RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 25]

Schedule of Controlled Substances; Clobazam

The Department of Health (Department) amends the schedules of controlled substances under the powers and duties in The Controlled Substance, 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 clobazam from a Schedule I substance to a Schedule IV substance to read as set forth in Annex A.

A. *Purpose of the Final-Omitted Rulemaking*

Section 25.72 is amended to reschedule the substance clobazam from a Schedule I substance to a Schedule IV substance in accordance with controlled substance scheduling requirements in the act. 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 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 provides that the Secretary of Health (Secretary) shall control the substances listed in Schedules I—V and may, by regulation, upon his own motion or on the petition of an interested party, add a substance as a controlled substance after requesting the advice of the Pennsylvania Drug, Device and Cosmetic Board (Board). Section 3 of the act (35 P. S. § 780-103) prohibits the Secretary from removing a substance from control unless authorized by the General Assembly and from rescheduling a controlled substance unless specifically authorized by the Board.

Until recently, there was not a legitimate medical use in the United States for clobazam. Accordingly, clobazam was listed as a Schedule I controlled substance and it was illegal to possess, administer, dispense, prescribe or distribute.

On October 21, 2011, the United States Food and Drug Administration (FDA) approved the drug Onfi™ (chemical name: clobazam) for the treatment of a rare but severe form of epilepsy in adults and in children 2 years of age and older. When the Department learned of the action of the FDA to approve the use of Onfi™ to treat certain forms of epilepsy, the Secretary acted as Chairperson to convene a meeting of the Board. The purpose of the meeting on March 27, 2012, was to determine whether, in consideration of the FDA's action regarding Onfi™, clobazam should be rescheduled as a Schedule IV controlled substance instead of a Schedule I controlled substance. The Board voted unanimously to authorize the rescheduling of clobazam as a Schedule IV controlled substance. The Secretary, upon being authorized by the Board, directed that the substance clobazam be rescheduled. The rescheduling was effective immediately upon the Secretary's action and the Department published notice of the rescheduling at 42 Pa.B. 1929 (April 7, 2012). The purpose of this final-omitted rulemaking is to amend § 25.72 to conform to the action taken by the Secretary under section 3(c) of the act to reschedule clobazam as a Schedule IV controlled substance.

Under section 204 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1204), known as the Commonwealth Documents Law (CDL), notice of proposed rulemaking may be omitted if the agency for good cause finds that the procedures in sections 201 and 202 of the CDL (45 P. S. §§ 1201 and 1202) are, under the circumstances, impracticable, unnecessary or contrary to the public interest. The Department finds justification for a final-omitted rulemaking to reschedule clobazam from a Schedule I substance to a Schedule IV substance because, under the circumstances, it is unnecessary and contrary to the public interest.

B. *Affected Persons*

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

Pharmacies and pharmacist in this Commonwealth, physicians, drug distributors, manufacturers and distributors will also be affected.

The general public will be affected and will benefit from the rescheduling of clobazam to Schedule IV classification. Patients in need of clobazam for treatment will have access to it through their physicians.

C. *Fiscal Impact*

This final-omitted rulemaking does not have measurable fiscal impact on the Commonwealth, local government, the private sector or the general public. This final-omitted rulemaking does not significantly affect costs or savings by the regulated community. This final-omitted rulemaking does not require new legal, accounting or consulting procedures not already being undertaking by the regulated community. There is not a measurable fiscal impact on local governments or State government because a system exists for the oversight of controlled substances.

D. *Paperwork Requirements*

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

E. *Statutory Authority*

The amendments to the schedules of controlled substances are adopted under the authority in section 3 of the act and section 4 of the act (35 P. S. § 780-104). The final-omitted rulemaking is also adopted under the authority in section 2012(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Section 3 of the act provides that the Secretary may control the substances listed in Schedules I—V of the act. Section 3(c) of the act provides that the "[S]ecretary shall not reschedule any controlled substance unless specifically authorized by the [B]oard to do so." The Board authorized the Secretary to reschedule clobazam.

