Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	
(2) I.D. Number (Governor's Office Use) DOH Reg. No. 10-167	IRRC Number: 2250

(3) Short Title

Drugs which may be used by certain optometrists

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers
28 Pa. Code §6.1	Primary Contact: John C. Hair, Director Bureau of Community Program Licensure and Certification (717) 783-8665 Secondary Contact:

(6) Type of Rulemaking (Check One)	(7) Is a 120-Day Emergency Certification Attached?
✓ Proposed Rulemaking Final Order Adopting Regulation Final Order, Proposed Rulemaking Omitted	✓ No Yes: By the Attorney General Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

This regulation amends the list of drugs which may be used by certain optometrists.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

Section 2 of the Optometric Practice and License Act, Act of June 6, 1980, (P.L. 197, No. 57), as amended, 63 P.S. §244.2.

Regulatory Analysis Form

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Additional therapeutic agents will be available for use by optometrists, which will provide patients with greater access to these drugs. These additions will enhance the practice of optometrists and benefit their patients.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Certain therapeutic agents will not otherwise be available for optometrists, thus limiting their practice and their ability to serve their patients.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Optometrists and their patients will benefit.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

No adverse effect is contemplated.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

No one will be required to comply. Certain optometrists and their patients, however, will benefit.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

Department of State, Board of Optometrists requested these additions.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

None

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

None

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

These agents are currently covered by medical assistance. Adding these agents to the list of approved drugs will not cause any cost increases to state government.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and state government for the current year and five subsequent years.

It is believed that there will be no fiscal costs associated with implementation and compliance for the regulated community, local government or state government.

	Current FY Year	FY + 1 Year	FY + 2 Year	FY + 3 Year	FY + 4 Year	FY + 5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community	$0	0	0	0	0	0
Local Government	$0	0	0	0	0	0
State Government	$0	0	0	0	0	0
Total Savings	$0	0	0	0	0	0
COSTS:						
Regulated Community	$0	0	0	0	0	0
Local Government	$0	0	0	0	0	0
State Government	$0	0	0	0	0	0
Total Costs	$0	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	$0	0	0	0	0	0

Local Government	$0	0	0	0	0	0
State Government	$0	0	0	0	0	0
Total Revenue Losses	$0	0	0	0	0	0

(20a) Explain how the cost estimates listed above were derived.

N/A

(20b) Provide the past three-year expenditure history for programs affected by the regulation.

N/A

Program	FY-3	FY-2	FY-1	Current FY
Planning	$			
Licensure (Hospital)	$			

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

N/A

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reason for their dismissal.

There are no nonregulatory alternatives. By statute, these agents must be listed in regulation in order for certain optometrists to be able to administer and prescribe them.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

None

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This regulation will not put Pennsylvania at a competitive disadvantage. Many other states currently allow optometrists to prescribe and administer these agents.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and location, if available.

No

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

None

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will become effective when published as final. It is anticipated that such publication will occur within 6 months.

(31) Provide the schedule for continual review of the regulation.

The regulation will be reviewed for revision on a regular basis.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2250

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General:	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or independent Agencies.
DEPUTY ATTORNEY GENERAL JAN 22 2002 DATE OF APPROVAL	DEPARTMENT OF HEALTH (AGENCY) DOCUMENT/FISCAL NOTE NO. 10-167 DATE OF ADOPTION: _____ BY: Robert S. Zimmerman, Jr. TITLE: Secretary of Health	BY _____ 1/2/02 DATE OF APPROVAL (Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (~~Strike inapplicable title~~)
Check if applicable. Copy not approved. Objections attached.		Check if applicable. No Attorney General approval or objection within 30 days after submission.

DEPARTMENT OF HEALTH

PROPOSED RULEMAKING

TITLE 28. HEALTH AND SAFETY

PART I. GENERAL HEALTH

[28 Pa. Code Chapter 6]
Drugs Which May Be Used By Certain Optometrists

Notice is hereby given that the Secretary of Health (Secretary) proposes to amend the list of drugs which may be used by certain optometrists, in 28 Pa. Code §6.1 (relating to approved drugs), as set forth in Annex A hereto.

