PROPOSED RULEMAKING

BOARD OF CLAIMS

[61 PA. CODE CH. 899]

Rules of Procedure

The Board of Claims (Board), under 72 P. S. §§ 4651-1—4651-10, and section 204(1) of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1204(1)), intends to submit new rules of procedure by final order, proposed rulemaking omitted.

The new rules of procedure will govern practice before the Board and will replace the current rules found in Chapter 899 (relating to rules of practice and procedure).

Interested persons may obtain a copy of the new rules from the Board of Claims, 200 North Third Street, Suite 700, Harrisburg, PA 17101-1501, or by contacting Connie Rode at (717) 787-3325, and may submit comments or suggestions within 15 days of the publication of this notice in the *Pennsylvania Bulletin*.

DAVID C. CLIPPER,
Chief Administrative Judge

[Pa.B. Doc. No. 97-591. Filed for public inspection April 18, 1997, 9:00 a.m.]

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 6 AND 25]

Drugs Which May Be Used By Qualified Optometrists; Schedules of Controlled Substances

The Department of Health (Department), Bureau of Community Program Standards, proposes to amend § 6.1 (relating to drugs which may be used by qualified optometrists) by adding Rev-Eyes (Dapriprazole HCL) to the list of drugs which optometrists may use in the course of their practice.

The Department also proposes to amend the schedules of controlled substances in § 25.72 (relating to schedules of controlled substances). The proposed amendment under this section will reschedule one substance from Schedule I to Schedule II and add three previously unscheduled substances to Schedule I of the controlled substances list. The proposals are set forth in Annex A.

A. *Statutory Authority*

The amendment to the list of drugs which optometrists may use in the course of their practice is proposed under section 2 of the Optometric Practice and Licensure Act (OPL act) (63 P. S. § 244.2). The amendments to the schedules of controlled substances are proposed under sections 103 and 104 of The Controlled Substance, Drug, Device and Cosmetic Act (CSDDC act) (35 P. S. §§ 780-103 and 780-104). Both amendments are also proposed under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

B. *Purpose of the Amendments*

Chapter 6 (relating to drugs which may be used by qualified optometrists)

Under the OPL act (63 P. S. §§ 244.1—244.12), optometrists who are certified by the State Board of Optometry to do so, may prescribe and administer certain drugs approved by the Secretary of Health (Secretary). The Department has approved a request from the State Board of Optometry to add Rev-Eyes (Dapiprazole HCL) to the list of approved drugs.

Chapter 25 (relating to controlled substances, drugs, devices and cosmetics)

The CSDDC act (35 P. S. §§ 780-101—780-144) recognizes the fact that there is a need to control substances which have potential for abuse while also recognizing that some of those substances have medical uses. The CSDDC act provides for a system of five schedules of controlled substances as a means of grouping potentially dangerous substances based on their differing potentials for abuse and on their potential for medical use. Penalties for illegal use of the controlled substances vary according to the schedule on which the substance is listed. The health and safety of the public is protected by having a substance placed on the proper schedule. Additionally, proper scheduling ensures appropriate enforcement when a substance is abused or otherwise used illegally.

The CSDDC act requires that a controlled substance be placed in Schedule I when there is : (1) a high potential for abuse; (2) no currently accepted medical use in the United States; and (3) a lack of accepted safety for use under medical supervision. A controlled substance is placed in Schedule II when there is : (1) a high potential for abuse; (2) currently accepted medical use in the United States or currently accepted medical use with severe restrictions; and (3) abuse may lead to severe psychic or physical dependence.

The amendments reschedule Levo-Alpha-Acetyl-Methodol (LAAM), previously listed in Schedule I of the schedules of controlled substances, to Schedule II. They further list Methcathinone, 4 Bromo 2, 5 Dimethoxyphenethylamine, and Dimethylamphetamine, all previously unscheduled substances, in Schedule I.

In proposing these amendments to the schedules of controlled substances, the Department is following the lead of the Federal Drug Enforcement Administration (DEA) which has previously scheduled all four substances as proposed herein.

C. *Requirements of the Amendments*

Rev-Eyes (Dapiprazole HCL)

The Secretary, upon the advice from the Drug, Device and Cosmetic Board, proposes to add the ophthalmic use only product Rev-Eyes (Dapiprazole HCL) to the approved drug products in § 6.1(a)(2). Rev-Eyes (Dapiprazole HCL) is a drug that reverses pupillary dilation (pupil enlargement) and partially reduces cyclopbegia (paralysis of focusing muscle), two effects of diagnostic eyedrops used in routine eye examinations. The reversal of these effects permits the patient to leave the doctor's office with less light sensitivity and improved visual performance.

