PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 25]

Schedules of Controlled Substances

The Department of Health (Department) proposes to amend the schedules of controlled substances under the powers and duties contained in The Controlled Substances, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144) (act). The Department proposes to amend § 25.72 (relating to schedules of controlled substances) to reschedule the substance estazolam from Schedule I to Schedule IV, to reschedule the substance buprenorphine from Schedule V to Schedule III and to schedule butorphanol, sibutramine and zolpidem as Schedule IV controlled substances, to read as set forth in Annex A.

A. *Purpose of the Proposed Rulemaking*

The 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 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 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.

The act requires that a controlled substance be placed in Schedule III when there is: (1) a potential for abuse less than the substances listed in Schedules I and II; (2) well documented and currently accepted medical use in the United States; and (3) abuse may lead to moderate or low physical dependence or high psychological dependence.

The act requires that a controlled substance be placed in Schedule IV when there is: (1) a low potential for abuse relative to substances listed in Schedule III; (2) currently accepted medical use in the United States; and (3) limited physical dependence or psychological dependence liability, or both, relative to the substances listed in Schedule III.

The act requires that a controlled substance be placed in Schedule V when there is: (1) a low potential for abuse relative to the substances listed in Schedule IV; (2) currently accepted medical use in the United States; and (3) limited physical dependence or psychological dependence liability, or both, relative to the substances listed in Schedule IV.

The Drug, Device and Cosmetic Board (Board) met on December 12, 2002. The meeting notice was published at 32 Pa.B. 5713 (November 16, 2002).

The Board heard the petition of Abbott Laboratories, which requested that estazolam be rescheduled from Schedule I to Schedule IV. The petition was based on the fact that the substance is listed by Drug Enforcement Agency (DEA) regulations as a Schedule IV controlled substance, there is a low potential for abuse and it has current acceptable medical use in the United States. Rescheduling would also allow for resolution of conflicting issues between physicians prescribing the substance and law enforcement officials who enforce the act. The Board unanimously approved a motion to authorize the Secretary of Health (Secretary) to reschedule the substance.

The Board also heard the petition of the Department, which requested that buprenorphine be rescheduled from Schedule V to Schedule III. The petition was based on the fact that the DEA has rescheduled the substance from Schedule V to Schedule III, significant abuse and diversion of buprenorphine has been in many countries, the potential for abuse is less than the substances listed in Schedules I and II and there is currently accepted medical use in the United States. Buprenorphine is used in treatment of narcotic addiction. Rescheduling allows access to users for treatment, but adds controls to minimize diversion. The Board unanimously approved a motion to authorize the Secretary to reschedule the substance.

The Secretary, upon being authorized by the Board, directed that the substance estalozam and buprenorphine be rescheduled.

The Board heard the petitions of the Office of Attorney General which requested that butorphanol, including its salts and optical isomers, and sibutramine and zolpidem, be scheduled as a Schedule IV controlled substance.

These substances are currently scheduled by the DEA as Schedule IV controlled substances. The fact that these substances are not scheduled at the State level hinders law enforcement agencies in their prosecution for illegal sale and illegal possession. These substances are abused but have a low potential for abuse relative to substances in Schedule III. There is current accepted medical use in the United States for these substances. Butorphanol is classified as an opiate agonist-antagonist analgesic for the relief of moderate to severe pain. Sibutamine is an amphetamine analog that produces central nervous system stimulation and is used for long-term management of obesity. Zolpidem is a sedative. The Board approved a motion to provide written advice to the Secretary to add these substances to Schedule IV of controlled substances. The Secretary then directed that the substances be scheduled.

The proposed rulemaking would reschedule estazolam, previously listed in Schedule I of the schedule of controlled substances, to Schedule IV, would reschedule buprenorphine, previously listed in Schedule V of the schedule of controlled substances, to Schedule III, and would schedule butorphanol, sibutramine and zolpidem as Schedule IV substances.

B. *Requirements of the Proposed Rulemaking*

This proposed rulemaking would reschedule or schedule substances on the lists of schedules of controlled substances as follows:

a. The substance estazolam would be deleted from Schedule I and rescheduled on Schedule II.

b. The substance buprenorphine would be deleted from Schedule V and rescheduled on Schedule III.

c. The substance butorphanol would be scheduled on Schedule IV.

d. The substance sibutamine would be scheduled on Schedule IV.

e. The substance zolpidem would be scheduled on Schedule IV.

C. *Affected Persons*

Patients using and physicians prescribing estazolam would benefit from its being rescheduled. Patients in need of the drug would be able to obtain it more readily and physicians would not be subject to criminal prosecutions for prescribing it.

The general public would benefit from the rescheduling of buprenorphine and the addition of butorphanol, sibutramine and zolpidem to Schedule IV. Rescheduling buprenorphine and including the other drugs in Schedule IV would allow for better enforcement and control of the drug abuse problems in this Commonwealth. Patients in need of buprenorphine for treatment would still have access to it through their physicians and drug abuse treatment clinics, but the changes would allow for stronger controls to minimize the risk that the substance will be diverted for illicit use.

