2. Subpart 101–35.7 is added to read as follows:

Subpart 101–35.7—Network Address Registration

Sec.

Subpart 101–35.7—Network Address Registration

§ 101–35.705 What does this subpart contain?

This subpart addresses registration services provided by GSA to Government agencies and the public.

§ 101–35.710 What registration services are available through GSA?

(a) The National Institute of Standards and Technology (NIST), Department of Commerce, has designated GSA as the Government Open Systems Interconnection Profile (GOSIP) Address Registration Authority for unique naming assignments of X.400 Private Management Domains (PRMD), X.500 Organizational Units (OU), and Network Service Access Point (NSAP) Administrative Authority Identifiers (AAI). GOSIP registration is limited to Government agencies, with the exception of NSAP AAIs, which may be used by commercial organizations to identify private asynchronous transfer mode (ATM) networks.

(b) For purposes of global interoperability, GSA will operate an X.500/LDAP Directory Service at the ''C=US'' level and at the ''O=U.S. Government'' level. Federal agencies may link operational directories to the ''O=U.S. Government'' level and commercial organizations may link to the ''C=US'' level in accordance with the fees set forth in § 101–35.704.

(c) The National Science Foundation (NSF) has delegated to GSA the authority to manage and administer the .GOV Internet domain. GSA provides second-level domain registrations in the GOV domain (*e.g.*, <Agency>.gov). Similarly, GSA provides third-level domain registrations in the ''fed.us'' domain under authority of the Internet Assigned Numbers Authority (IANA). Internet registration services are limited to Federal, State, and local Government organizations. GSA is not responsible for and will not charge fees for any further delegation of a domain name assigned to an agency. For example, the U.S. Department of the Treasury has registered ''ustreas.gov,'' but registrations such as ''irs.ustreas.gov'' would be the responsibility of the domain manager for Treasury.

§ 101–35.715 Who should I contact for more information or to register?

Individuals or organizations that want to register or would like more information should contact the registration officials at GSA by sending an e-mail message to *registration@fed.gov* or by using the Web site at *http://www.nic.gov*.

§ 101–35.720 Is there a fee for these services?

GSA will assess Government agencies and commercial organizations nominal fees to cover the cost of registration and other services as listed in the table in this section. The fees are based on anticipated costs for providing the services and are consistent with industry charges. The table follows:

Service	Setup	Recurring (annual)
(a) Network Naming and Address Registration (GOSIP)	$1,000.00	$500.00
(b) Governmentwide Directory Operation (X.500/LDAP)	1,000.00	500.00
(c) Internet Domain Name Registration	250.00	50.00

Note to § 101–35.720: Setup fees may be waived at the discretion of GSA. When levied, setup fees include the annual fee for 1 year.

§ 101–35.725 How and where do I pay these fees?

GSA will invoice registrants according to the fee schedule in § 101–35.720. Government registrations must be paid by Government credit card. Commercial organizations are encouraged to pay by credit card. All other payments should be made to: GSA Registration Services, 1800 F Street NW, Suite G–222, Washington, DC 20405.

Dated: May 11, 1999.

David J. Barram,

Administrator of General Services.

[FR Doc. 99–15023 Filed 6–15–99; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 416

[HCFA–3831–F]

RIN 0938–AH15

Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

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

ACTION: Final rule.

SUMMARY: This final rule establishes a process under which interested parties may request a review of whether the current Medicare payment amount for intraocular lenses furnished by participating ambulatory surgical centers is appropriate for a class of new technology intraocular lenses. This rule implements section 141(b) of the Social Security Act Amendments of 1994, which requires us to develop and implement this process.

This rule also serves as the initial notice to those wishing to submit requests for review of the appropriateness of the payment amount with respect to a particular intraocular lens, in accordance with § 416.195 of this rule.

DATES: *Effective date:* These regulations are effective on July 16, 1999.

Applicability date: We will accept requests for review under this part 416, subpart F, until September 14, 1999.

FOR FURTHER INFORMATION CONTACT: Claude Mone, (410) 786–5666.

SUPPLEMENTARY INFORMATION: *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

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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 the scope of benefits under the Medicare supplementary medical insurance (Part B) program includes certain services furnished in connection with surgical procedures that are performed in an ambulatory surgical center (ASC). 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 in our regulations at 42 CFR part 416. In addition, our regulations at 42 CFR part 416 contain the coverage and payment rules for services furnished by participating ASCs.

