VI. Regulatory Impact Statement

We have examined the impact of this final notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes CHAP as a national accreditation organization for HHAs that request participation in the Medicare program. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this final notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this final notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in HHAs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem HHAs accredited by CHAP as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this final notice will not significantly affect the rights of States, local or tribal governments.

Authority: Section 1863 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)


Mark B. McClellan, Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3112–FN; 0938–ZA49]

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: In this final notice, we summarize timely public comments received in response to our July 23, 2004 notice with public comment period and announce our decision concerning applications submitted by Alcon Laboratories, Incorporated (Alcon) and Advanced Medical Optics (AMO) (formerly Pharmacia & Upjohn Company) to adjust the Medicare payment amounts for certain intraocular lenses (IOLs) on the basis that they are new technology intraocular lenses (NTIOLs).

This is the third of three statutorily required Federal Register documents. On February 27, 2004, we published a notice in the Federal Register that solicited interested parties to submit requests for review of the appropriateness of the payment amount for an IOL furnished by an ambulatory surgical center. On July 23, 2004, we published a notice with comment period entitled “Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers” acknowledging timely receipt of application materials from Alcon and AMO. In this final notice, we announce our decision to disapprove the NTIOL applications submitted by both Alcon and AMO.

FOR FURTHER INFORMATION CONTACT: Michael Lyman, (410) 786–6938.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1994, the Social Security Act Amendments of 1994 (SSAA 1994) (Pub. L. 103–432) were enacted. Section 141(b)(1) of SSAA 1994 required us to develop and implement a process under which interested parties may request a review of the appropriateness of the payment amount for intraocular lenses furnished by ASCs under section 1833(i)(2)(A)(iii) of the Social Security Act (the Act) on the basis that those lenses constitute a class of new technology intraocular lenses. On June 16, 1999, we published a final rule in the Federal Register entitled “Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers” (64 FR 32198), which added subpart F to 42 CFR part 416. The June 16, 1999 final rule established a process for adjusting payment amounts for NTIOLs furnished by ambulatory surgical centers (ASCs), defined the terms relevant to the process, and established a flat rate payment adjustment of $50 for IOLs that we determine are NTIOLs. The payment adjustment applies for a 5-year period that begins when we recognize a payment adjustment for the IOL in a new class of technology, as explained below. Any subsequent IOLs having the same characteristics as the first IOL recognized for a payment adjustment will receive the same adjustment for the remainder of the 5-year period established by the first recognized NTIOL. In accordance with the payment review process specified in §416.185, after July 16, 2002, the $50 adjustment amount can be modified through proposed and final rulemaking in connection with ASC services. To date, we have made no changes to the payment amount and have opted not to change the adjustment for calendar year 2004 (CY 2004).

We have previously approved two classes of NTIOLs: Multifocal and Reduction in Preexisting Astigmatism. These IOLs were approved for NTIOL status during calendar year 2000.

II. NTIOL Applications Submitted for Calendar Year 2004

On February 27, 2004, we published a notice in the Federal Register entitled...
“Medicare Program; Calendar Year 2004
Review of the Appropriateness of
Payment Amounts for New Technology
Intraocular Lenses (NTIOLs) Furnished
by Ambulatory Surgical Centers (ASCs)”
(69 FR 9322). In response to the
February 27, 2004 notice, we received
the following timely requests for review:

1. Manufacturer: Alcon Laboratories,
Inc. Model Numbers: ACRYSOF
Natural IOL; Models: SB30AL (5.5 mm
optic) and SN60AT (6.0 mm optic).

2. Manufacturer: Advanced Medical
Optics. Model Numbers: Tecnis®,
with Z-Sharp Optic Technology, Foldable
Posterior Chamber IOL; Models Z9000
(12 mm diameter) and Z9001 (13 mm
diameter). These two models are also
made out of the same material and differ
only in optic size. Accordingly, we are
also treating these lenses as the same
lens.

On July 23, 2004, we published in the
Federal Register a notice with comment
period entitled “Medicare Program;
Adjustment in Payment Amounts for
New Technology Intraocular Lenses
Furnished by Ambulatory Surgical
Centers” (69 FR 44029) that summarized
timely applications and solicited
public comments on the IOLs submitted
by Alcon and AMO.

III. Criteria and Process for NTIOL
Determination

We will classify an IOL as an NTIOL
if the lens meets the definition of a
“new technology IOL” in §416.180,
which incorporates section 141(b)(2)
of SSA 1994. Under that section, a “new
technology IOL” is defined as “an IOL
that CMS 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.”

The process we use for evaluating
requests for NTIOL designation and
reviewing the appropriateness of the
payment amount for a NTIOL furnished
by ASCs is described in our regulations
at part 416, subpart F and in the
February 27, 2004 Federal Register
notice.

