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) hereby adopts amendments to § 25.72 (relating to schedules of controlled substances) to read as set forth in Annex A.

Purpose and Background

The Controlled Substance, Drug, Device and Cosmetics Act (act) (35 P. S. §§ 780-101—780-144) 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 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 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 provides for the scheduling of various substances. The act also provides for adding, removing or rescheduling of substances by regulation.

The Drug, Device and Cosmetic Board (Board) met on December 9, 1999. The meeting notice was published at 29 Pa.B. 5957 (November 20, 1999). The Board heard the petition of Roxane Laboratories, Inc., which requested that dronabinol be rescheduled from Schedule II to Schedule III. The Board unanimously approved a motion to authorize the Secretary of Health to reschedule the substance. This motion was based on several factors:

1. The United States Drug Enforcement Agency (DEA) rescheduled dronabinol from Schedule II to a Schedule III substance under the Controlled Substances Act (63 FR 59,751). Both the DEA and the Food and Drug Administration (FDA) determined that dronabinol should be rescheduled based on an eight-factor analysis of the scientific and medical data as required by Federal law.

2. The DEA and FDA determined that there is little evidence of actual abuse of dronabinol.

3. In 1996 the Haight Ashbury Clinics, Inc., conducted a study on the abuse potential of dronabinol. No evidence of current abuse or diversion of dronabinol among populations having access to the medicine was found.

4. Cannabis-dependent populations have demonstrated no interest in abuse of dronabinol. Studies demonstrate that dronabinol is not a substitute for the problem of marijuana abuse or misuse.

5. The Haight Ashbury study concluded that there is no street market for dronabinol, and no evidence of any diversion of dronabinol for sale as a street drug.

6. A review of the Drug Abuse Warning Network (DAWN) data from 1988 to 1994 shows no reports of dronabinol misuse.

7. The DEA and FDA scientific and medical evaluation determined that dronabinol had only a low to moderate potential to lead to physical dependence and an abuse potential less than Schedule II drugs.

The Secretary of Health, upon advice of the Board, finds that placing dronabinol on Schedule III permits patients to obtain prescription refills and possibly reduce trips to physicians' offices. This action allows pharmacies to accept telephone or facsimile prescriptions from physicians rather than mandated written prescriptions. This action also allows pharmacies to obtain the drug product more quickly for patients. The amendment to the schedules of controlled substances follows similar actions by DEA on July 2, 1999. Dronabinol was approved for marketing by the FDA on May 31, 1985, for use as a treatment for nausea and vomiting in cancer therapy patients who have failed to respond adequately to conventional antiemetic treatments. In 1992, dronabinol was approved by the FDA for use in the treatment of anorexia associated with weight loss of patients with AIDS. Studies have shown that dronabinol has improved the lives of cancer and AIDS patients. Dronabinol has demonstrated short and long term safety and effectiveness relative to appetite stimulation in AIDS patients. Patients who received dronabinol also experienced a stabilization of weight.

Summary

This final-form rulemaking amends § 25.72 to reschedule the substance dronabinol from Schedule II to Schedule III.

Comments

The Department received no comments to the proposed rulemaking.

Fiscal Impact

The amendment to the schedules of controlled substances will have no measurable fiscal impact on the Commonwealth, local government or the general public. Manufacturers will benefit in that the rescheduling will increase the marketability of the drug and the ease by which it will be able to reach consumers. The benefits, however, are not quantifiable.

Paperwork Requirements

A system already exists for the handling of controlled substances under the act and the amendments will not increase paperwork.

Effective Date/Sunset Date

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

Statutory Authority

The amendment to the schedules of controlled substances are adopted under sections 3 and 4 of the act (35 P. S. §§ 780—103 and 780-104), which authorize the Secretary to move a controlled substance from one schedule of controlled substances to another based upon the scheduling criteria set forth in the act.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on July 26, 2000, the Department submitted a copy of the proposed rulemaking published at 30 Pa.B. 3945 (August 5, 2000) 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 for review and comment. In compliance with Section 5.1(a) of the Regulatory Review Act (71 P. S. § 745.5a(a)), the Department submitted a copy of the final-form regulation to IRRC and the Committees on February 5, 2001. In addition, the Department 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 is available to the public upon request.

This final-form regulation was deemed approved by the House Health and Human Services Committee and the Senate Public Health and Welfare Committee on February 26, 2001. The final-form regulation was deemed approved by IRRC on February 27, 2001, in accordance with section 5(g) of the Regulatory Review Act. The Office of Attorney General approved the final-form regulations on April 20, 2001.

Contact Person

Questions regarding this final-form regulation may be submitted to John C. Hair, Director, Bureau of Community Program Licensure and Certification, Pennsylvania Department of Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-8665. Persons with disabilities may submit questions in alternative formats such as by audio tape or Braille at V/TT (717) 783-6514. Speech or learning impaired persons may use the Pennsylvania AT&T Relay Service at 1-800-654-5984 [TT]. Persons with disabilities who would like to obtain this document in an alternative format (such as, large print, audio tape or Braille) may contact John Hair so that necessary arrangements may be made.

Findings

The Department finds that:

(1) Public notice of intention to adopt the regulation 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 regulation is necessary and appropriate.

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 at 30 Pa.B. 3945.

(b) The Secretary of Health shall submit this order and 30 Pa.B. 3945 to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Secretary of Health shall submit this order, 30 Pa.B. 3945 and a Regulatory Analysis From to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(d) The Secretary of Health shall certify this order and 30 Pa.B. 3945 and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

ROBERT S. ZIMMERMAN, Jr.,
Secretary

[Pa.B. Doc. No. 01-777. Filed for public inspection May 4, 2001, 9:00 a.m.]