Section 1833(i)(2)(A) of the Act authorizes us to pay ASCs a prospectively-determined rate for facility services. ''Facility services'' includes services that are furnished in conjunction with covered surgical procedures performed in an ASC. Section 416.61 of our regulations sets forth included and excluded facility services. ASC 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 physicians' 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 pays an ASC facility fee for approximately 2,300 surgical procedures performed in an ASC. These surgical procedures are identified by codes established by the American Medical Association's Current Procedural Terminology (CPT). 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 5—$674
Group 2—$419	Group 6—$785
Group 3—$479	Group 7—$935
Group 4—$591	Group 8—$923

This is further discussed in our September 4, 1997 proposed rule, ''Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses'' (62 FR 46699).

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

In the proposed rule, we explained that 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. Subsequently, the statute was amended 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. 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 (for example, irrigation and aspiration or phacoemulsification).

Section 4151(c)(3) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Public Law 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) (Public Law 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.

In a proposed rule in the June 12, 1998 **Federal Register** (63 FR 32290) entitled ''Medicare Program; Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998,'' we proposed new payment rates and an ambulatory payment classification (APC) system based on facility costs and procedure charges collected in a 1994 survey of ASCs. In that proposed rule, we stated that the 1994 survey data revealed that the current IOL allowance of $150 is higher than the cost of acquiring the lens. The survey data indicated that the weighted mean lens cost was $100, and the weighted median cost was $97. We

stated that before December 31, 1998, we would propose a revised payment rate for lens insertion procedures to include an IOL allowance that is reasonable and related to the cost of the lens. However, we subsequently issued notices in the **Federal Register** on October 1, 1998 (63 FR 52663) and November 13, 1998 (63 FR 63430) that extended the comment period on the proposed rule and announced that a final rule would be issued as soon as possible after January 1, 2000.

II. Provisions of the Proposed Regulations

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

On October 31, 1994, the Social Security Act Amendments of 1994 (SSAA 1994) (Public Law 103–432) were enacted. 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.

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.

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 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. We proposed that the criterion for identifying an IOL to be treated as a new technology IOL be that all claims of the IOL's clinical advantages and superiority over existing IOLs must have been approved by the FDA for labeling and advertising purposes. An explanation of the reasons for relying on the FDA's determination is explained in the proposed rule (62 FR 46700 through 46701). We received favorable public comments on the proposal and adopted them in this final rule.

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

We proposed to impose certain constraints on payment adjustments that result from the process that is the subject of this rule. For instance, we did not believe that all IOLs that could satisfy the overall criteria of ''new technology'' in the proposed 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 for belonging to a ''class of new technology lenses,'' we proposed 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 proposed 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 have considered 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 have paid any ''new technology'' adjustment for 1 year only.

We proposed a 5-year limit because defining a ''new technology'' characteristic as ''new'' for fewer than 5 years did 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 seemed 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.

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. Because SSAA 1994 itself does not provide explicit guidance on the standard for judging the appropriateness of the current IOL payment amount, we looked to section 1833(i)(2)(A)(iii) of the Act, which 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 in this rule, we reasoned that we must next determine if the current IOL payment amount is reasonable and related to the cost of acquiring that IOL. We have reconsidered this issue in light of the public comments, which are addressed later in this final rule.

We also proposed that in order to determine IOL acquisition costs, we would be required 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 received several public comments concerning this proposal. We have reconsidered the process for adjusting payments for new technology IOLs in light of these comments, and we are no longer requiring the submission of data concerning the costs of acquiring the new technology IOL in order to determine the appropriateness of the IOL payment amount. Rather, as we discuss in the *Analysis and Responses to Public Comments* section of this rule, once an IOL is determined to be a new technology IOL, we will pay a flat premium in the amount of $50, over and above the payment allowance already included in the ASC facility fee for a standard IOL.

D. Payment Adjustment When Current Payment Amount Is Inappropriate

The final step in the process that was the subject of the proposed rule involved determining the amount of a payment adjustment if we find that the current IOL payment amount is inappropriate. Among the factors that we proposed in order to determine the amount of the adjustment to be made if the current IOL allowance was found to be inappropriate with respect to the acquisition cost of the particular IOL were 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 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.
- The percentage of sales attributable to an IOL for which a review was requested.