Levo-Alpha-Acetyl-Methodol (LAAM)

The Secretary, upon the advice of the Drug, Device and Cosmetic Board, finds that placing the Schedule I narcotic known as Levo-Alpha-Acetyl-Methodol (LAAM) into Schedule II will make it available as an alternative to methadone in substance abuse treatment facilities in this Commonwealth. In 1993, the DEA transferred LAAM from Schedule I into Schedule II of the Federal Controlled Substances Act.

LAAM is a synthetic opiate developed in 1948 and clinically tested for treatment of opiate dependence since 1968. LAAM's primary advantage over methadone, the current approved drug for maintenance treatment, is its ability to relieve and prevent opiate withdrawal symptoms in addicts for up to 72 hours. Due to its long duration of action, the frequency of visits to a clinic can be reduced from daily to three times weekly even for patients just entering treatment. In general, addicts find participation in treatment more acceptable and return to the clinic more regularly. This is especially true for those addicts trying to engage in work, education or rehabilitation activities outside of the clinic, because travel time and effort is greatly reduced.

In addition, researchers found that LAAM offers the patient a smoother, sustained drug effect. Oral consumption even during the period of escalating doses did not produce excessive sedation or subjective euphoria. Researchers also emphasize that LAAM is less likely to be a reinforcer of daily drug taking behavior than methadone since a three times weekly dosage schedule frees the patient from the daily necessity of engaging in drug seeking and drug taking behavior.

Facilities utilizing LAAM for treatment of narcotic addiction will be subject to compliance with the requirements of the Narcotic Addict Treatment Act of 1974 (Pub. L. 93-281), and numerous regulations, both State and Federal, concerning narcotic treatment programs. The Department's Division of Drug and Alcohol Program Licensing currently inspects narcotic treatment facilities twice per year for compliance with these regulations.

Methcathinone HCL, 4 Bromo 2, 5 Dimethoxyphenethylamine and Dimethylamphetamine

In addition, the Secretary, upon the advice of the Drug, Device and Cosmetic Board is proposing the placement of Methcathinone HCL; 4 Bromo 2, 5 Dimethoxyphenethylamine; and Dimethylamphetamine into Schedule I of the controlled substances listing.

Methcathinone HCL

Methcathinone HCL is produced for street distribution in clandestine laboratories. There are no indications of current medical use of Methcathinone HCL in or outside of the United States. It has a high potential for abuse and is administered by nasal insufflation, oral ingestion, intravenous injection and smoking. Methcathinone HCL produces pharmacological effects and appears to have an abuse potential similar to that of amphetamines. It is usually sold as itself under street names of "CAT" and "GOOB." In 1993, the DEA placed Methcathinone HCL into Schedule I of the Federal Controlled Substances Act (21 U. S.C.A. § 823).

4 Bromo 2, 5 Dimethoxyphenethylamine

4 Bromo 2, 5 Dimethoxyphenethylamine has been represented as 3, 4 Methylenedioxy Methamphetamine (MDMA) and has been sold in sugar cubes as LSD. More recently, it has been promoted as an aphrodisiac and distributed under the product name of NEXUS whose purported active ingredient is brominated cathinine. It is produced for street distribution in clandestine laboratories and has no known medical use. In 1994, the DEA placed this drug into Schedule I of the Federal Controlled Substances Act.

Dimethylamphetamine

Dimethylamphetamine is a drug which produces a significant central nervous system stimulant. Dimethylamphetamine is routinely sold on the street as methamphetamine or speed and is produced in clandestine laboratories. There are no know medical uses for this drug. In 1990, the DEA placed Dimethylamphetamine into Schedule I of the Federal Controlled Substances Act.

D. *Who is Affected by the Proposed Amendments*

The proposed amendment rescheduling LAAM will impact mostly on existing narcotic treatment programs in this Commonwealth. They will be afforded the use of an alternative to methadone. Facilities utilizing LAAM will be required to comply with Federal regulations at 21 CFR Parts 291.501 and 291.505, pertaining to the use of narcotic drugs in the treatment of addiction.

The amendment pertaining to Rev-Eyes (Dapiprazole HCL) will affect optometrists who will have the drug Rev-Eyes (Dapiprazole HCL) available for use on their approved drug products listing.

E. *Cost and Paperwork Estimates*

The proposal to the schedules of controlled substances will have no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public because a system already exists for the handling of controlled substances. Similarly, the proposal will not increase paperwork, since a paperwork system is already in place and will not measurably change with the addition of more substances.

