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INDEPENDENT REGULATORY REVIEW COMMISSION

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 adds six substances to 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 provide patients with greater access to these drugs. These additions 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 are not otherwise 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 is 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.

Regulatory Analysis Form

(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 does 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 are 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

(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

Regulatory Analysis Form

(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 does 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.

(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

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INDEPENDENT REGULATORY REVIEW COMMISSION

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.
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY _____
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-167	5/8/02 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title)
Check if applicable. Copy not approved. Objections attached.	BY: Robert S. Zimmerman, Jr.	Check if applicable. No Attorney General approval or objection within 30 days after submission.
	TITLE: Secretary of Health	

DEPARTMENT OF HEALTH

FINAL RULEMAKING

TITLE 28. HEALTH AND SAFETY

PART I. GENERAL HEALTH

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

The Department of Health (Department) hereby adopts amendments to 28 Pa. Code §6.1 (relating to approved drugs), as set forth in Annex A.

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. The added drugs will also be listed by the generic name only. The Secretary 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 did not approve the request to add these agents. As broad-spectrum oral antibiotics, ciproflaxacin, zyvox,

and levofloxacin 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. The FDA has recommended that alternatives should be considered before initiating treatment with these antibiotics 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, it is advisable that periodic assessment of organ system functions, including renal, hepatic, and hematopoietic functions, be done during prolonged therapy.

For these reasons, the antibiotics 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. SUMMARY

The Department has not changed the proposed regulation. Section 6.1 is amended by adding the following drugs to the approved drugs listed in 28 Pa. Code §6.1(b):

1. Levofloxacin.
2. Tramadol.
3. Pemirolast potassium.
4. Emedastine difumarate.

5. Azelastine hydrochloride.

6. Ketotifen fumerate.

The Department received two comments, one from the Pennsylvania College of Optometry and one from the Pennsylvania Optometric Association (POA). Both comments supported the proposed amendments. The POA requested copies of the final-form regulation and comment and response documents.

C. AFFECTED PERSONS

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

D. FISCAL IMPACT

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

E. PAPERWORK REQUIREMENTS

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

F. EFFECTIVE DATE/SUNSET DATE

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

G. STATUTORY AUTHORITY

The amendments to the list of drugs which certain 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 drugs for therapeutic purposes. The amendments 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. § 745.5(a)), on January 30, 2002, the Department submitted a copy of the notice of proposed rulemaking published at 32 Pa. B. 796 (February 9, 2002) to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment. In compliance with Section 5 (c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation. In compliance with Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745(5)a(a)), the Department submitted a copy of the final-form regulations to

IRRC and the Committees on May 14, 2002. In addition, the Department provided IRRC and the Committees with a copy of the 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.

These final-form regulations were deemed approved by the House Health and Human Services Committee and the Senate Public Health Welfare Committee on _____. IRRC met on _____ and approved the regulation in accordance with Section 5.1(e) of the Regulatory Review Act. The Office of Attorney General approved the regulations on _____.

J. CONTACT PERSON

Questions regarding this final-form regulation may be submitted 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. Persons with a disability may submit questions regarding the regulations 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.

K. FINDINGS

The Department finds:

1. Public notice of intention to adopt the regulations adopted by this order has been given under Sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.
2. A public comment period was provided as required by law.
3. The adoption of the final-form regulations is necessary and appropriate.

L. ORDER

The Department, acting under the authorizing statutes, orders that:

(a) A regulation of the Department, 28 Pa. Code § 6.1, is amended by adding drugs which may be used by certain optometrists as set forth in 32 Pa. B. 796 and Annex A hereto.

(b) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Secretary of Health shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(d) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin.*

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

May 14, 2002

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Re: Department of Health Final Regulations No. 10-167
List of Drugs Which May be Used by Certain Optometrists

Dear Mr. Nyce:

Enclosed is a copy of final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1-745.15). This package adds 6 drugs to the list of drugs which may be used by certain optometrists. Section 5.1 (a) of the Act provides that, upon completion of the agency's review of the comments following proposed rulemaking, the agency is to submit to the Commission and the standing committees a copy of the agency's response to the comments received, the names and addresses of commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

The Department received 2 comments to the proposed amendments. These comments supported the proposed amendments. Copies of the final-form regulations are being forwarded to both commentators.

Section 5.1 (e) of the Act provides that within 10 days following the expiration of the Standing Committee review period, or at its next regularly scheduled meeting, the Commission shall approve or disapprove the final-form regulations.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Deborah Griffiths, Director, Office of Legislative Affairs.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Enclosure

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

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

TYPE OF REGULATION

Proposed Regulation

X 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
5/14	J. Chan	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
5/14	N. Wil	
5/14	Kristi Kreiser	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
5/14		
5/14	E. Payan	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

May 8, 2002