RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 25]

Schedules of Controlled Substances

The Department of Health (Department) amends the schedules of controlled substances under the powers and duties in The Controlled Substances, Drug, Device and Cosmetic Act (act) (35 P. S. §§ 780-101—780-144). The Department amends § 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 Final-Form Rulemaking*

The act recognizes the fact that there is a need to control substances that 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: (1) there is a potential for abuse less than the substances listed in Schedules I and II; (2) there is 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 in 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. As a Schedule I substance at the State level, serious problems existed relating to the inability of physicians to prescribe the substance and how law enforcement officials prosecute crimes relating to the illegal manufacture, distribution and possession of the substance. Resolution of this conflict is critical since estazolam is commonly prescribed for the short-term management of insomnia. Rescheduling would allow for the resolution of these conflicting issues between physicians prescribing the substance and law enforcement officials who enforce the act. Based on this information, the Board unanimously approved a motion to authorize the Secretary of the Department (Secretary) to reschedule the substance.

The Board 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, there has been significant abuse and diversion of buprenorphine in many countries, the potential for abuse of buprenorphine is less than the substances listed in Schedules I and II and there is a currently accepted medical use for this substance in the United States. The abuse potential of buprenorphine is high and closely resembles other narcotics in Schedule II. However, buprenorphine is a safer drug in overdose than other Schedule II narcotics. Therefore, buprenorphine appears to have somewhat less abuse potential than Schedule I or Schedule II narcotic substances, but more abuse potential than partial agonists in Schedule IV.

Further, buprenorphine is used in treatment of narcotic addiction. Rescheduling allows access to users for treatment, but adds controls to minimize the risk that the substance will be diverted for illicit use. Based on this information, 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 substances 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 Schedule IV controlled substances.

The scheduling of butorphanol, sibutramine and zolpidem allows law enforcement to improve enforcement and prosecution for the illegal manufacture, transport, distribution, sale, possession and use of these substances. There has been a tremendous increase in abuse of these substances over the past several years. 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 prosecutions for illegal sale and illegal possession of these drugs, so that including them in Schedule IV would provide law enforcement with much needed tools to address this problem.

Further, although these substances are abused, they 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.

Based on this information, 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 added to Schedule IV of controlled substances.

The Department published proposed rulemaking at 33 Pa.B. 2169 (May 3, 2003). The Department proposed scheduling estazolam, previously listed in Schedule I, to Schedule IV, buprenorphine, previously listed in Schedule V, to Schedule III and would have scheduled butorphanol, sibutramine and zolpidem as Schedule IV substances. The Department provided a 30-day public comment period.

B. *Summary*

The Department received no comments to the proposed rulemaking and is adopting its proposed amendments to § 25.72 without change. The final-form rulemaking reschedules or schedules substances on the lists of schedules of controlled substances as follows:

a. The substance estazolam is deleted from Schedule I and rescheduled on Schedule IV.

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

c. The substance butorphanol is scheduled on Schedule IV.

d. The substance sibutamine is scheduled on Schedule IV.

e. The substance zolpidem is scheduled on Schedule IV.

C. *Affected Persons*

Patients using and physicians prescribing estazolam will be affected by its rescheduling. Patients in need of the drug will be able to obtain it more readily and physicians will not be subject to criminal prosecutions for prescribing it.

Pharmacies and pharmacists in this Commonwealth, physicians, hospitals and certain health clinics and drug distributors, manufacturers and distributors who are already complying with the current regulations will also be affected. They will have to become aware of which substances have been scheduled or rescheduled and deal with those substances appropriately.

The general public will be affected and will 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 allows for better enforcement and control of the drug abuse problems in this Commonwealth. Patients in need of buprenorphine for treatment will continue to have access to it through their physicians and drug abuse treatment clinics, but the changes in scheduling will allow for stronger controls to minimize the risk that the substance will be diverted for illicit use.

D. *Fiscal Impact*

The final-form rulemaking has no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public. This amendment does not significantly affect costs or savings by the regulated community. The final-form rulemaking does not require new legal, accounting or consulting procedures not already being undertaken by the regulated community. There is no measurable fiscal impact on local governments because a system exists for the oversight of controlled substances, and no measurable fiscal impact on State government.

E. *Paperwork Requirements*

A system already exists for the handling of controlled substances under the act and the final-form rulemaking does not increase paperwork.

F. *Effective Date/Sunset Date*

The final-form rulemaking will become effective upon publication. There is no sunset date. The regulations will be continually monitored and updated as needed.

G. *Statutory Authority*

The final-form rulemaking is adopted under sections 3 and 4 of the act (35 P. S. §§ 780-103 and 780-104). The final-form rulemaking is also adopted under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Section 3 of the act provides that the Secretary may control all substances listed in Schedules I—V of the act. Section 3(c) of the act provides that the Secretary shall 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 should 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 notice of proposed rulemaking, published at 33 Pa.B. 2169, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the House and Senate Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on March 8, 2004, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5(g) of the Regulatory Review Act, the final-form rulemaking was deemed approved by IRRC effective March 10, 2004.

I. *Contact Person*

Questions regarding the final-form rulemaking should be submitted to Carol Williams, Director, Bureau of Community Program Licensure and Certification, Department of Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-8665. Persons with a disability may

submit questions in alternative formats, such as audio tape or Braille, or for speech or hearing impaired persons, V/TT: (717) 783-6514 or the Pennsylvania AT&T Relay Services at (800) 654-5984 (TT). Persons who require an alternative format of this document (that is, large print, audio tape or Braille) should contact Carol Williams at the previous address or telephone numbers to make necessary arrangements.

J. *Findings*

The Department finds that:

(1) Public notice of the intention to adopt the amendment 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 rulemaking in the manner provided by this order is necessary and appropriate for the administration of the authorizing statutes.

K. *Order*

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

(a) The regulations of the Department, 28 Pa. Code Chapter 25, are amended by amending § 25.72 to read as set forth in Annex A, with ellipses referring to the existing text of the regulation.

(b) The Secretary 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 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 review and action as required by law.

(d) The Secretary 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*.

CALVIN B. JOHNSON, M.D., M.P.H.,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 34 Pa.B. 1726 (March 27, 2004).)

Fiscal Note: Fiscal Note 10-173 remains valid for the final adoption of the subject regulation.

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.

* * * * *

(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) Ethyl loflazepate.

(xi) Fludiazepam.

(xii) Flunitrazepam.

(xiii) Haloxazolam.

(xiv) Ketazolam.

(xv) Loprazolam.

(xvi) Lormetazepam.

(xvii) Medazepam.

(xviii) Nimetazepam.

(xix) Nitrazepam.

(xx) Nordiazepam.

(xxi) Oxazolam.

(xxii) Pinazepam.

(xxiii) Tetrazepam.

(xxiv) 3, 4-Methylenedioxymethamphetamine (MDMA)

(xxv) 4-methylaminorex.

(xxvi) Cathinone.

(xxvii) Methcathinone HCL.

(xxviii) Dimethylamphetamine.

* * * * *

(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:

* * * * *

(xi) Butorphanol.

(xii) Sibutramine.

* * * * *

(f) *Schedule V.* In determining that a substance comes within this schedule, the Secretary 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:

* * * * *

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

(3) Pyrovalerone.

[Pa.B. Doc. No. 04-904. Filed for public inspection May 21, 2004, 9:00 a.m.]