The addition of Rev-Eyes (Dapiprazole HCL) to the list of approved drugs under the OPL act will not result in additional costs or paperwork.

F. *Effective Date/Sunset Date*

The amendments will be effective immediately upon final adoption. These regulations are continually monitored and updated as needed. Therefore, no sunset date has been set.

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 9, 1997, the Department submitted a copy of the proposed amendments, to the Independent Regulatory Review Commission (IRRC) 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 amendments, the Department has provided IRRC and the Committees with a copy of a 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 IRRC has objections to any portion of the proposed amendments, it will notify the Department within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the amendments, by the Department, the General Assembly and the Governor of objections raised.

H. *Contact Person*

Interested persons are invited to submit all comments, suggestions or objections regarding the proposal to John C. Hair, Director, Bureau of Community Program Standards, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-8665, within 30 days of publication of this notice in the *Pennsylvania Bulletin*. If you are a person

with a disability, comments, suggestions or objections regarding the proposed amendments may also be submitted to John Hair in alternative formats, such as by audio tape, braille or by using TDD: (717) 783-6514. If you are a person with a disability and require an alternative format of this document (that is, large print, audio tape, braille) please contact John Hair so that he may make the necessary arrangements.

DANIEL F. HOFFMANN,
Secretary

Fiscal Note: 10-144. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART I. GENERAL HEALTH

CHAPTER 6. DRUGS WHICH MAY BE USED BY QUALIFIED OPTOMETRISTS

§ 6.1. Approved drugs.

(a) Optometrists who are appropriately qualified under the Optometric Practice and Licensure Act (63 P. S. §§ 244.1—244.12) are permitted to utilize the following drugs in their practice of optometry:

* * * * *

(2) *Miotics*. Miotics shall conform with the following:

* * * * *

(iv) Dapiprazole HCL.

* * * * *

PART III. PREVENTION OF DISEASES

CHAPTER 25. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND COSMETICS

SCHEDULES OF CONTROLLED SUBSTANCES

§ 25.72. Schedules of controlled substances.

* * * * *

(b) *Schedule I*. In determining that a substance comes within this schedule, the Secretary will find: a high potential for abuse; no currently accepted medical use in the United States; and a lack of accepted safety for use under medical supervision. The following controlled substances are included in this schedule:

(1) The following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

(i) **[Acetylmethadol] (Reserved).**

* * * * *

(3) A material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

* * * * *

(xx) 4 Bromo 2, 5 Dimethoxyphenethylamine.

* * * * *

(6) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture or preparation which contains any quantity of the following substances including the salts, isomers and salts of isomers:

* * * * *

(xxviii) Methcathinone HCL.

(xxix) Dimethylamphetamine.

(c) *Schedule II*. In determining that a substance comes within this schedule, the Secretary will find: a high potential for abuse; currently accepted medical use in the United States; or currently accepted medical use with severe restrictions and abuse may lead to severe psychic or physical dependence. The following controlled substances are included in this schedule:

* * * * *

(2) The following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, of any quantity, unless specifically excepted or listed in another schedule, whenever the existence of the isomers, esters, ethers and salts is possible within the specific chemical designation:

* * * * *

(xxvi) Levo-Alpha Acetyl-Methodol

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[Pa.B. Doc. No. 97-592. Filed for public inspection April 18, 1997, 9:00 a.m.]

INSURANCE DEPARTMENT

[31 PA. CODE CH. 131]
Deductible Program

The Insurance Department (Department) proposes to delete Chapter 131 (relating to deductible program) to read as set forth in Annex A, under the authority of sections 206, 506, 1501 and 1502 of The Administrative Code of 1929 (71 P. S. §§ 66, 186, 411 and 412). Chapter 131 was previously promulgated under section 13(d) of the Casualty and Surety Rate Regulatory Act (40 P. S. § 1193) and section 13(d) of the Fire, Marine and Inland Marine Rate Regulatory Act (40 P. S. § 1233(d)) (acts).

Purpose

The purpose of this rulemaking is to delete Chapter 131 to eliminate redundant and obsolete regulations. The regulations, adopted in 1973, imposed several requirements on insurance companies licensed to do business in this Commonwealth with respect to deductibles used for property or casualty policies. The regulations authorized insurance companies to offer previously prohibited small deductible or full coverage programs, overruling an Insurance Commissioner order issued in 1971. The regulations instructed insurance companies offering the expanded deductible choices to consumers to first file their revised rates with the Department. Finally, the regulations announced that a company would be in violation of The Insurance Unfair Practices Act (40 P. S. §§ 1151—1162) (Repealed) if it implemented lowered deductibles without the insured's consent, or otherwise failed to fully disclose and explain the available options to consumers.