This process includes—

- Publishing a public notice in the
  Federal Register identifying
  requirements and the deadline for
  submitting a request;
- Processing requests to review the
  appropriateness of the payment amount
  for an IOL;
- Compiling a list of the requests we
  receive that identify the IOL
  manufacturer, IOL model number under
  review, name of the requester, and a
  summary of the request for review of the
  appropriateness of the IOL payment
  amount;
- Publishing an annual public notice in
  the Federal Register that lists the
  requests and provides for a public
  comment period;
- Reviewing the information
  submitted with the applicant’s request
  for review, and requesting confirmation
  from the FDA about labeling
  applications that have been approved
  on the IOL model under review. We also
  request the FDA’s recommendations as
  to whether or not the IOL model
  submitted represents a new class of
  technology that sets it apart from other
  IOLs. Using a baseline of the date of the
  last determination of a new class of
  IOLs, the FDA states an opinion based
  on proof of superiority over existing
  lenses of the same type of material or
  over lenses providing specific clinical
  advantages and superiority over existing
  IOLs as described in the preceding
  paragraph;
- Determining which lenses meet the
criteria to qualify for the payment
  adjustment based on clinical data and
  evidence submitted for review, the
  FDA’s analysis, public comments on the
  lenses, and other information;
- Designating a type of material or a
  predominant characteristic of an NTIOL
  that sets it apart from other IOLs to
  establish a new class;
- Publishing a notice in the Federal
  Register announcing the IOLs that we
  have determined are “new technology”
  IOLs. These NTIOLs qualify for the
  following payment adjustment: (a)
  Determinations made before July 16,
  2002—$50; (b) Determinations made
  after July 16, 2002—$50 or the amount
  announced through proposed and final
  rules in connection with ASC services;
  and
- Adjusting payments effective 30
days after the publication of the final
  notice announcing our determinations
  described in paragraph (8) of this
  section.

In accordance with our NTIOL
application review procedures, we
asked the FDA to review the Alcon and
AMO NTIOL applications to determine
whether the manufacturers’ claims of
specific clinical advantages and
superiority over existing IOLs had been
approved for labeling and advertising
purposes. Our regulations require the
FDA’s approval of a requester’s claims
for advertising and labeling in order for
an IOL to be classified as a NTIOL.

IV. Analysis of and Responses to Public
Comments

We received 14 timely public
comments in response to the July 23,
2004 notice with comment period on
the NTIOLs under review. Of these, 11
were from ophthalmologists, two were
from IOL manufacturers, and one was
from a private citizen. The comments
we received and our responses are as
follows:

Comment: Five commenters
supported the Alcon Laboratories, Inc.
Acrysof® lenses without distinguishing
between the two models presented, and
five commenters supported the AMO
Tecnis® lenses without distinguishing
between the two models presented.

Based on their positive experiences with
the IOLs, these commenters requested
that the IOLs under review be classified
as NTIOLs, and therefore, eligible for
the payment adjustment.

Response: We appreciate the
commenters’ interests in these lenses
and are pleased that these lenses have
improved the quality of life of Medicare
beneficiaries. However, anecdotal
evidence supporting NTIOL status is not
sufficient to characterize an IOL as a
NTIOL. Our regulations at §416.180
prohibit us from characterizing an IOL
as a NTIOL unless the FDA has
approved for use in labeling and
advertising the IOL’s claims of specific
clinical advantages and superiority over
existing IOLs. The FDA must rely on
published clinical data to make this
determination. Testimonials in support
of an IOL being reclassified as a NTIOL
cannot substitute for the FDA’s
approval. We present the FDA review in
section V.

Comment: Two comments from
ophthalmologists opposed NTIOL status
for the Alcon Laboratories, Inc.
Acrysof® lenses, contending that the
relationship between blue light and
macular degeneration is speculative.
The comments did not distinguish
between the two models presented.

Response: Based upon our review of
the literature, we agree with the
commenters that the relationship
between blue light and macular
degeneration is speculative and not
proven by available evidence. We
present our review of the literature in
section V.

Comment: We received one comment
from an IOL manufacturer opposing
AMO NTIOL status, contending that the
FDA failed to approve Alcon’s claims of
specific clinical advantages. The comment did not distinguish between the two models presented.

Response: While the manufacturer claims clinical advantages for blue light filtering in its application for NTIOL status, the manufacturer does not make this claim in its FDA-approved labeling. As previously stated, claims of clinical superiority must be approved by the FDA for use in labeling and advertising for an IOL to qualify as a NTIOL under § 416.180. We believe that the relationship between blue light and macular degeneration is not adequately substantiated by the literature.

Comment: We received one comment from an IOL manufacturer opposing NTIOL status for the AMO Tecnis® lenses, claiming they provide no useful improvements over existing IOLs.

Response: The literature submitted by the manufacturer validates AMO’s claims of increased contrast sensitivity for the Tecnis® IOLs only when the lenses are compared to one other IOL. However, both the literature submitted by AMO and our independent review of the literature did not show that the Tecnis® lenses demonstrate increased contrast sensitivity over the spectrum of available IOLs. We believe that for a lens to be approved as an NTIOL, it must offer benefits superior to those offered by more than one other available lens.

