# 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 Substance, 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 schedule the substances 1-(3—trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy—4—(N)—Propylthiophenethylamine, and 5—Methoxy—N, N—Diisopropyltryptamine (5-MEO-DIPT) as Schedule I substances, to read as set forth in Annex A.

A. *Purpose of the Proposed Amendment*

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 Drug, Device and Cosmetic Board (Board) met on April 21, 2004. The meeting notice was published at 34 Pa.B. 2135 (April 17, 2004).

The Board heard the petitions of the Office of Attorney General which requested that 1-(3—trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy—4-(N)—Propylthiophenethylamine, and 5—Methoxy—N, N—Diisopropyltryptamine (5-MEO-DIPT) be scheduled as Schedule I controlled substances.

These substances are currently scheduled by the Federal government as Schedule I 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 and have a high potential for abuse. There is no currently accepted medical use for these substances in the United States. Further, there is a lack of accepted safety for use under medical supervision. The Board approved a motion to provide written advice to the Secretary to add these substances to Schedule I of controlled substances. The Secretary then directed that the substances be scheduled.

The proposed rulemaking would schedule 1-(3—trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy—4-(N)—Propylthiophenethylamine, and 5—Methoxy—N, N—Diisopropyltryptamine (5-MEO-DIPT) as Schedule I substances.

B. *Requirements of the Amendment*

The proposed rulemaking would schedule substances on the lists of schedules of controlled substances as follows:

The substances 1-(3—trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy—4-(N)—Propylthiophenethylamine, and 5—Methoxy—N, N—Diisopropyltryptamine (5-MEO-DIPT) would be scheduled as Schedule I.

C. *Affected Persons*

The general public would benefit from the scheduling of these substances because it would allow for State law enforcement officials to begin to work to remove these substances from this Commonwealth and allow for enforcement and control of the drug abuse problems in this Commonwealth. State law enforcement officials would also benefit because they would be better equipped to enforce the laws to protect the citizens of this Commonwealth.

D. *Fiscal Impact*

The proposal amendment 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*

The proposed rulemaking would become effective immediately upon publication as final-form rulemaking. There is no sunset date; the regulations would 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(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 advice following their April 21, 2004, meeting. The Board recommended that the substances 1-(3—trifluoromethylphenyl) Piperazine (TFMPP), N-Benzylpiperazine (BZP), Alpha-Methyltryptamine (AMT), 2, 5 Dimethoxy—4-(N)—Propylthyophenethylamine, and 5—Methoxy—N, N—Diisopropyltryptamine (5-MEO-DIPT) be added as Schedule I controlled substances. The Secretary then decided that these substances should scheduled.

H. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on October 22, 2004, 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 act specifies detailed procedures for review, prior to final publication of the regulation, 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 Carol Williams, 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 proposed rulemaking in the *Pennsylvania Bulletin*. Persons with a disability who require an alternative format of the proposal; for example, large print, audiotape or Braille should contact Carol Williams at (717) 783-8665, for speech and/or hearing impaired persons, V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Services (800) 654-5984.

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

**Fiscal Note:** 10-177. No fiscal impact; (8) recommends adoption.

**Annex A**

**DEPARTMENT OF HEALTH**

**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**

**SCHEDULE 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:

* * * * *

**(xxix) 1—(3-fluoromethylphenyl) Piperazine (TFMPP)**

**(xxx) N-Benzylpiperazine (BZP)**

**(xxxi) Alpha-Mehyltryptamine (AMT)**

**(xxxii) 2,5 Dimethoxy—4—(N)—Propylthiophenethylamine (2C-T-7)**

**(xxxiii) 5—Methoxy—N, N—Diisopropyltryptamine (5-MEO-DIPT)**

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