We rejected these options at that time, primarily because we believed they were inconsistent with the overall statutory mandate that payment be reasonable and related to the cost of acquiring an IOL. We received public comments concerning this position, and one commenter expressly disagreed with our interpretation of the statute. We have reconsidered our position in light of this comment. Further discussion can be found in the *Analysis of and Responses to Public Comments* section.

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 proposed 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 in this rule. At the conclusion of the 2-year payment adjustment period, Medicare payment for the IOL would then revert to the standard 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. However, after considering the public comments on this issue, we have developed an alternative to this 2-year payment adjustment. See the *Analysis of and Responses to Public Comments* section for further discussion.

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 proposed 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 in this rule, the payment adjustment amount would have been 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 had 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 had the benefit of a payment adjustment for 1 year. Again, we have modified this proposal. Further discussion can be found in the *Analysis of and Responses to Public Comments* section.

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 in this final rule.

We will 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, will be published periodically in the **Federal Register**. Billing for any other IOLs using ''new technology'' billing codes may constitute fraud.

F. Review and Adjustment Process

In this section of the proposed rule, we described the process that we intended to implement in order to determine the appropriateness of IOL pricing as required under section 141(b) of SSAA 1994. The process, which was designed to be repeated annually on a 365-day cycle, would have involved publishing a series of **Federal Register** notices with built-in comment periods and allowance of time to review the appropriateness of payment amounts for new technology IOLs. However, since we are revising this review process, we believe we can shorten the timeframe to accomplish this to 180 days. For a further discussion of this issue see the *Analysis of and Responses to Public Comments* section.

G. Requirements for Content of a Request To Review

In the proposed rule, interested parties requesting a review of the IOL payment amount with respect to a particular IOL would have been 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. Because of the revisions made to this process in the final rule, interested parties will not be required to submit information that is related to costs or sales as stated above. For a further discussion of this issue, see the *Analysis of and Responses to Public Comments* section.

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. Analysis of and Responses to Public Comments

We received 16 timely items of correspondence. The comments were from ophthalmologists, professional organizations, IOL manufacturers, and ASCs. A summary of the major issues and our responses follow:

Comment: Several commenters suggested that, in addition to using FDA product labeling to identify what qualifies as a new technology lens, we should also consider data from well-designed and controlled health outcomes and economic studies through consultation with medical and industry experts.

Response: As we stated in the proposed rule, we considered convening an expert panel to evaluate claims of the clinical superiority of an IOL. Because the expertise and review process already exist within another Health and Human Services agency, namely the FDA, it would be duplicative for us to convene such a panel of experts. We, therefore, are not accepting this suggestion, and will rely on the FDA approval process for labeling and advertising purposes to determine that an IOL will be treated as a new technology lens.

Comment: Several commenters disagreed with the 2-year payment limit on single model new technology IOLs and the 5-year limit on the adjustment for subsets of new technology IOLs. The commenters thought that the payment adjustment should be extended to 7 years.

Response: After carefully considering the arguments made by these commenters, we believe we can resolve this issue with a compromise. We will extend the payment limit for single model new technology IOLs to 5 years beginning with the date that we recognize this particular IOL as a new technology IOL. Any subsequent IOL with the same characteristics will receive the payment adjustment for the remainder of the 5-year period established by the initial new technology IOL. For example, if new technology IOL ''A'' is recognized to receive a payment adjustment effective July 1, 1999, the payment adjustment would expire on June 30, 2004. The payment adjustment would then terminate, and revert back to the standard IOL payment rate in effect at that time. If new technology IOL ''B'' is recognized to receive a payment adjustment effective July 1, 2000, and has the same characteristics as ''A,'' the payment adjustment for ''B'' would expire on June 30, 2004, and then revert back to the IOL payment rate in effect at that time.

We realize that we cited the 1994 OIG 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. However, we believe that the initial developer of a particular new technology lens should have some advantage over subsequent developers of a similar lens, and consequently we are extending the payment adjustment limit to 5 years for those initial developers. We do not believe, however, that extending the limit to 7 years is justified, given the data presented in the above-mentioned OIG report.