V. NTIOL Decision—Disapproval of July 23, 2004 Applications by Alcon and AMO

A. Alcon Acrysof® Natural Lenses; Model Numbers SB30AL and SN60AT

Alcon claims to have created a class of IOL that reduces chronic blue light exposure to the retina and reduces long-term retinal damage (macular degeneration). However, these claims are absent from the IOLs’ FDA-approved labeling and advertising. In addition, a July 12, 2004 FDA letter to CMS concerning Alcon’s NTIOL application states, in part, as follows: "* * * * At this point, it appears as though there is no definitive explanation in regards to the extent blue light plays in retinal damage. Retinal damage is a multifactorial issue, because so many things (e.g., environment, nutrition, etc.) may also impact the degree of damage, if any."

The same FDA letter also states that Alcon did not receive FDA approval to make the claim in its labeling that “the blue light filtering quality of the ACRYSOF® Natural IOL provides a specific clinical advantage over existing IOLs in mitigating the risk of blue light-mediated damage to the retina.” In contrast, the FDA approved labeling states only that blue light transmittal is reduced “without negatively affecting color vision.” No claims of clinical superiority for reducing blue light transmission are made in the labeling. Accordingly, because the FDA has not approved labeling supporting Alcon’s claim that these lenses, independent of the other influencing factors, reduce long-term retinal damage, we cannot approve Alcon’s application to adjust the Medicare payment amounts for these lenses. Additionally, we reviewed the literature submitted by Alcon and performed our own literature search. There is insufficient published peer-reviewed evidence addressing the cause and effect relationship between the blue light filtering effects of an IOL and retinal damage.

B. AMO Tecnis® Lenses with Z-Sharp Optic Technology, Foldable Posterior Chamber IOL; Models Z9000 and Z9001

In a July 12, 2004 letter to CMS regarding AMO’s NTIOL application, the FDA states that " * * * * significantly less with the Tecnis® lens than with the acrylic lens. The simulated night driving results (functional vision) under several of the conditions tested and the visual acuity results were statistically significantly better in [the] eye implanted with the Tecnis® lens. However, another objective of the study was to demonstrate the mesopic (6 cd/m²) intra-individual difference in the postoperative quality of vision using sine-wave contrast sensitivity testing between the Tecnis® lens (Z9000) and a lens with a spherical optic. In this clinical investigation, the contrast sensitivity results were not significantly different as stated in the labeling."

We interpret this FDA statement, as well as our own literature review, to mean that while there may be a difference in contrast sensitivity between the Tecnis® lens and two other IOLs tested, that difference is not statistically significant. We also reviewed the literature submitted by AMO and performed our own literature search. We believe there is insufficient published peer-reviewed evidence addressing the cause and effect relationship between the implanted Tecnis® lens and a reduction in contrast sensitivity. However, we encourage AMO to resubmit this application with additional data from published peer-reviewed evidence.

VI. Collection of Information Requirements

Because the requirements referenced in this final notice will not affect 10 or more persons on an annual basis, this notice does not impose any information collection and record keeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

VII. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132.

Executive Order 12866, (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that this final notice is not a major rule. The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $8.5 million or less in any 1 year. We have determined that this final notice will not affect small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a regulation may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 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 100 beds. We have determined that this final notice does not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the
private sector, of $110 million. We have determined that this final notice will not have a consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State, local, or tribal governments, preempts State law, or otherwise has Federalism implications. We have determined that this final notice does not have an economic impact on State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this final notice was not reviewed by the Office of Management and Budget.

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

We published a notice in the November 23, 2001 Federal Register (66 FR 58743) with information regarding the establishment of the public meeting process for DME.

The public meeting process previously limited to DME has been expanded to include all new public requests for revisions to the HCPCS. This change will provide more opportunities for the public to become aware of coding changes under consideration, as well as opportunities for CMS to gather public input.

II. Registration

Registration Procedures: Registration can be completed online at http://www.cms.hhs.gov/medicare/hcpcs. To register by telephone, contact Public Meeting Coordinators Gloria Knight at (410) 786–4598 or Jennifer Carver at (410) 786–6610. The following information must be provided when registering: name, company name and address, telephone and fax numbers, e-mail address, and special needs information. Registrants must also indicate whether they are the “primary speaker” for an agenda item. Primary speakers must be designated by the entity that submitted the HCPCS coding request. A CMS staff member will confirm your registration by mail, e-mail, or fax.

Registration Deadline: Individuals must register for each date they plan either to attend or to provide a presentation. The deadline for registration of all the meeting dates is Tuesday, May 17, 2005.

III. Presentations and Comment Format

A. Primary Speaker Presentations

The entity that requested revisions to the HCPCS coding system for a particular agenda item may designate one “primary speaker” to make a presentation for a maximum of 15 minutes. Fifteen minutes is the total time interval for the presentation, and must incorporate the demonstration, set-up, and distribution of material. In establishing the public meeting agenda, we may group multiple, related requests under the same agenda item. In that case, we will decide whether additional time will be allotted, and may opt to increase the amount of time allotted to