment is approved must be identified in the list of determinations HCFA publishes in the **Federal Register** 125 days after publication of the list of requests for review.

(i) HCFA assigns a unique billing code to each IOL for which it determines a payment adjustment is appropriate.

(ii) Using the billing code assigned to an IOL for which HCFA determines a payment adjustment is appropriate under this subpart in order to bill for a different IOL constitutes fraud.

(Sections 1832(a)(2)(F)(i) and 1833(i)(2)(a) of the Social Security Act (42 U.S.C. 1395k(a)(2)(F)(i) and 1395l(i)(2)(a)))

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

Dated: January 17, 1997.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

Dated: March 10, 1997.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 97–23380 Filed 9–3–97; 8:45 am]

BILLING CODE 4120–01–P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[MM Docket No. 97–189, RM–9135]**

### Radio Broadcasting Services; Nassawadox, VA

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by Ken Robol requesting the allotment of Channel 252A to Nassawadox, Virginia, as the community's first local aural transmission service. Channel 252A can be allotted to Nassawadox in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 252A at Nassawadox are 37–28–24 NL and 75–51–30 WL.

**DATES:** Comments must be filed on or before October 20, 1997, and reply comments on or before November 4, 1997.

**ADDRESSES:** Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Ken Robol, 303 Amherst Court, Chesapeake, Virginia 23320 (petitioner).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 97–189, adopted August 20, 1997, and released August 29, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW, Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

Federal Communications Commission.

**John A. Karousos,**

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 97–23437 Filed 9–3–97; 8:45 am]

BILLING CODE 6712–01–P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[MM Docket No. 97–187, RM–9149]**

### Radio Broadcasting Services; Patterson, IA

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition by West Wind Broadcasting requesting the allotment of Channel 290A to Patterson, Iowa, as the community's first local aural transmission service. Channel 290A can be allotted to Patterson in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 290A at Patterson are 41–20–54 NL and 93–52–49 WL.

**DATES:** Comments must be filed on or before October 20, 1997, and reply comments on or before November 4, 1997.

**ADDRESSES:** Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Victor A. Michael, Jr., President, West Wind Broadcasting, c/o Magic City Media, 1912 Capitol Avenue, Suite 300, Cheyenne, Wyoming 82001 (petitioner).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 97–187, adopted August 20, 1997, and released August 29, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.