Comment: One commenter disagreed with our view that the overall statutory mandate would have precluded the adoption of a single flat rate across-the-board percentage increase. That commenter indicated that ''the new technology IOL enabling legislation provides no specific guidance on the standard for judging the appropriateness of the current IOL payment vis-a-vis the rate adjustment for the new technology IOL. Given the fact that the purpose of the new technology IOL provision is to facilitate beneficiary access to new IOL technology, we do not believe the Congress would have intended HCFA to rely on historical pricing data. With a new lens, there will be no history. Awaiting the submission of acquisition data would delay the ability of providers to purchase the products under current facility reimbursement constraints.''

Response: In developing the process for adjusting payment rates for new technology IOLs that we proposed in the September 4, 1997 **Federal Register**, we rejected applying a single flat, across-the-board percentage increase to the IOL payment amount for every IOL that we had determined satisfied the definition of new technology IOLs (62 FR 46702). Initially, we rejected that approach, believing that it might be viewed as inconsistent with a statutory requirement in section 1833(i)(2)(c) of the Act that the ASC allowance for IOLs be reasonable and related to IOL acquisition costs. We have reconsidered our interpretation in light of the public comment.

While it is true that section 141(b) of SSAA 1994 refers to section 1833(i)(2)(A)(iii) of the Act, the reference does not require the conclusion that the amount of an adjustment for new technology IOLs must also be reasonable and related to the cost of acquiring the IOL. Indeed, the commenter's point is well taken that by focussing on the clinical advantages of new technology IOLs, the Congress was attempting to encourage beneficiary access to new technologies. The statutory reference to section 1833(i)(2)(A)(iii) of the Act thus requires a comparison of the clinical advantages of new technology to the standard technology, and an adjustment to the payment rate to reflect the added benefits of the new technology. It does not require a comparison of the costs of acquiring standard IOLs to the costs of acquiring new technology IOLs in determining the amount of any adjustment. We agree that the statute can be reasonably interpreted to permit an adjustment that is not related to the cost of acquiring the particular new technology IOL. Since the flat rate adjustment for new technology IOLs was one of the more frequently suggested comments, we have decided to adopt this recommended approach.

Comment: Several commenters recommended that we develop a standard payment rate that would apply to any lens that we find is in compliance with the definition of a new technology IOL under the provisions of this regulation. Commenters suggested as a new technology IOL premium either a flat dollar amount between $50 and $75 or an amount equal to between 30 percent and 50 percent of the allowance for a standard IOL.

One consequence of this approach would be to reduce the data collection burden associated with our proposed requirement that interested parties submit information related to manufacturing, selling, overhead, and research and development costs, reducing the burden for manufacturers. In other words, our determination that a lens meets the criteria for being considered a new technology IOL would alone be sufficient to trigger a payment adjustment. Several commenters argued that the clinical outcomes resulting from use of the new technology IOL so substantially exceed the outcomes expected from a standard IOL as to justify payment of a premium. By definition, the payment allowance for a standard IOL could not be appropriate for a new technology IOL because the new technology IOL affords so many more clinical advantages and outcomes than a standard IOL, and the new technology IOL's additional features would not have been realized without additional costs having been incurred.

Response: Having considered these comments, we have decided to modify our original proposal and to adopt

instead payment of a flat, across-the-board $50 premium for any lens for which a payment review is requested in accordance with the provisions of the final regulations and that we find to comply with the definition of a new technology IOL. We will adopt this $50 payment at least until July 16, 2002.

During this 3-year period, we will monitor whether the flat payment of $50 has provided beneficiaries access to new technology. We will also monitor market parameters for IOLs. After this 3-year period, we may adjust our payment rate for NTIOLs through proposed and final rulemaking for ambulatory surgical centers.

The effect of adopting this approach will be to permit an expedited consideration of a request for payment review, and a standard $50 payment adjustment for any lens that we determine is a new technology IOL. We believe that a flat $50 premium per new technology IOL is a reasonable amount and is enough to encourage manufacturers to continue their IOL research and development programs. In fact, an industry-sponsored study found that the use of a certain type of new technology IOL, such as a multi-focal lens, enables a certain percentage of cataract patients to forego Medicare-reimbursed post-cataract eyeglasses. A payment adjustment of $50 for this type of lens seems to be justified since it offers certain benefits to both the beneficiary and the Medicare program. A flat rate adjustment also will expedite our review process and gives Medicare beneficiaries quicker access to new technology. By adopting a flat dollar amount, rather than a percentage of the standard IOL allowance, we hold the premium constant against potential increases or reductions in the IOL allowance for standard lenses.