D. *Fiscal Impact*

This proposed rulemaking to the schedules of controlled substances would have no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public.

E. *Paperwork Requirements*

A system already exists for the handling of controlled substances under the act and the proposed rulemaking would not increase paperwork.

F. *Effective Date/Sunset Date*

This proposed rulemaking will become effective immediately upon publication as a final-form rulemaking. There is no sunset date. Section 25.72 will be continually monitored and updated as needed.

G. *Statutory Authority*

The amendment to the schedules of controlled substances is proposed under sections 3 and 4 of the act (35 P. S. §§ 780-103 and 780-104.) The amendment is also proposed under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Section 3 of the act provides that the Secretary controls all substances listed in Schedules I—V of the act. Section 3(c) of the act provides that the Secretary will not reschedule any controlled substance unless specifically authorized by the Board to do so. The Board has authorized the Secretary to reschedule estazolam and buprenorphine. Section 3(a) of the act provides that the Secretary may add a substance as a controlled substance, and that before doing so, shall request advice in writing from the Board as to whether a substance should be added as a controlled substance. The Secretary sought that advice and the Board provided it following its December 12, 2002, meeting. The Board recommended that the substances butorphanol, sibutramine and zolipidem be added as Schedule IV controlled substances. The Secretary then decided that these substances be scheduled.

H. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 17, 2003, the Department submitted a copy of the proposed rulemaking 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 rulemaking, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

I. *Contact Person*

Interested persons are invited to submit questions, comments, suggestions or objections regarding the proposal to John C. Hair, Director, Bureau of Community Program Licensure and Certification, Department of Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-8665, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Persons with a disability who require an alternative format of the proposal, for example, large print, audiotape, Braille, should contact John Hair at (717) 783-8665, for speech or hearing impaired persons, V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Services at (800) 654-5984.

ROBERT S. MUSCALUS, D.O.,
Acting Secretary

Fiscal Note: 10-173. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASES

CHAPTER 25. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND COSMETICS

SCHEDULES OF CONTROLLED SUBSTANCES

§ 25.72. Schedules of controlled substances.

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(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; a lack of accepted safety for use under medical supervision. The following controlled substances are included in this schedule:

* * * * *

(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:

* * * * *

(x)	**[Estazolam.**
(xi)]	Ethyl loflazepate.
[(xii)] (xi)	Fludiazepam.
[(xiii)] (xii)	Flunitrazepam.
[(xiv)] (xiii)	Haloxazolam.

[(xv)] (xiv)	Ketazolam.
[(xvi)] (xv)	Loprazolam.
[(xvii)] (xvi)	Lormetazepam.
[(xviii)] (xvii)	Medazepam.
[(xix)] (xviii)	Nimetazepam.
[(xx)] (xix)	Nitrazepam.
[(xxi)] (xx)	Nordiazepam.
[(xxii)] (xxi)	Oxazolam.
[(xxiii)] (xxii)	Pinazepam.
[(xxiv)] (xxiii)	Tetrazepam.
[(xxv)] (xxiv)	3, 4-Methylenedioxymethamphetamine (MDMA).
[(xxvi)] (xxv)	4-methylaminorex.
[(xxvii)] (xxvi)	Cathinone.
[(xxviii)] (xxvii)	Methcathinone HCL.
[(xxix)] (xxviii)	Dimethylamphetamine.

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(d) *Schedule III*. In determining that a substance comes within this schedule, the Secretary will find: a potential for abuse less than the substances listed in Schedules I and II; well documented and currently accepted medical use in the United States; and abuse may lead to moderate or low physical dependence. The following classes of controlled substances are included in this schedule:

* * * * *

(10) Buprenorphine.

(e) *Schedule IV*. In determining that a substance comes within this schedule, the Secretary will find: a low potential for abuse relative to substances in Schedule III; currently accepted medical use in the United States; and limited physical or psychological dependence liability relative to the substances listed in Schedule III. The following controlled substances are included in this schedule:

(1) A material, compound, mixture or preparation, unless specifically excepted or unless listed in another schedule, which contains a quantity of the following substances:

* * * * *

(xxv) Estazolam.
(xxvi) Zolpidem.

* * * * *

(3) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture or preparation which contains any quantity of the following substances including its salts, isomers whether optical position or geometric, and salts of the isomers whenever the existence of the salts, isomers and salts of isomers is possible within the specific chemical designation:

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(xi) Butorphanol.
(xii) Sibutramine.

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(f) *Schedule V*. In determining that a substance comes within this schedule, the Secretary **[shall] will** find: a low potential for abuse relative to the substances listed in Schedule IV; currently accepted medical use in the United States; and limited physical dependence or psychological dependence liability relative to the substances listed in Schedule IV. The following controlled substances are included in this schedule:

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(2) **[Buprenorphine.**

(3)] Propylhexadrine, except when labeled for over-the-counter drug sale in conformity with 21 CFR 1308.15 (relating to schedule V).

[(4)] (3) Pyrovalerone.

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