The Department has determined that the regulations are redundant and unnecessary. The provisions of the regulations are sufficiently within the acts, and the regulations in no manner enhance the authorizing stat-

utes. Additionally, the Department, through its market conduct activities, monitors insurers to ensure compliance with statutory requirements for filing and approval of rates and forms. Therefore, the Department recommends deletion of Chapter 131 in its entirety.

Comments regarding the deletion of these regulations were solicited from various trade associations representing the insurance industry. Comments were received from the Insurance Federation of Pennsylvania, Inc. The Insurance Federation agrees with the Department that this chapter should be deleted.

Fiscal Impact

There will be no fiscal impact as a result of the deletion of these regulations.

Paperwork

There will be no impact on paperwork as a result of the deletion of these regulations.

Affected Parties

The deletion of these sections will affect licensed property and casualty insurers in this Commonwealth.

Effectiveness/Sunset Date

The rulemaking will become effective upon final publication in the *Pennsylvania Bulletin*. Because the rulemaking proposes to delete obsolete regulations, no sunset date has been assigned.

Contact Person

For information on this matter, contact Randy Rohrbaugh, Director, Bureau of Property and Casualty, Insurance Department, 1311 Strawberry Square, Harrisburg, PA 17120, (717) 787-4192.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Department submitted a copy of this proposal on March 28, 1997, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Insurance Committee and the Senate Banking and Insurance Committee. In addition to the submitted proposal, the Department has provided IRRC and the 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 the material is available to the public upon request.

If IRRC has objections to any portion of the proposal, it will notify the Department within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the final-form regulations, by the Department, the General Assembly and the Governor of objections raised.

LINDA S. KAISER,
Insurance Commissioner

Fiscal Note: 11-143. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 31. INSURANCE

PART VIII. MISCELLANEOUS PROVISIONS

CHAPTER 131. **[DEDUCTIBLE PROGRAM] (Reserved)**

§ 131.1. **[Optional deductible programs] (Reserved).**

[(a) Insurance companies may offer optional lower deductibles or full coverage programs which had previously been prohibited by the order of the Commissioner dated August 14, 1971 (1 Pa.B. 1650) and subsequent related notices.

(b) The optional coverages may be made available as soon as properly filed with and approved by the Department.]

§ 131.2. **[Mandatory deductible programs] (Reserved).**

[(a) Deductibles which were mandatory before the August 14, 1971 order, such as the $50 all perils deductible on homeowners policies, shall remain mandatory requirements.

(b) Mandatory deductibles required by the August 14, 1971 order and subsequent related notices shall remain fully available as options to the insured.]

§ 131.3. **[Rates] (Reserved).**

[(a) Insurance companies wishing to offer optional lower deductibles or full coverage may file for reinstatement of the same rates suspended by the August 14, 1971 order of the Commissioner.

(b) Those insurance companies which have received rate reductions on deductible coverage since January 1, 1972, and who now wish to reoffer the lower optional deductibles or full coverage programs, may file proportionately reduced rates when reinstating the programs.]

§ 131.4. **[Filing requirements] (Reserved).**

[(a) In a filing incorporating optional lower deductibles or full coverage, the insurer shall state the method whereby the coverage will be offered.

(b) A filing shall include the applicable marketing, solicitation and underwriting procedures that will be incorporated in making the optional coverages known and available to the public.

(c) The filing shall clearly specify that the following minimal requirements will be met in the sale of lower deductibles or full coverage:

(1) Prior to completion of the sale, there will be a clear and full disclosure and explanation to the consumer of all and each of the deductibles available.

(2) The disclosure and explanation of all and each of the deductibles available to the insured will be made regardless of whether the solicitation is by broker, agent, mail or otherwise.]

§ 131.5. **[Violations] (Reserved).**

[Companies found to be rolling on lower deductibles or full coverage, or otherwise failing to fully and clearly disclose and explain available options to the consumer shall be deemed to have violated the terms and basis for the reimplementation of the optional lower deductible or full coverage program, as well as being in violation of The Insurance Unfair Practices Act (40 P. S. §§ 1151—1162).]

§ 131.6. **[Previous restrictions] (Reserved).**

[This chapter relieves previous restrictions relating to the availability of certain kinds of insurance coverage by making the coverages available at the option of the insured.]

§ 131.7. **[Participation in program] (Reserved).**

[An insurer or insured is not required to participate in an optional program.]

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