Comment: Several commenters stated that the application process is cumbersome, time-consuming, and not possible due to the proprietary nature of the information that will have to be supplied by IOL manufacturers. Along the same line, several commenters thought that we should make the adjusted payment amount available within 90 to 180 days.

Response: As discussed above, by adopting a flat rate payment amount of $50, the time required for the application process would be dramatically reduced. The payment adjustment amount could be implemented within 180 days after receipt of the request to review a new technology IOL.

The commenters were also concerned that due to the proprietary nature of the information that would have to have been supplied, businesses could be reluctant to submit the requested information. By reducing the types of data necessary to make the determination, the final rule should alleviate some of the public's concern. In addition, as we stated in the proposed rule, 45 CFR 5.65(c) provides that a submitter of information may designate all or part of the information that he or she is submitting as being exempt from mandatory disclosure under Exemption 4 of the Freedom of Information Act. We reiterate that we will abide by the submitter's request if the submitter wishes any information to be withheld from disclosure.

Comment: Two commenters requested that we provide for appeals of our new technology IOL decisions.

Response: The SSAA 1994 does not require any appeal of this determination. Moreover, section 1869 of the Act already provides beneficiaries and certain other individuals the ability to challenge the amount of benefits paid if a claim is denied. We do not believe additional appeal rights are warranted and, therefore, are not accepting this comment.

Comment: Two commenters thought that interested parties who request a payment adjustment for new technology IOLS should be able to demonstrate that the payment adjustment be continued past the time limit.

Response: As discussed earlier in this section, we are increasing the time limit for an adjusted payment from 2 years to 5 years for the initial new technology IOL approved for the adjusted payment. Any subsequent new technology IOL with the same characteristics as the initial IOL will get the adjusted payment for the remainder of the 5-year period. Given the data presented in the 1994 OIG report, we believe this extension is sufficient to alleviate the need for a demonstration to extend payment beyond this time period.

IV. Provisions of the Final Regulations

In response to the comments we received, we are making several revisions to the proposed rule that we believe will streamline the process for determining an appropriate payment amount for new technology IOLS.

We are revising § 416.185, ''Payment review process.'' In the proposed rule, interested parties seeking an adjustment in the current IOL payment rate for a new technology lens would have been required to submit information related to manufacturing, selling, overhead, research and development costs in addition to any other information that would be considered appropriate in determining a payment adjustment. In the final rule, we are eliminating the need for this information to establish a payment adjustment. Instead, we are establishing a flat rate adjustment of $50 over the current rate for standard IOLs for 3 years beginning on July 16, 1999. After this 3-year period, we may adjust our payment rate for IOLs through proposed and final rulemaking for ambulatory surgical centers.

This change also has an impact on § 416.195, ''A request to review.'' In this section of the proposed rule, we were requiring documented evidence of the cost of the IOL and the manufacturer's investment in the IOL. This will no longer be necessary, since the final rule establishes a flat rate payment adjustment.

Another revision to the proposed rule is § 416.200, ''Application of the payment adjustment.'' In the proposed rule, a single model IOL was recognized for a payment adjustment for a period of 2 years. We have revised that provision to extend the payment adjustment period to 5 years for the first IOL in a subset that we approve for the payment adjustment. Any subsequent IOL with the same characteristics as the first IOL recognized for a payment adjustment would receive the adjustment for the remainder of the 5-year period established by the first recognized IOL.

With these revisions to the proposed rule in place, we will then be able to shorten the time it takes to complete the review process in order to establish a payment adjustment. The proposed rule set up a 365-day cycle for the completion of this process. Although we are still required to publish two **Federal Register** notices in this review process, one with a 30-day comment period showing the list of requests received, and another within 90 days after the close of the comment period indicating the determinations that were made, we should be able to decrease the time to 180 days.

