

LICENSING ALERT

Molly Raphael
Deputy Secretary for Quality Assurance

January 1998

Division of Drug and Alcohol Program Licensure
Licensing Alert 2-98

RESCHEDULING OF LEVO-ALPHA-ACETYL-METHODOL (LAAM)

On November 22, 1997, the Department of Health published final regulations rescheduling Levo-Alpha-Acetyl-Methodol (LAAM) from a Schedule I controlled substance to a Schedule II controlled substance. This action will make LAAM available as an alternative to methadone in the treatment of opiate addiction. LAAM's primary advantage over methadone is its ability to relieve and prevent opiate withdrawal for up to 72 hours, thereby reducing the frequency of visits to a clinic.

Facilities interested in utilizing LAAM must first be approved to provide methadone maintenance. For further information regarding approval to utilize methadone or LAAM, facilities should send a letter of inquiry to:

Division of Drug and Alcohol Program Licensure
132 Kline Plaza, Suite A
Harrisburg, PA 17104

Enclosed is a copy of the Pennsylvania Bulletin regarding this action. Questions may be directed to the Division of Drug and Alcohol Program Licensure at (717) 783-8675.

Enclosure

RULES AND REGULATIONS

Title 28--HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 6 AND 25]

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

[27 Pa.B. 6088]

The Department of Health (Department) is amending Chapter 6 (relating to drugs which may be used by certain optometrists) by adding Rev-Eyes (Dapriprazole HCL) to the list of drugs which optometrists may use in the course of their practice in § 6.1 (relating to approved drugs).

The Department is also amending the schedules of controlled substances in Chapter 25 (relating to controlled substances, drugs, devices and cosmetics). The amendments 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 in § 25.72 (relating to schedules of controlled substances).

A. Statutory Authority

The statutory authority for the amendment to the list of drugs which optometrists may use in the course of their practice is derived from section 2 of the Optometric Practice and Licensure Act (OPL act) (63 P. S. § 244.2). The statutory authority for the amendment to the schedules of controlled substances are 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 adopted 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 certain optometrists)

Under the OPL act, 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 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 final-form regulations reschedule Levo-Alpha-Acetyl-Methadol (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.

C. Summary of Regulations

Rev-Eyes (Dapiprazole HCL)

The Secretary of Health, upon the advice from the Drug, Device and Cosmetic Board, is adding the ophthalmic use only product Rev-Eyes (Dapiprazole HCL) to the approved drug products listed in § 6.1(a)(2). Rev-Eyes (Dapiprazole HCL) is a drug that reverses pupillary dilation (pupil enlargement) and partially reduces cycloplegia (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-Methadol (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-Methadol (LAAM) into Schedule II will make it available as an alternative to methadone in substance abuse treatment facilities in this Commonwealth. In 1993, the Federal Drug Enforcement Administration 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 Dimethoxy- phenethylamine and Dimethylamphetamine

In addition, the Secretary, upon the advice of the Drug, Device and Cosmetic Board is placing 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 Drug Enforcement Administration 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 Methylendioxy 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 Drug Enforcement Administration 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 known medical uses for this drug. In 1990, the Drug Enforcement Administration placed Dimethylamphetamine into Schedule I of the Federal Controlled Substances Act.

D. Public Comments

Notice of proposed rulemaking was published at 27 Pa.B. 1939 (April 19, 1997) and provided a 30-day comment period. The Department received one comment to the proposed amendments. The comment was from the president of the Pennsylvania Medical Society in support of the rescheduling of LAAM as a Schedule II controlled substance. No comments were received from either the Independent Regulatory Review Commission (IRRC) or the Senate Public Health and Welfare Committee or the House Health and Human Services Committee.

E. Fiscal Impact

The amendments to the schedules of controlled substances will have no measureable fiscal impact on the Commonwealth, local government, the private sector or the general public. Similarly, the addition of Rev Eyes (Dapiprazole HCL) to the list of approved drugs under the OPL act will not result in additional costs.

F. Paperwork Requirements

A system already exists for the handling of controlled substances under the CSDDC act and the amendments will not increase paperwork. Similarly, the addition of Rev Eyes (Dapiprazole HCL) to the list of approved drugs under the OPL act will not result in additional paperwork requirements.

G. Effective Date/Sunset Date

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

H. 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 notice of proposed rulemaking, published at 27 Pa.B. 1939, to IRRC and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for review and comment. In compliance with sections 5(c) and 5.1(a) of the Regulatory Review Act (71 P.S. §§ 745.5(c) and 745.5a(a)), the Department also provided IRRC and the Committees with copies of all comments received as well as other documentation. In addition, 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 this material is available to the public upon request.

In preparing these final-form regulations, the Department has considered the comments received from IRRC, the Committees and the public.

These final-form regulations were deemed approved by the House Committee on Health and Human Services on October 20, 1997, and deemed approved by the Senate Committee on Public Health and Welfare on October 20, 1997. IRRC met on October 23, 1997, and approved the final-form regulations in accordance with section 5.1(e) of the Regulatory Review Act.

I. *Contact Person*

Any questions regarding the amendments may be addressed to John C. Hair, Director, Bureau of Community Program Standards, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-8665. Persons with a disability who have questions regarding the amendments may submit their questions to John Hair in alternative formats, for example, by audio tape, braille or by using TDD: (717) 783-6514. Persons with a disability who require an alternative format of this document (for example, large print, audio tape, braille) should contact John Hair to make the necessary arrangements.

J. *Findings*

The Department finds that:

(1) Notice of proposed rulemaking was published at 27 Pa.B. 1939, as required by 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 and that the comments received were considered.

(3) The adoption of the amendments in the manner provided by this order is necessary and appropriate for the administration of the authorizing statutes.

Order

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

(a) The regulations of the Department, 28 Pa. Code Chapters 6 and 25, are amended by amending §§ 6.1 and 25.72 to read as set forth at 27 Pa.B. 1939.

(b) The Secretary shall submit this order and 27 Pa.B. 1939 to the Office of General Counsel and to the Office of Attorney General for approval as required by law.

(c) The Secretary shall certify this order and 27 Pa.B. 1939 and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall be effective upon publication in the *Pennsylvania Bulletin*.

DANIEL F. HOFFMANN,
Secretary

Fiscal Note: Fiscal note 10-144 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 97-1852. Filed for public inspection November 21, 1997, 9:00 a.m.]

No part of the information on this site may be reproduced for profit or sold for profit.

This material has been drawn directly from the official *Pennsylvania Bulletin* full text database. Due to the limitations of HTML or differences in display capabilities of different browsers, this version may differ slightly from the official printed version.