F. *Effective Date and Sunset Date*

This final-omitted rulemaking will be effective upon publication. A sunset date has not been assuaged as the regulation will be continually monitored and updated as needed.

G. *Regulatory Review*

Under section 5.1(c) of the Regulatory Review Act (71 P. S. § 745.5a(c)), on May 7, 2015, the Department submitted a copy of the final-omitted rulemaking and a copy of a Regulatory Analysis Form 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. On the same date, the regulations were submitted to the Office of Attorney General for review and approval under the Commonwealth Attorneys Act (71 P. S. §§ 732-101—732-506).

Under section 5.1(j.2) of the Regulatory Review Act, on June 17, 2015, the final-omitted rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on June 18, 2015, and approved the final-omitted rulemaking.

H. *Contact Person*

Questions or comments regarding the final-omitted rulemaking may be submitted to Susan Coble, Director, Bureau of Community Program Licensure and Certification, Department of Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-1379.

Persons with a disability who require an alternative format of this notice (for example, large print, audiotape, Braille) should contact the Department of Health, Bureau of Community Program Licensure and Certification, Division of Home Health, Drug, Device and Cosmetic Program, 132A Kline Plaza, Harrisburg, PA 17104, (717) 783-1379 or for speech and/or hearing impaired persons, V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Services at (800) 654-5984.

I. *Findings*

The Department finds that:

(1) This final-omitted rulemaking satisfies the requirements of section 204 of the CDL. Under the circumstances, notice is impractical, unnecessary or contrary to the public interest.

(2) The adoption of the final-omitted rulemaking in the manner provided by this order is necessary and appropriate for the administration of the act and is in the public interest.

J. *Order*

The Department, acting under the act, 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 regulations.

(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 to form and legality as required by law.

(c) The Secretary shall submit this order, Annex A and a Regulatory Analysis Form to IRRC and the House and Senate Committees 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*.

KAREN M. MURPHY, PhD, RN,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 45 Pa.B. 3640 (July 4, 2015).)

Fiscal Note: 10-193. 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

Subchapter A. 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:

* * * * *

(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:

(i) Fenethylline.

(ii) N-ethylamphetamine.

(iii) Methaqualone.

(iv) Bromazepam.

(v) Camazepam.

(vi) Clotiazepam.

(vii) Cloxazolam.

(viii) Delorazepam.

(ix) Ethyl loflazepate.

(x) Fludiazepam.

(xi) Flunitrazepam.

(xii) Haloxazolam.

(xiii) Ketazolam.

(xiv) Loprazolam.

(xv) Lormetazepam.

(xvi) Medazepam.

(xvii) Nimetazepam.

(xviii) Nitrazepam.

(xix) Nordiazepam.

(xx) Oxazolam.

(xxi) Pinazepam.

(xxii) Tetrazepam.

(xxiii) 3, 4-Methylenedioxymethamphetamine (MDMA).

(xxiv) 4-methylaminorex.

(xxv) Cathinone.

(xxvi) Methcathinone HCL.

(xxvii) Dimethylamphetamine.

(xxviii) 1-(3-trifluoromethylphenyl) Piperazine (TFMPP).

(xxix) N-Benzylpiperazine (BZP).

(xxx) Alpha-Methyltryptamine (AMT).

(xxxi) 2-5 Dimethoxy-4-(N)-Propylthiophenethylamine (2C-T-7).

(xxxii) 5-Methoxy-N, N-Diisopropyltryptamine (5-MEO-DIPT).

(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:

* * * * *

(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:

* * * * *

(xxvi) Zolpidem.

(xxvii) Clobazam. (added March 27, 2012)

(2) A material, compound, mixture, or preparation which contains any quantity of the following substance 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:

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[Pa.B. Doc. No. 15-1266. Filed for public inspection July 10, 2015, 9:00 a.m.]