A. PURPOSE OF THE AMENDMENT

Under section 2 of the Optometric Practice and Licensure Act (P.L. 197, No. 57) (63 P.S. §244.2) optometrists may use pharmaceutical agents for diagnostic purposes, and for certain therapeutic purposes, only as approved by the Secretary. The pharmaceutical agents, and the purposes for which they may be used by optometrists, are set forth in 28 Pa. Code §6.1. The drugs included on the list must be approved by the Secretary. The State Board of Optometry (Board) requested that the Secretary approve certain additional therapeutic drugs. In its request to the Secretary, the Board identified the drugs by brand name and generic name, which are shown below with the generic name in parentheses. Currently, the regulations identify drugs only by the generic name. It is proposed that any added drugs will also be listed by the generic name only. The Secretary has approved a request from the Board to add antibacterial agent Quixin (levofloxacin); oral analgesic Ultram (tramadol); and topical analgesics Alamast (pemirolast potassium), Emadine (emedastine difumarate), Optivar (azelastine hydrochloride), and Zaditor (ketotifen fumerate) to the list of approved drugs. Antibacterial agents destroy bacteria. Analgesic drugs are used as pain relievers.

The Board also requested that certain oral antibiotics [Cipro (ciprofloxacin), Lenezolid (zyvox) and Levaquin (levofloxacin)] be added to the list. The Secretary

declined the request to add these agents. As broad-spectrum oral antibiotics, Cipro, zyvox, and Levaquin should be limited to treating resistant or serious infections only. Further, the Federal Food and Drug Administration (FDA) has expressed concerns about inappropriate use of antibiotics leading to increase in resistant organisms; thereby recommending that alternatives should be considered before initiating treatment with antibiotics such as zyvox in the outpatient setting.

Using broad-spectrum antibiotics also creates a higher risk of certain side effects, such as the development of pseudomembranous colitis and superinfections. Also, due to the pharmacological profile of these antibiotics, periodic assessment of organ system functions, including renal, hepatic, and hematopoietic functions, is advisable during prolonged therapy.

For these reasons, the antibiotic drugs rejected for inclusion in the list of drugs that optometrists may use in their practice should only be prescribed by a licensed health professional with extended pharmacological, diagnostic and treatment education.

B. REQUIREMENTS OF THE AMENDMENT

The Secretary proposes to add the following pharmaceutical agents to the approved drug products listed in 28 Pa. Code §6.1(b):

1. Levofloxacin
2. Tramadol
3. Pemirolast potassium

4. Emedastine difumarate

5. Azelastine hydrochloride

6. Ketotifen fumerate

C. AFFECTED PERSONS

Optometrists will be able to use, administer and prescribe additional pharmaceutical agents and their patients will be able to receive them for therapeutic purposes. The patients would potentially benefit in that they would have a wider range of agents available to them, thus potentially enhancing their care and treatment.

D. FISCAL IMPACT

These amendments will have no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public. These regulations merely enhance the availability of therapeutic agents to patients of certain optometrists.

E. PAPERWORK REQUIREMENTS

The addition of these agents to the list of approved drugs under the Optometric Practice and Licensure Act will not result in additional costs or paperwork.

F. EFFECTIVE DATE/SUNSET DATE

The amendments will become effective immediately upon publication as final regulations. These regulations are continually monitored and updated as needed. There is no sunset date.

G. STATUTORY AUTHORITY

The amendment to the list of drugs which optometrists may use in the course of their practice is made pursuant to section 2 of the Optometric Practice and Licensure Act, (63 P.S. §244.2) which defines the "practice of optometry" to include the administration and prescription of legend and nonlegend drugs as approved by the Secretary for treatment. Treatment may include the prescription or administration of pharmaceutical agents for therapeutic purposes. The regulations are also authorized under 71 P.S. §532(g), which provides the Department with general authority to adopt its regulations.

H. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act, 71 P.S. §745.1 et seq., the Department submitted a copy of the proposed regulations on January 31, 2002 to the Independent Regulatory Review Commission and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. In addition to submitting the proposed regulations, the Department has provided the Commission and Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If the Commission has any objections to any portion of the proposed regulations, it will notify the Department by April 11, 2002. Such notification shall specify the

regulatory review criteria which have not been met by the portion. The Act specifies detailed procedures for review, prior to final publication of the regulations, by the Department, the General Assembly and the Governor, of objections raised.

I. CONTACT PERSON

Interested persons are invited to submit all questions, comments, suggestions or objections regarding the proposal to: John C. Hair, Director, Bureau of Community Program Licensure and Certification, Pennsylvania Department of Health, 132 Kline Plaza, Suite A, Harrisburg, Pennsylvania 17104, (717) 783-8665, within 30 days after publication of this notice in the Pennsylvania Bulletin. Persons with a disability who wish to submit comments, suggestions, or objections regarding the proposed regulations may do so by using V/TT (717) 783-6514 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800) 654-5984 [TT]. Persons who require an alternative format of this document may contact Mr. Hair so that necessary arrangements may be made.

ANNEX A
CHAPTER 6. DRUGS WHICH MAY BE USED BY CERTAIN OPTOMETRISTS

* * *

§6.1 Approved drugs

* * *

(b) *Allowable pharmaceutical products.* Optometrists may prescribe and administer the following pharmaceutical products or the A-rated generic therapeutically equivalent drug:

* * *

(7) Antimicrobial agents.

(i) Antibacterial – topical use only.

* * *

(D) DNA synthesis inhibitors.

* * *

(IV) Levofloxacin.

* * *

(8) Analgesic drugs – oral and topical.

(i) Analgesic drugs – oral.

* * *

(E) Tramadol.

(ii) Antihistamines and mast cell stabilizers – topical only.

* * *

(I) Pemirolast potassium.

(J) Emedastine difumarate.

(K) Azelastine hydrochloride.

(L) Ketotifen fumerate.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH

January 30, 2002

Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg , PA 19101

Re: Department of Health Proposed Regulations No. 10-167
Drugs Which May Be Used By Certain Optometrists

Dear Mr. Nyce:

Attached are proposed regulations for review by the Commission in accordance with the Regulatory Review Act, (71 P.S. §§ 745.1-745.15). The proposed regulations will amend 28 Pa. Code § 6.1, which lists of drugs that may be used by certain optometrists.

Section 5(g) of the Regulatory Review Act, 71 P.S. § 745.5(g), provides that the Commission shall, within 10 days after the expiration of the Standing Committee review period, notify the proposing agency of any objections to the proposed regulations. The regulations are expected to be published February 9, 2002. A 30-day comment period is provided.

Section 5.1(a) of the Regulatory Review Act, 71 P.S. § 745.5a(a), provides that upon completion of the agency's review of comments, the agency shall submit to the Commission a copy of the agency's response to the comments received and the text of the final-form regulations which the agency intends to adopt.

The Department will provide the Commission within 5 days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it required to facilitate a thorough review of the proposed regulations. If you have any questions, please contact Deborah Griffiths, Director of the Office of Legislative Affairs at (717) 783-3985.

Sincerely,

Robert S. Zimmerman, Jr
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-167
SUBJECT:	Drugs Which May be Used by Certain Optometrists
AGENCY:	Department of Health

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
1/31/02	Nancy Thompson	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
1/31/02		
1-31-02	Debbie Eaton	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
1/31/02	Lauraine Calen	
1/31/02	Elena Pagán	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
1/31/02	C. Lee-Bevan	LEGISLATIVE REFERENCE BUREAU

January 28, 2002