Finally, this rule will serve as the initial notice to those wishing to submit requests for review of the appropriateness of the payment amount with respect to a particular IOL, in accordance with § 416.195 of this rule. We will accept requests for 60 days following the effective date of this regulation. Subsequent requests for review of payment amounts will be made in accordance with the regulations as stated in this final rule. Please submit requests to: Grant Bagley, M.D., Director, Coverage and Analysis Group, Office of Clinical Standards and Quality, S3–02–01, 7500 Security Boulevard, Baltimore, Maryland 21244.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we 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 PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on the information collection requirement discussed below.

Section 416.195 A Request To Review

Section 416.195(a) states that the request must include all of the following information:

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

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

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

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

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

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

We believe the above requirement is not subject to the Act in accordance with 5 CFR 1320.3(c)(4) since this requirement does not collect information from 10 or more entities on an annual basis.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above.

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, ATTN: Louis Blank, HCFA–3831–F

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Eydt, HCFA Desk Officer

VI. 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 rule 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 definitions of a small entity. We are not preparing a regulatory flexibility analysis because we have determined, and the Secretary certifies, that this regulation will 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 rule will have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 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 regulation will not have a significant impact on the operations of a substantial number of small rural hospitals.

Although this rule is not an ''economically significant'' rule under Executive Order 12866, we present below a voluntary analysis of the effects of this 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 will be negligible. We do not expect that making this payment adjustment will have an impact on the availability or prices of other IOLs. We do not expect that is will 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. In our June 12, 1998 proposed rule, ''Medicare Program; Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998'' (63 FR 32303), we stated that we would be proposing a new payment amount for the standard IOL that reflects the cost of acquiring the lens. New technology IOLs will 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 will substitute for spectacles in some cases, and in others will allow the patient to wear a single vision prescription rather than bifocals.

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 is 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 Furnished by Ambulatory Surgical Centers

Sec.

Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

§ 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 meet 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 has been approved by the FDA 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 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 a request to review the appropriateness of the payment amount for an IOL.

(c) HCFA compiles a list of the requests it receives 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 public 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 as specified in § 416.200. HCFA makes a determination of whether the IOL meets the definition of a new technology IOL in § 416.180.

(f) If HCFA determines that a lens is a new technology IOL, HCFA establishes a payment adjustment as follows:

(1) Before July 16, 2002—$50.

(2) After July 16, 2002—$50 or the amount announced through proposed and final rulemaking in connection with ambulatory surgical center services.

(g) 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 a specific subset of new technology within the ''class of new technology IOLs.''

(h) Within 90 days of the end of the comment period following the **Federal Register** notice identified in paragraph (d) of this section, HCFA publishes in the **Federal Register** its determinations with regard to IOLs that it has determined are ''new technology'' lenses that qualify for a payment adjustment.

(i) 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 A request to review.

(a) *Content of a request.* The request must include all of the following information:

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

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

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

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

(5) Reports of modifications made after the original FDA approval.

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

(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, HCFA maintains the confidentiality of the information and protects it from disclosure not otherwise authorized or required by Federal law as allowed under 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).

§ 416.200 Application of the payment adjustment.

(a) HCFA recognizes the IOL(s) that define a new technology subset for purposes of this subpart as belonging to the class of new technology IOLs for a period of 5 years effective from the date that HCFA recognizes the first new technology IOL for a payment adjustment.

(b) Any IOL that HCFA subsequently recognizes as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with HCFA's recognition of the first IOL in the subset.

(c) Beginning 5 years after the effective date of HCFA's initial recognition of a new technology subset, payment adjustments cease for all IOLs that HCFA designates as belonging to that subset and payment reverts to the standard payment rate set under section 1833(i)(2)(A)(iii) of the Act for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by HCFA as belonging to the class of new technology IOLs must submit claims using specific billing codes to receive the new technology IOL payment adjustment.

(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 15, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: March 8, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 99–15067 Filed 6–14–99; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 51

[CC Docket No. 96–98; FCC 99–86]

Implementation of the Local Competition Provisions of the Telecommunications Act of 1996; Deaveraged Rate Zones for Unbundled Network Elements

AGENCY: Federal Communications Commission.

ACTION: Final rule; temporary stay.

SUMMARY: In this Order, the Commission temporarily stays the effectiveness of its